

FDA-AACR Workshop on How Much Is Enough? Trial Designs for Treatment Regimens with Multiple Phases

Bethesda Marriott Pooks Hill

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Oladimeji AKINBORO, MD

Medical Oncologist & Clinical Reviewer

Office of Oncologic Diseases, FDA

Oladimeji (Ladi) Akinboro is a medical oncologist and clinical reviewer on the thoracic/head and neck cancer team. He has research interests in clinical trial design and cancer immunotherapy. In his spare time, he enjoys hiking/camping with friends, reading history books and visiting history museums, running, and playing soccer (and cheering for FC Barcelona!)



Anup AMATYA, PhD

Statistical Reviewer

Office of Biostatistics, FDA

Anup Amatya is a statistical reviewer in the Division of Biostatistics V. He is a member of various working groups and committees within the Office of Biostatistics and OCE. Prior to joining FDA, he served as an Associate Professor at the New Mexico State University. He received his Ph.D. in Biostatistics from the University of Illinois at Chicago.



Valsamo ANAGNOSTOU, MD, PhD

Associate Professor, Oncology

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

Dr. Anagnostou is an Associate Professor of Oncology, director of the Thoracic Oncology Biorepository, leader of Precision Oncology Analytics and co-leader of the Molecular Tumor Board and the Thoracic Oncology Precision Medicine Center of Excellence in the Sidney Kimmel Cancer Center at Johns Hopkins. She graduated from Medical School of the National and Kapodistrian University of Athens, Greece and received a PhD from the same institution. After completing her internal medicine residency at Yale-New Haven Hospital, she subsequently trained in Medical Oncology at Johns Hopkins. Dr. Anagnostou is a translational cancer investigator, focusing on large-scale genomic and liquid biopsy analyses in human cancers. Her group has discovered novel genomic mechanisms of response and resistance to immunotherapy and her research is particularly focused on understanding the molecular mechanisms of response and resistance to these therapies, capturing these by minimally invasive methods and translating this knowledge into novel technologies and innovative therapeutic approaches for cancer patients. She is the international study chair of the first ctDNA-based molecular response adaptive immunotherapy clinical trial for metastatic non-small cell lung cancer (NCT04093167). Her long-term goal is to transform medical oncology to personalized molecular oncology, where treatment decisions are tailored to cancer genomics and molecular real-time response assessments informed by liquid biopsies.



Michael AXELSON, MD

Vice President, Clinical Development

Loxo@Lilly

Michael Axelson, MD, is a Vice President in Clinical Development at Loxo@Lilly, leading early development programs. His previous experience in oncology includes roles at the FDA, BMS, and Tempus, including development of nivolumab. He completed medical school at the University of Michigan and trained in internal medicine and medical oncology and hematology at UT Southwestern. He has also worked internationally in Japan and outside of work, he enjoys running, cooking, music, and reading, residing in Princeton, NJ.



Vishal BHATNAGAR, MD

Associate Director for Patient Outcomes

Oncology Center of Excellence, FDA

Dr. Vishal Bhatnagar is a medical oncologist/hematologist and the Associate Director for Patient Outcomes in the OCE. His interests include patient reported outcomes, patient preference and incorporation of patient experience in oncology trials. His work focuses on the operational management of the OCE's Patient-

Focused Drug Development program. Additionally, Dr. Bhatnagar has a strong clinical interest in multiple myeloma and was previously a clinical reviewer in the Division of Hematology Products. Dr. Bhatnagar received his BA in Political Science and his medical degree at the George Washington University. He completed his internal medicine residency and hematology/oncology fellowship at the University of Maryland.



Thelma BROWN

Patient Advocate, Breast Cancer

Translational Breast Cancer Research Consortium

Thelma Brown is a two-time breast early-stage breast cancer survivor. Additionally, her mother and five of her sisters also had breast cancer. She is deeply committed to supporting research that will lead to better understanding of this disease. Thelma's

analytical skills, which were honed by her formal education in engineering, her keen interest in the sciences, as well as her perspective of that of a survivor and co-survivor, are a unique, but perfect fit for patient and research advocacy. Thelma has been involved in patient and research advocacy for over 15 years. As a member of the Breast Cancer Working Group at Birmingham (UAB) Comprehensive Cancer Center, she has worked closely with basic science, clinical, and translational researchers. She has also worked with numerous breast cancer organizations including, the Translational Breast Cancer Research Consortium (TBCRC), acting as co-chair of the Patient Advocate Working Group, the I-SPY2 trial as a member of the Safety Working Group, the Metastatic Breast Cancer Alliance Executive Group, American Society of Clinical Oncologists-Cancer LINQ Patient Advisory Committee, American Society of Clinical Oncologists - Breast Cancer Guidelines Committee, and the National Cancer Institute -Patient Advocate Steering Committee and Breast Immuno-Oncology Task Force. She is a Susan G. Komen Scholar and a vice of Komen Advocates in Science Steering Committee.



Angelo de Claro, MD

Division Director, Hematologic Malignancies I
Office of Oncologic Diseases, FDA

R. Angelo de Claro is a hematology-oncology physician and currently the Division Director for the Division of Hematologic Malignancies I in the Office of Oncologic Diseases, Center for Drug Evaluation and Research. He is also 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.



Patrick FORDE, MBCCH

Division Director, Upper Aerodigestive Malignancies
Johns Hopkins

Dr. Forde treats patients with lung cancer, mesothelioma, and other thoracic cancers. He completed training in internal medicine and oncology in Ireland prior to undertaking a further fellowship at Johns Hopkins. He is currently Co-Director of the Division of Upper Aerodigestive Malignancies in the Department of Oncology at

Johns Hopkins and directs the multidisciplinary Thoracic Oncology Clinical Research Program. He has led the development of a clinical-translational research program focused on the immuno-oncology of upper aerodigestive malignancies. Dr. Forde's research examines the role of immunotherapy for mesothelioma and lung cancer and his work has led to the development of several ongoing phase 3 trials. In 2022, his work over several years, published in the *New England Journal of Medicine*, led to the FDA approval of neoadjuvant chemo-immunotherapy for the treatment of surgically operable lung cancer. Dr. Forde serves as principal investigator for the thoracic cancer immunobiology biospecimen repository protocol at Johns Hopkins. He is focused on providing compassionate, state-of-the-art care for his patients in conjunction with a team of oncology specialist nurses, nurse practitioners, and dedicated staff.



Christine GAUSE, PhD

Vice President, Late Development Statistics
Merck

Christine Gause is currently Vice President of Biostatistics at Merck, leading a group that encompasses Late Development Statistics, Clinical Safety Statistics, Early Oncology Statistics, and Scientific Communications and Information Sciences. In this role, she is responsible for overseeing end-to-end statistical support for the entire late development pipeline across therapeutic areas, partnering with colleagues in clinical, regulatory, and other quantitative groups. Prior to her current role, Christine led the late development oncology statistics group where she supervised a team of more than 70 statisticians focusing on critical project strategy, data analysis and interpretation, novel study design, and innovative statistical methodology for multiple high-profile oncology products. Christine has held positions of increasing responsibility in statistics across several therapeutic areas including vaccines, biosimilars, diabetes, and oncology, and she has contributed to multiple publications and presentations. She holds a bachelor's degree in biology from Bucknell University and a Ph.D. in biostatistics from the University of Pittsburgh.



Manju GEORGE, PhD, MVSc
Patient Advocate, Colorectal Cancer
Colontown

Dr. Manju George MVSc PhD is a stage IIIb colorectal cancer (CRC) survivor and patient advocate, who joined COLONTOWN, a CRC patient & caregiver support and education community, immediately after her diagnosis in 2017. Participation in COLONTOWN made her own cancer journey much less lonely. In her attempt to give back to the community, she realized that she was in a great position with her training as a veterinarian and biomedical researcher, and personal experience as a colorectal cancer patient & survivor to provide some unique perspectives to both patients and clinicians. Dr. George also serves as the Scientific Director at Paltown Development Foundation and the scientific editor for content at COLONTOWN University.



Guiseppe GIACCONE, MD, PhD
Professor of Medicine and Associate Director of Clinical Research
Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine

Giuseppe Giaccone, M.D., Ph.D. is an internationally recognized expert in the field of lung cancer and developmental therapeutics. Dr. Giaccone received his M.D. cum laude from the University of Torino Medical School in 1980, followed by training in clinical oncology and internal medicine, which he completed at the University of Torino in 1988. He spent the next two years in the NCI's Medical Oncology Branch under the direction of Dr. John Minna. Following his training at the NCI, Dr. Giaccone received his Ph.D. from the Vrije University Medical Center in Amsterdam, The Netherlands. He served as a senior medical oncologist at the Medical Center from 1990 to 2000, when he was appointed Professor of Medical Oncology. Dr. Giaccone became Head of the Center's Department of Medical Oncology in 2003. He played a major role in the European Organization for Research and Treatment of Cancer (EORTC), serving as a member of the EORTC's Lung Cancer Cooperative Group since 1982 and as its Chair from 1993 to 2000. During his leadership of this Group, Dr. Giaccone led several major clinical studies focusing on lung cancer and mesothelioma. Dr. Giaccone was appointed Chief of the Medical Oncology Branch of the Center for Cancer Research of the National Cancer Institute in April 2007. During his presence at NCI Dr. Giaccone helped restructure the intramural medical oncology and clinical trial organization. He developed cutting edge clinical, basic and translational research in the field of thoracic malignancies. Dr. Giaccone has published more than 500 peer-reviewed papers and contributed to more than 30 book chapters.



Nicole GORMLEY, MD
Division Director, Hematologic Malignancies II
Office of Oncologic Diseases, FDA

Nicole Gormley, MD, is the Division Director for the Division of Hematologic Malignancies II at the U.S. Food and Drug Administration (FDA). 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 has 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 FDA.



Bernardo HADDOCK LOBO GOULART, MD

Medical Officer

Office of Oncologic Diseases, FDA

Bernardo Haddock Lobo Goulart is a Medical Officer in the Office of Oncologic Diseases. He obtained his MD at the Federal University of Rio de Janeiro in 1997. After completing residency in internal medicine and medical oncology, Dr. Goulart moved to the U.S. in 2003, where he pursued a residency in internal medicine followed by a fellowship in medical oncology at the University of Washington (UW) in Seattle, completing his US-based training in 2011. Dr. Goulart also obtained a master's in science in Pharmaceutical Outcomes Research and Policy at the UW School of Pharmacy in 2010. From 2011 to 2014, Dr. Goulart served as Acting Instructor at Fred Hutch and joined the UW faculty as Assistant Professor in 2014. Dr. Goulart became an Associate Professor of Medicine in 2018 and transitioned to the U.S. Food & Drug Administration (FDA) in 2021. Dr. Goulart's areas of expertise include Thoracic and Head & Neck oncology, outcomes and Pharmacoeconomics research, and clinical trial design.



Jhanelle GRAY, MD

Department Chair & Program Leader, Thoracic Oncology

Moffitt Cancer Center

Dr. Gray obtained her Medical Degree from Cornell University Medical College and completed her internship and residency in Internal Medicine at The New York Presbyterian Hospital - Cornell. Following residency training, she completed her Hematology/Medical Oncology Fellowship at Moffitt Cancer Center. Dr. Gray is currently the Department Chair, Program Leader, and a Senior Member for Thoracic Oncology at Moffitt Cancer Center (MCC), co-Leader of the Cancer Center Support Grant Molecular Medicine Program and Professor in the Department of Oncologic Sciences at the University of South Florida Morsani College of Medicine. A renowned thoracic medical oncologist and clinical investigator, Dr. Gray actively leads numerous clinical research trials that investigate novel immunotherapeutic and targeted therapy drug combinations for lung cancer which have greatly influenced standard of care treatment. Her research has generated over 120 publications in scholarly, peer-reviewed journals, including original research and review articles. As a leader in NCI cooperative group trials, Dr. Gray is actively involved as a member of the MCC Scientific Leadership Council. Globally, she is the current Chair of the Southwest Oncology Group (SWOG) Lung Committee, member of the IASLC Board of Directors Committee, and IASLC Women in Thoracic Oncology Working Group. Dr. Gray is an elected member to the Board of Directors for the American Society for Clinical Oncology (ASCO) and will start her service in June 2024. She previously served as Chair of the ASCO Education Program Committee (2022) and was a member of the ASCO Scientific Program Committee, while serving as a member of the ASCO Lung Scientific Program Committee.



Roy HERBST, MD, PhD

Deputy Director

Yale Cancer Center

Roy S. Herbst, MD, PhD is Ensign Professor of Medicine at Yale School of Medicine, Deputy Director for Yale Cancer Center (YCC), Chief of Medical Oncology, Director of Center for Thoracic Cancers, Assistant Dean for Translational Research at Yale School of Medicine, and Program Director, Master of Health Science - Clinical Investigation Track (MHS-CI). He is the principal investigator (PI) of the Yale SPORE in Lung Cancer, PI of the YCC Advanced Training Program for Physician-scientists, PI on the NCI NCTN LAPS Grant, and PI of the Yale-AstraZeneca Alliance, which has 12 projects spanning various cancer types. Dr. Herbst has led Phase I development of multiple targeted agents for non-small cell lung cancer, including gefitinib, cetuximab, bevacizumab, axitinib, atezolizumab, and anti-PD1/ PDL1 therapies. Additionally, he has helped

bring targeted therapy to early-stage disease as the PI of the adjuvant osimertinib study (ADAURA). He co-led MD Anderson's BATTLE-1 effort, which led to the BATTLE-2 trial. He served as the national PI of the SWOG 0819 trial and held the role of founding PI for the NCI Lung Cancer Master Protocol (LungMAP, S1400) for a decade. He has more than 300 publications, and his work published in Nature was awarded Clinical Research Forum's 2015 Herbert Pardes Clinical Research Excellence Award. He is an elected member of the NCI Thoracic Malignancies Steering Committee and the Chair of the AACR Scientific Policy and Legislative Affairs Committee. Most recently, Dr. Herbst received the 2022 Giants of Cancer Care® award for Lung Cancer as one of their 25 scientific and advocacy leaders who have been instrumental over the course of the last 25 years in making significant advancements for patients.



Fred HIRSCH, MD, PhD

Executive Director, Center for Thoracic Oncology
Tisch Cancer Institute at Mount Sinai

Fred R. Hirsch, MD, PhD, is Executive Director at the Center for Thoracic Oncology in The Tisch Cancer Institute at Mount Sinai (TCI) and the Joe Lowe and Louis Professor of Medicine (Hematology and Medical Oncology) at the Icahn School of Medicine at Mount Sinai. He is also Associate Director of Biomarker Discovery for TCI.

Before joining Mount Sinai, Dr. Hirsch was a Professor of Medicine and Pathology at the University of Colorado for 18 years and Chief Executive Officer of the International Association for the Study of Lung Cancer (IASLC) for five years. Dr. Hirsch has received a number of awards and honors, including the IASLC Mary Matthews Award for Translational Research in Lung Cancer in 2007; the Japanese Lung Cancer Society Merit Award in 2010; the Addario Foundation Lecture Award in 2015; and the Wuan Ki Hong Lectureship Award in 2019. Dr. Hirsch has contributed to more than 400 publications in peer-reviewed journals. He is an internationally renowned authority on lung cancer treatment and research.



Naomi HORIBA, MD, MPH

Scientific Liaison, Gastroesophageal and Hepatobiliary Malignancies
Office of Oncology Drugs, FDA

Naomi Horiba, MD, MPH, is a graduate of Tulane University Medical School where she also completed her public health degree and residency training in internal medicine. She performed her medical oncology and hematology training at the University of Maryland Marlene and Stewart Greenebaum Cancer Center and continued as a faculty member for 6

years, subspecializing in gastrointestinal malignancies. During that time, she participated in and co-authored numerous multicenter clinical trials. She maintains board certification in internal medicine and medical oncology. In 2015, Dr. Horiba @FDAOncology @AACR @IASLC Join the conversation with #OCETobaccoUse joined the U.S. Food and Drug Administration's Office of Hematology and Oncology Products (now the Office of Oncology Drugs) as a medical officer and is currently serving as the scientific liaison for gastroesophageal and hepatobiliary malignancies.



Elizabeth JAFFEE, MD, FAACR, FCP

Deputy Director
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

Dr. Jaffee's initial work focused on developing vaccine-based immunotherapy for the treatment of pancreatic cancer. She was the first to show that a vaccine given in the neoadjuvant setting to pancreatic cancer patients with resectable cancer induce tertiary lymphoid structures that educate cancer specific T cells (Cancer

Immunology Research, 2014). Since then, her work has focused on developing novel biomarker driven immunotherapy clinical trials to dissect the complex inflammatory signals within the tumor microenvironment. She has employed a rapid

bidirectional translational platform trial approach for testing novel combinations of vaccine plus immune modulators to achieve an effective antitumor immune response (Cancer Cell, 2020; Nature Communications, 2023). She was also the first to develop an oncogene targeted vaccine approach that prevents early premalignant pancreatic lesions from progressing to pancreatic cancer in mice (Gastroenterology, 2014). This work led to two novel clinical trials testing a mutated KRAS vaccine in subjects at high risk for pancreatic cancer. Through collaborations with computational biologists, her team employs novel machine learning approaches to further delineate regulatory signaling pathways in human tumors (Cancer Discovery, 2023). This work will ultimately lead to computational approaches for predicting patient specific therapies. Dr. Jaffee is an internationally recognized expert in cancer immunology and pancreatic cancer. She is Deputy Director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Co-Director of the Skip Viragh Pancreatic Cancer, and Associate Director of the Bloomberg Kimmel Institute for Cancer Immunotherapy. Dr. Jaffee is known for developing the most successful translational pancreatic cancer program in the country that has served as a model for other outstanding programs. Dr. Jaffee is a Past President of AACR. She has served on several committees at the National Cancer Institute, including the co-chair of the Biden Moonshot Blue Ribbon Panel which identified high impact research priorities for the NCI. She currently serves as Chief Medical Advisor to the Lustgarten Foundation for Pancreatic Cancer Research. She is the inaugural director of the Convergence Institute for Integrating Technologies and Computational Sciences at Johns Hopkins. Dr. Jaffee is a member of the National Academy of Medicine, a Fellow of the American College of Physicians, a Fellow of American Association for the Advancement of Science, a Fellow of the SITC Academy of Immuno-Oncology and a Fellow of the AACR Academy. Most recently, she was appointed chair of President Biden's Cancer Panel.



Pallavi KALYANI, PhD, MS

Lead Mathematical Statistician

Office of Biostatistics, FDA

Dr. Mishra-Kalyani is a Team Leader in the Division of Biometrics V in the Office of Biostatistics in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). She received a Ph.D. in Biostatistics from Emory University and a master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design.



Mark KRIS, MD

William and Joy Ruane Chair in Thoracic Oncology

Memorial Sloan Kettering Cancer Center

Dr. Kris, a medical oncologist, currently serves as William and Joy Ruane Chair in Thoracic Oncology at Memorial Sloan-Kettering Cancer Center, where he has been on the staff since 1983. He also is a Professor of Medicine at Weill Cornell Medical College. He specializes in thoracic malignancies including lung cancer, thymoma, and cancer of unknown primary site. His research interests include targeted therapies for lung cancer, multimodality therapy, the development of new anticancer drugs, and symptom management with a focus on preventing emesis, the most dreaded side effect of cancer and cancer treatment. Dr. Kris received his medical degree from Cornell University Medical College, completed residencies at the New York Hospital-Cornell Medical Center/Memorial Sloan-Kettering Cancer Center program, and performed his fellowship at Memorial Sloan-Kettering.



Kelley KIDWELL, PhD

Professor and Associate Chair of Academic Affairs of Biostatistics
University of Michigan School of Public Health

Kelley Kidwell, Ph.D., is a Professor and Associate Chair of Academic Affairs of Biostatistics at the University of Michigan School of Public Health. She is an expert in large and small sample sequential, multiple assignment, randomized trial (SMART) design and analysis. She is the primary investigator of current FDA and Patient-Centered Outcomes Research Institute (PCORI) contracts, also had previous FDA and PCORI methods contracts, all related to SMART design, and has been a co-investigator on many NIH and industry funded, clinical trial grants. Her current focus is on advancing small sample clinical trial design and methods and incorporating patient treatment preferences into clinical trials.



Laleh AMIRI-KORDESTANI, MD

Division Director, Oncology I
Office of Hematology Oncology Products, FDA

Dr. Amiri-Kordestani is the division 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 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 (NCI). She is also an assistant professor at Georgetown University Hospital where she remains clinically active, practicing inpatient medicine.



Erin LARKINS, MD

Clinical Reviewer & Team Lead, Thoracic, Head & Neck Tumors
Office of Oncologic Diseases, FDA

After obtaining her degree in Molecular Biochemistry and Biophysics at Yale University, Dr. Larkins attended medical school at the Uniformed Services University of the Health Sciences as a Naval officer, graduating in 2000. She completed residency training in Internal Medicine at the Bethesda Naval Hospital followed by fellowship training in Medical Oncology and Hematology at the National Cancer Institute in Bethesda, MD. She served as a medical oncologist in the U.S. Navy for 8 years and was the Associate Program Director for the National Capital Consortium Hematology-Oncology fellowship program from 2011 to 2014. In 2014, Dr. Larkins transferred to the US Public Health Service and came to work at the Federal Drug Administration (FDA) as a clinical reviewer and then a Cross-Disciplinary Team Lead for the Thoracic and Head & Neck Tumors Team in the Division of Oncology II (DO II). She is currently Supervisory Associate Director in DO II. She continues to provide clinical care to patients with thoracic and head & neck cancer as a volunteer at Walter Reed National Military Medical Center.



Steven LEMERY, MD

Division Director, Oncology III

Office of Hematology & Oncology Products, FDA

Dr. Steven Lemery is the Director of the Division of Oncology 3 (DO3) within the Office of Oncologic Diseases in CDER/FDA and Acting Associate Director for Tissue Agnostic Drug Development with the FDA Oncology Center of Excellence. In addition to duties regarding general drug development for patients with gastrointestinal cancers, melanoma, and sarcoma, Dr. Lemery has also focused on tissue-agnostic development and biosimilar

development. Dr. Lemery is a medical oncologist who completed his clinical training in hematology and medical oncology at the National Institutes of Health in Bethesda, Maryland. He also graduated with a Master of Health Sciences in Clinical Research degree awarded by the Duke University School of Medicine (joint NIH/Duke program).



Aarón SOSA MEJIA, MD

Clinical Assessor/Alternate CHMP Member

European Medicines Agency

Aarón Sosa Mejia is a Medical Oncologist with main expertise in lung cancer. He has worked as a clinical assessor in the Danish Medicines Agency for the last 7 years and is currently the Danish alternate member for The Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency.



Cristina MIGALI, MD, PhD

Clinical Assessor

Office of the Italian Medicines Agency

Cristina Migali, MD, PhD, is a medical oncologist working as Clinical Assessor at the Centralized Procedure Office of the Italian Medicines Agency (AIFA) in Rome since 2016. In her role, she is involved in the regulatory review of drug marketing authorization requests submitted to the European Medicines Agency (EMA) for medicinal

products in the field of oncology. She is also a Member of the Scientific Advice Working Party at EMA since 2019. She previously worked at the European Institute of Oncology in Milan (Italy) and at the Royal Marsden Hospital in London (United Kingdom), where she gained clinical experience in the treatment of various solid tumors, including clinical management of patients enrolled in phase I-III clinical trials. She holds a medical degree and a specialty degree in Medical Oncology from the University of Siena (Italy) and a PhD in Pharmacology and Toxicology from University “La Sapienza” in Rome (Italy).



Jane PERLMUTTER, PhD, MBA

Patient Advocate, Breast, Esophageal and Lung Cancer

Gemini Group

Jane Perlmutter is a long-term survivor of multiple cancers and an active advocate. While her advocacy is largely rooted in her own experiences, it is also informed by her formal training in cognitive psychology and experimental methods (Ph.D.), computer and information science (MS) and business (MBA),

as well as her career experiences which included many years in academia, not-for-profit R&D, corporate senior management, and independent consulting. During her early advocacy Jane was a peer counselor and board member

for Y-ME, as well as a grant reviewer for ACS, DOD and PCORI. More recently she focuses much of her advocacy on clinical trials, ensuring that the patient voice is considered in selection of research questions and that trial protocols are sensitive to patient issues. She is especially interested in innovative trial designs that can speed up new treatments to patients who need them. Jane serves on the steering committees and is lead advocate on the I-SPY2 and TAPUR trials, two groundbreaking Master Protocol trials. She has been an advocate on NCI's Breast Steering Committee and CALGB's Breast and Health Outcomes Committees and is currently on NCI's Cancer Imaging Steering Committee and the Alliance for Clinical Trials in Oncology's DSMB and Cancer Control Executive Committee. Jane has also been involved in health advocacy beyond cancer and works with many government and not-for profit groups. She is past chair of the Patient Centered Outcomes Research Institute's (PCORI) Patient Engagement Advisory Panel and a member of their Clinical Trials Advisory Committee. Jane is especially passionate about developing the next generation of advocates and fostering collaboration between advocates and researchers. She has developed and delivered training for many advocacy groups and been a long-term faculty member of the ASCO/AACR Methods in Clinical Research Workshop as well as the similar SITC workshop. In 2023 Jane was honored with AACR's 2023 Distinguished Public Service Award for Exceptional Leadership in Cancer Advocacy as well as ASCO's 2023 Patient Advocate Award.



Thomas POWLES, MD

Director and Professor of Urology

Barts Cancer Centre & The University of London

Thomas Powles is a professor of urology cancer at the University of London and the Director of Barts Cancer Centre. He trained as an Oncologist at Imperial College. Professor Powles has had a major role in the development of biomarkers and new drug strategies in urology cancers. This includes multiple EMA and FDA approvals. Notably, front line

immune/targeted therapy combinations in RCC, immune checkpoint inhibitions alone or in combination in bladder cancer and antibody drug conjugates in urothelial cancer. His biomarker work has resulted in a greater understanding of resistance to immune therapy (TGFb), personalized therapy in bladder cancer (PD-L1, CD8) and renal cancer (MET) and the development of circulating biomarkers (ctDNA). He has authored 10 NEJM or Lancet publications with two first author NEJM publications and 2 first author Nature publications. He authors over 40 peer-reviewed publications per annum. He has presented plenary data at major global meetings. Prof. Powles has led many clinical trials (including 21 randomized trials) and translational oncology projects that have appeared in the major journals. He leads both university-led and pharmaceutical company sponsored work in equal balance. His grant income over the last 10 years for university sponsored studies is over £15 million. He has presented plenary data at ASCO 2020 and was awarded the Bladder Cancer annual award at ASCO/GU in 2018. His current work focuses on early bladder and kidney cancer with novel adjuvant/neoadjuvant therapies and the identification of patients at risk of relapse after surgery.



Tatiana PROWELL, MD

Breast Cancer Scientific Liaison

Office of Hematology & Oncology Products, FDA

Dr. Prowell is breast cancer scientific liaison in the Office of Hematology and Oncology Products at the U.S. Food and Drug Administration (FDA) and assistant professor of oncology in the Breast Cancer Program at the Johns Hopkins Kimmel Comprehensive Cancer Center. She was the principal architect of the FDA's policy on accelerated approval using pathological

complete response as a novel regulatory endpoint in the neoadjuvant high-risk breast cancer setting and was a member of the Cancer Moonshot Blue Ribbon Panel Cancer Immunology Working Group. Dr. Prowell received her BA from Bard College in languages and literature and her medical degree from the Johns Hopkins School of Medicine with election to the Phi Beta Kappa and Alpha Omega Alpha honor societies. She completed her internal medicine residency and medical oncology fellowship at Johns Hopkins Hospital.



Joshua REUSS, MD

Thoracic Medical Oncologist
MedStar Georgetown University Hospital

Joshua Reuss, MD, is a thoracic medical oncologist at MedStar Georgetown University Hospital. He also serves as an assistant professor in the Department of Medicine at Georgetown University Medical Center. Dr. Reuss specializes in lung cancer, mesothelioma, and thymoma. His research focuses on incorporating novel concepts and groundbreaking science to develop innovative clinical trials that advance the care of patients with lung cancer and mesothelioma. He has a particular interest in collaborating with scientific investigators to develop studies that help improve our understanding of the response and resistance mechanisms to immunotherapy in lung cancer and mesothelioma, as well as to develop trials that incorporate novel therapies that overcome immunotherapy resistance. He received the Young Investigator Award from the Conquer Cancer Foundation of the American Society of Clinical Oncology in 2019 for his research. Dr. Reuss earned his bachelor's degree in biology at Brandeis University and his MD from the University of Rochester School of Medicine & Dentistry. He completed his internship and residency in Internal Medicine at the University of Virginia's Department of Medicine. He subsequently completed a fellowship in the Department of Oncology at the Johns Hopkins University School of Medicine. MedStar Georgetown is part of the MedStar Georgetown Cancer Institute, which combines medical expertise, the latest therapies, and research across MedStar Health. Our research engine, the Georgetown Lombardi Comprehensive Cancer Center, is the only National Cancer Institute-designated comprehensive cancer center in the Washington, D.C., region. This partnership means we provide access to cutting-edge clinical trials and the latest breakthroughs in cancer care.



Mirat SHAH, MD, MHS

Medical Oncologist
Office of Oncologic Diseases, FDA

Mirat Shah, MD, MHS is a medical oncologist on the Breast, Gynecologic, and Supportive Oncology team within the Office of Oncologic Diseases at the FDA. She also serves as Clinical Lead for FDA Oncology Center of Excellence's Project Optimus which is an initiative to reform the dose selection paradigm for oncology drugs. She completed her internal medicine residency at Vanderbilt University Medical Center. She completed her medical oncology and clinical pharmacology fellowship at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, including one year as chief oncology fellow. She obtained a master's degree in health sciences through the Johns Hopkins Bloomberg School of Public Health. Her main interests are improving dose selection for oncology drugs and providing medical education in regulatory science. She currently maintains a supportive oncology clinic at Johns Hopkins.



Minghua (Michael) SHAN, PhD

Senior Director, Expert Statistician
Bayer Pharmaceuticals

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.



Harpreet SINGH, MD

Division Director, Oncology II
Office of Oncologic Diseases, FDA

Harpreet Singh, M.D., is director of the Division of Oncology 2 in the Office of Oncology Diseases, as well as the Acting Associate Director for Cancer in Older Adults and Special Populations in the Oncology Center of Excellence at the FDA. Dr. Singh received her M.D. 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. As Director of the Division of Oncology 2, Dr. Singh oversees drug development for lung cancer, head and neck cancer, neurologic tumors, pediatric solid tumors, and rare cancers. Her scope of expertise includes precision medicine and targeted therapy, novel trial design, innovative regulatory initiatives designed to expedite drug approvals, and use of real-world data in regulatory decision making. Recent notable approvals in lung cancer include targeted therapies for MET exon 14 skipping mutations and RET fusions. 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 Journal of Clinical Oncology. She serves as the lead for OCE's Project Silver, a global regulatory effort to increase the evidence base for older adults with cancer. Under Project Silver, global regulatory agencies will discuss key applications and development programs with indications affecting older adults with cancer, consider more detailed labeling information that reflects the clinical experience of older adults, and conduct educational programs with global stakeholders. Dr. Singh maintains her clinical credentials at the National Cancer Institute.



Chi (Chuck) SONG, PhD

Statistical Team Lead
Office of Biostatistics, FDA

Dr. Chi (Chuck) Song is a statistical team lead in FDA Center for Drug Evaluation and Research, Office of Biostatistics since December 2023, and a statistical reviewer since May 2021. Dr. Song received his PhD degree in Biostatistics from University of Pittsburgh and did postdoctoral training at Yale University. Before joining the FDA, he was a faculty member in biostatistics at The Ohio State University. His research interests include adaptive trial design, causal inference, meta-analysis, and high-throughput data analysis.



Craig TENDLER, MD

Vice President/Global Head, Oncology Therapeutic Area
Johnson & Johnson Innovative Medicine

Craig Tandler, M.D. is Vice President and Global Head of Clinical Development, Diagnostics, and Medical Affairs for the Oncology Therapeutic area at Johnson & Johnson Innovative Medicine. 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. Prior to this role, Craig served as Vice President of Medical Affairs for Tibotec Therapeutics and then Ortho-Biotech, where he led medical affairs teams in lifecycle management and

data generation for the Janssen Virology and Oncology franchises. Craig has overseen and coordinated more than 30 major drug approvals by national regulatory agencies, including at least ten NDAs by the US Food and Drug Administration (FDA). He and his team have 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 12 FDA breakthrough designations for accelerating the early development 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. In addition to his pharmaceutical industry experience, he has 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 National Cancer Institute in Bethesda, Maryland. 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.



Sara TOLANEY, MD, MPH
Chief, Division of Breast Oncology
Dana-Farber Cancer Institute

Dr. Tolaney received her undergraduate degree from Princeton University in 1998 and her medical degree from UC San Francisco in 2002. She subsequently completed her residency in Internal Medicine at Johns Hopkins University, and fellowships in hematology and medical oncology at Dana-Farber Cancer Institute. She obtained a master's in public health from the Harvard School of Public Health in 2007. In 2008, she joined the staff of Dana-Farber Cancer Institute and Brigham and Women's Hospital, where she serves as Chief of the Division of Breast Oncology. She is a breast medical oncologist whose research focuses on the development of novel therapies in the treatment of breast cancer. She has been instrumental in developing several treatment approaches for breast cancer, including approaches focused on tailoring therapy for early stage HER2+ disease, use of cdk 4/6 inhibitors, antibody drug conjugates, and immunotherapy.



Paz Vellanki, MD, PhD
Clinical Reviewer, Thoracic, Head, & Neck Cancer
Office of Oncologic Diseases, FDA

Paz Vellanki 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.



Stephanie WETHINGTON, MD

Medical Officer

Office of Oncology Drugs, FDA

Stephanie received her Bachelor of Arts from Brandeis University and her Master of Science in Economic and Social History from the University of Oxford prior to matriculating at The College of Physicians and Surgeons at Columbia University where she obtained her Medical Degree. She completed residency in Obstetrics and Gynecology at the Sloane Hospital for Women, Columbia University Medical Center, and fellowship in Gynecologic Oncology at Memorial Sloan-Kettering Cancer Center. Prior to joining the FDA, Stephanie was on faculty in the Johns Hopkins University School of Medicine in the Departments of Oncology and Gynecology and Obstetrics where she served as the Vice Chair of Quality, Safety and Service for the Department of Gynecologic and Obstetrics and the Director of Clinical Operations for the Division of Gynecologic Oncology. She is now a Medical Officer at the FDA in the Office of Oncology Drugs, Division of Oncology 1.



Kathleen WINSON, MS

Executive Group Director, Regulatory

Genentech/Roche

Kathleen Winson is an Executive Group Director in Regulatory at Genentech/Roche. In her role, she oversees regulatory strategy for Oncology Lung and pan-tumor development. With over 25 years of experience in clinical research and drug development, Kathleen has garnered extensive expertise in both biotech/pharmaceutical and academic settings. Her knowledge spans numerous therapeutic areas, including cardiovascular health, neuroscience, immunology, infectious diseases, and oncology. Over the past decade, Kathleen has been leveraging her development expertise to advance innovative approaches aimed at optimizing and accelerating drug development. Current areas of focus include working, as part of a broad collaboration with industry, government, academic, and advocacy groups, to advance ctDNA as a potential early endpoint, as well as leading efforts to explore more holistic and streamlined approaches to evidence generation. The latter includes spearheading an effort to build more strategic partnerships with academic centers and cooperative groups to address important clinical and regulatory questions throughout the development lifecycle. Kathleen is passionate about seeking out opportunities and partnerships that can improve and expedite the process of getting new therapies to patients.



Mark YARCHOAN, MD

Medical Oncologist & Associate Professor, Oncology

Johns Hopkins University

Dr. Mark Yarchoan is an oncologist in Baltimore, caring for patients with gastrointestinal cancers. His clinical focus is on cancers of the liver, including hepatocellular carcinoma and biliary tract cancer (cholangiocarcinoma). Dr. Yarchoan received his undergraduate degree (cum laude) in neuroscience from Amherst College and earned his M.D. from the Perelman School of Medicine at the University of Pennsylvania. He completed his residency in internal medicine at the Hospital of the University of Pennsylvania and performed a fellowship in medical oncology at Johns Hopkins University School of Medicine. Dr. Yarchoan joined the Johns Hopkins faculty in 2018. He directs a National Cancer Institute funded laboratory focused on the discovery of novel cancer immunotherapies for hepatobiliary cancers. Dr. Yarchoan co-leads the Liver Cancer Multidisciplinary Clinic. He has been recognized with an ASCO Young Investigator Award, and the Director's Teaching Award in Clinical Science, the Cholangiocarcinoma Foundation's Mark R. Clements Award, and a Conquer Cancer Foundation/ASCO Career Development Award.

