

*Second Annual Workshop on*

## **Getting the Dose Right:**

**Optimizing Dosage Selection Strategies in Combination Anticancer Therapies**

**An FDA-ASCO Virtual Workshop**

**September 6-7, 2023**

### **Biographies – Day 1**

#### **Introduction to Workshop**



**R. Donald Harvey, PharmD**  
**Professor, Hematology and Medical Oncology**  
**Emory University School of Medicine**

R. Donald Harvey, PharmD, is Professor in the Department of Hematology and Medical Oncology with a joint appointment in the Department of Pharmacology and Chemical Biology at Emory University School of Medicine. A board-certified oncology pharmacist, Dr. Harvey serves as director of Winship Cancer Institute's Phase I Clinical Trials Unit and as Medical Director of Winship's Clinical Trials Office, where he works to ensure the quality and compliance of clinical research practices at all Winship locations. He is a Fellow of the American College of Clinical Pharmacy and a Fellow of the Hematology/Oncology Pharmacy Association. Dr. Harvey has also active nationally and internationally in several cancer and pharmacology professional organizations. He is also a past president of the Hematology and Oncology Pharmacy Association, an international professional organization. Dr. Harvey obtained his BS Pharmacy and Doctor of Pharmacy degrees at the University of North Carolina at Chapel Hill (UNC).



**Mirat Shah, MD, MHS**  
**Medical Oncologist, Office of Oncologic Drugs**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Mirat Shah, MD, MHS is a medical oncologist and clinical team lead on the Breast, Gynecologic, and Supportive Oncology team within the Division of Oncology 1, Office of Oncologic Diseases. She joined the FDA in 2019, after completing her internal medicine residency at Vanderbilt University, and her medical oncology and clinical pharmacology fellowships at Johns Hopkins, where she also served as the Chief Oncology Fellow. She has an interest in improving tolerability of oncology therapies through dosage optimization and is the Clinical Lead for OCE's Project Optimus. She also has an interest in oncology regulatory education, serving as the co-lead for the 2021-2022 FDA-AACR Oncology Educational Fellowship. She enjoys hiking and birding in her spare time

## Opening Remarks



**Richard Pazdur, MD**  
**Director, Oncology Center of Excellence**  
**U.S. Food and Drug Administration**

Richard Pazdur, M.D., is director of the FDA Oncology Center of Excellence, which leverages the combined skills of FDA's scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel cancer products.

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 600 articles, book chapters, and abstracts, and received many awards, including recognition in Fortune magazine's 2015 list of "50 World's Greatest Leaders," the Massachusetts General Hospital Cancer Center's "The One Hundred" list in 2016, and one of "The Bloomberg 50" in 2017.

## Session 1: Current State of Dosage Optimization in Combination Anticancer Therapies

**Mirat Shah, MD, MHS (Moderator)**  
**Medical Oncologist, Office of Oncologic Drugs**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

See biography above

## Session 1 Presenters:



**Patricia LoRusso, MD (Keynote Speaker)**  
**Professor of Medicine (Medical Oncology)**  
**Chief, Experimental Therapeutics**  
**Associate Cancer Center Director, Experimental Therapeutics**  
**Yale School of Medicine**

Dr. Patricia LoRusso has been a practicing academic medical oncologist performing clinical/translational research in early phase clinical trials for 30 years, spending the first 25 years at Wayne State University/Karmanos Cancer Institute in Detroit, MI and transitioning to Yale University/Yale Cancer Center in 2014. Both institutions have NCI comprehensive designation status. She has had continuous NIH/NCI peer review funding for 28 years, having held a U-grant for early phase clinical trials through the NCI Cancer Therapy Evaluation Program (CTEP) for 26 years. She has also collaborated on numerous other grants and have been an investigator in P01 and P30 funding mechanisms. Understanding the need for team science, she has participated in P50 mechanisms and has been awarded team science grants through such organizations as Stand Up to Cancer (Co-Leader: Melanoma Dream Team), the Department of Defense (DOD) and the Komen Foundation (Co-leader,

KG111063: Targeting Stem Cells in Triple-Negative Breast Cancer (TNBC) in Different Racial Populations).

Dr. LoRusso has also been involved in many service disciplines at the NCI. She has reviewed grants for many study sections and has either been an ad hoc (e.g. CCSG, NeXT study sections) or permanent study section member (e.g. Program Project Subcommittee D and Clinical Oncology study sections). She has served on the Investigational Drug Steering Committee (IDSC) since inception (2005-present) and served as its chair from 2011-2013. She was a member of the steering committee that convened after the Blue-Ribbon Panel to execute on their recommendations. She served a 4-year term (2015-2019) on the Board of Scientific Council (BSC), reviewing the intramural programs for quality, content, productivity and funding.

In addition to serving in NCI positions, Dr. LoRusso has served in leadership positions of several other organizations. She has served on the Board of Directors and numerous scientific and education committees of the American Association for Cancer Research (AACR), the education and scientific committees of the American Society of Clinical Oncology (ASCO), and the steering committee for the Food and Drug Administration (FDA) Accelerating Anticancer Agent Development and Validation Workshop, as examples. Internationally, she has taught several clinical trials educational workshops, educating many physicians and scientists across the globe. She understands how critically important it is to train the next generation of early career investigators to be knowledgeable and proficient in clinical and translational research by providing them leadership opportunities and mentoring. She has worked closely with Cancer Research United Kingdom (CRUK), a UK Wellcome Trust which is the second largest funding agency for cancer research. She is currently serving a 3-year term as the chair of their New Agents Committee (NAC), reviewing international proposals relative to drug development of novel agents.

Working closely over the past 3 decades with patients suffering from advanced malignancies, Dr. LoRusso has become an advocate, not only for cancer researchers and clinicians, but more importantly for the patients and their caregivers. Having experienced at a young age the death of her own parents from cancer, she understands the urgent need for new cancer discoveries and the potential for longevity and quality of life.



**Steve Shafer, MD**  
**Emeritus Faculty, Stanford University**

Dr. Shafer is an anesthesiologist and clinical pharmacologist. He completed his undergraduate education at Princeton, his medical training at Stanford, and his anesthesiology training at the University of Pennsylvania. Dr. Shafer trained in clinical pharmacology at Stanford University under the mentorship of Dr. Donald Stanski (Stanford) and Dr. Lewis Sheiner (UCSF). Dr. Shafer's research characterized the pharmacokinetics, pharmacodynamics, and interactions of intravenous opioids and hypnotics used in anesthetic practice, including propofol, thiopental, diazepam, midazolam, dexmedetomidine, fentanyl, alfentanil, sufentanil, remifentanil, lidocaine, and many experimental drugs that did not reach clinical practice. Dr. Shafer developed numerous novel PK/PD models, including models of drug interaction. Dr. Shafer served as a member and subsequently chair of the FDA Anesthesia and Life Support Advisory Committee. In collaboration with Dr. Dennis Fisher, Dr. Shafer taught population PK/PD modeling to hundreds of pharmacometricians through the "Fisher/Shafer NONMEM Course". Dr. Shafer is also founder / cofounder of two biotechnology companies. For ten years Dr. Shafer served as Editor-in-Chief of Anesthesia & Analgesia, the oldest peer-reviewed journal in perioperative medicine, and presently serves as Editor-in-Chief of the Monitor, an official publication of the American Society of Anesthesiologists. Dr. Shafer retired from Stanford in April 2023. He continues his research in oxytocin

pharmacokinetics and pharmacodynamics, funded by the NIH, and continues to advise pharmaceutical companies in novel drug development.

## Session 1 Panelists:



**Janice Cowden**  
**Patient Centered Dosing Initiative**

Diagnosed with Stage IV triple negative breast cancer in 2016, five years after an early-stage breast cancer diagnosis, Janice launched into patient advocacy following training through Living Beyond Breast Cancer's Hear My Voice Outreach program in 2017. As a peer-to-peer support and research patient advocate, Janice is passionate about supporting others with metastatic breast cancer, in addition to continually furthering her scientific knowledge base of this disease, treatments, and clinical trials. Her professional life as a Pediatric nurse (retired) and Professional Pharmaceutical Sales Representative fuels her passion for scientific learning and dissemination of the most up to date disease-related information, which she acquires through attending evidence-based breast cancer conferences and webinars.

Janice works with several patient-founded and -led organizations including PCDI, GRASP, and Project Life MBC. As a trained peer support volunteer, she is founder of an international online peer support group for patients newly diagnosed with MBC. She serves on the Board of Directors for METAvivor Research and Support, Inc., and is an Advisory Board member for Project Life MBC. In 2022, she attended ASCO as a patient advocate scholarship recipient. In October 2022, she was invited to serve as a lead patient advocate, representing PCDI, on a research study with ASCO. When she's not busy with advocacy work, Janice enjoys traveling, reading, outdoor activities, and spending time with family, including her husband, two adult children and three grandchildren.



**Nicole Gormley, MD**  
**Division Director, Division of Hematologic Malignancy 2**  
**Office of Oncologic Drugs**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

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.



**Alice Tseng, B.Sc.PhM., Pharm.D, FCSHP, AAHIVP**  
**HIV Pharmacotherapy Specialist, Immunodeficiency Clinic**  
**Toronto General Hospital**  
**Associate Professor, Faculty of Pharmacy**  
**University of Toronto**

Alice Tseng obtained her Bachelor of Science in Pharmacy and Doctor of Pharmacy degrees from the University of Toronto, and completed a hospital Pharmacy Residency at Toronto Western Hospital. Dr. Tseng co-founded the Ontario HIV Pharmacists Specialty Group and the Canadian HIV and Viral Hepatitis Pharmacists Network (CHAP). She is a specialist consultant at the Immunodeficiency Clinic, Toronto General Hospital, and Associate Professor with the Leslie Dan Faculty of Pharmacy, University of Toronto. She has published extensively on drug interactions, adverse reactions, and HIV pharmacology and maintains an internationally recognized website/mobile app on HIV and hepatitis C drug interaction and pharmacology information (<http://app.hivclinic.ca>). Dr. Tseng is a Fellow of the Canadian Society of Hospital Pharmacists and is credentialed as an HIV Pharmacist through the American Academy of HIV Medicine. Dr. Tseng was the inaugural recipient of the [Hall of Distinction Alumni Award](#) (2020) from the Leslie Dan Faculty of Pharmacy, recognizing her significant achievements in the profession of pharmacy, and recipient of the 2022 Arbor Award, in recognition of outstanding volunteer service to the University of Toronto.



**Jennifer Lauchle, MD**  
**Vice President, Genentech**  
**Head of Oncology Early Clinical Development, Genentech Research and Early Development (gRED)**

Jennifer (Jen) Lauchle is Vice President and Head of Oncology Early Clinical Development at Genentech. Jen leads a team of talented physicians and scientists in the design and execution of early stage oncology trials for therapeutics in diverse areas of cancer biology, including cell signaling and cellular immunotherapy. Jen joined Genentech in 2009 and had held positions of progressive responsibility leading the clinical development of novel therapeutics (PI3K inhibitors, oral SERDs, T cell engaging bispecific antibodies, and cancer vaccines) from first in human through proof of concept studies, including studies designed to optimize dose selection and development of combination regimens.

Jen received her BS in Biology at Pennsylvania State University followed by her MD at the University of Maryland Medical School. She completed both her Pediatric Residency and Pediatric Hematology and Oncology Fellowship at the University of California at San Francisco, where she also conducted postdoctoral research evaluating potential therapeutics for cancers with altered RAS signaling in the laboratory of Kevin Shannon, MD. Prior to joining Genentech, she was an Assistant Clinical Professor at UCSF with a NCI Mentored Clinical Scientist Research Career Development Award (K08) and co-principal investigator in the Children's Tumor Foundation Preclinical Consortium for new target discovery.

## Session 2: The Nuts and Bolts of Combination Dosage Optimization



**Julie Bullock, PharmD (Moderator and Introductory Comments)**  
**Senior VP, Global Head of Clinical Pharmacology and Translational Medicine**  
**Certara, Integrated Drug Development**

Dr. Bullock is currently a Senior Vice President with Certara Drug Development Solutions (Consulting) Division of Certara. She has over 20 years of drug development experience and is a recognized drug development scientist with scientific and regulatory expertise focused in the therapeutic areas of oncology/hematology and coagulation. Julie has extensive experience in all development phases including regulatory interactions with major global health authorities (FDA, EMA, PMDA), due diligence, design of clinical development plans, pediatrics, dose-finding strategy and streamlining development for breakthrough therapies and accelerated approval. Julie is a Key Opinion Leader on the FDA's Project Optimus (oncology dose finding) initiative and has provided risk-assessment and tactical dose justification support for over 100 early and late-stage oncology assets since the launch of Project Optimus in 2022. In her current role, Dr. Bullock supports a global team of clinical pharmacologists with regulatory strategy and drug development experience who provide program level and strategic support to Biotech and Pharma company portfolio programs.

Prior to her role at Certara Dr. Bullock was a Team Leader for the Hematology/Oncology review team in the Office of Clinical Pharmacology at the Center for Drug Evaluation and Research at the FDA. Julie's FDA career spanned 10 years where she contributed to over 14 new molecular entity NDA/BLA filing applications, multiple supplemental NDA/BLA applications and countless IND related submissions submitted to the hematology/oncology division. Dr. Bullock received her Doctor of Pharmacy from Drake University and completed a drug development fellowship with the State University of New York at Buffalo and Novartis Pharmaceuticals.

### Session 2 Presenters:



**Mallika Singh, PhD**  
**Vice President, Translational Research**

Mallika has over 20 years of industry research and drug development experience across the spectrum of current oncology therapeutics, including small and large molecules. She is an acknowledged scientific and strategic thought leader in translational research and in the use of sophisticated mouse models of human cancer for oncology drug development. Her research endeavors have driven insights into determinants of therapeutic response to RAS/MAP kinase pathway inhibition in RAS and RAF mutant cancers. She has established and led scientific programs in small biotechnology as well as biopharmaceutical companies including Genentech and Novartis. Mallika has contributed to multiple investigational new drug applications including for vismodegib (Genentech/Roche), the clinical-stage RAF inhibitor LXH254 (Novartis).

Since joining RevMed in 2017, Mallika has overseen the establishment of a world-class Translational Research function which has had significant impact on all pipeline programs, including comprehensive pharmacology approaches, biomarker discovery, and preclinical to clinical translation of a diverse pipeline focused on natural product-inspired tri-complex inhibitors of RAS-GTP for RAS-addicted cancers. The Translational Research group she leads is also responsible for research diagnostics and combination

strategies, all focused on driving RevMed's pipeline assets towards clinical success and ultimately, patient benefit.

Mallika received a Ph.D. from the University of Utah and postdoctoral training at the University of California at San Francisco. She is a co-author on numerous publications and a named inventor on several patents and applications.



**Giovanni Abbadessa, MD, PhD**  
**Vice President, Head of Oncology Early Development**  
**Sanofi**

Giovanni Abbadessa is an MD, PhD, specialized in Medical Oncology. As Vice President, Head of Oncology Early Development at Sanofi, he has been leading teams on almost 20 clinical projects (oncology and hematology) and clinical strategy on as many lab projects. Prior to joining Sanofi in 2017, he has worked in small (15-110 employees) Boston biotechs since 2007, leading preclinical and clinical research teams, Ph1-3 clinical trials with 11 experimental agents, medical affairs, strategy, business development, investor relations, board and partnership management.



**J. Jack Lee, Ph.D, M.S., D.D.S.**  
**Professor of Biostatistics**  
**Kenedy Foundation Chair in Cancer Research**  
**MD Anderson Cancer Center**

Jack Lee, Ph.D., M.S., D.D.S. is Professor of Biostatistics and Kenedy Foundation Chair in Cancer Research. His areas of expertise include design and analysis of cancer clinical trials, Bayesian adaptive designs, statistical computation/graphics, drug combination studies, and biomarkers identification and validation. He is an elected Fellow of American Statistical Association, Society for Clinical Trials, and American Association for the Advancement of Science. He has more than 500 publications in statistical and medical journals. He co-authored two books entitled: "Bayesian Adaptive Methods for Clinical Trials" and "Model-Assisted Bayesian Designs for Dose Finding and Optimization: Methods and Applications."



**Percy Ivy, MD**  
**Associate Chief, Investigational Drug Branch**  
**National Cancer Institute**

S. Percy Ivy, MD is the Associate Chief (2005-present) of the Investigational Drug Branch (IDB) which is part of the Cancer Therapy Evaluation Program (CTEP) (1997-present) in the Division of Cancer Treatment and Diagnosis of the National Cancer Institute. She received her medical and subspecialty training at Tulane University Medical School, Vanderbilt University Medical Center, and the National Cancer Institute, respectively. During her fellowship she worked in the Molecular Pharmacology Section, Medicine Branch, NCI which focused on the molecular mechanisms of drug resistance mediated by the ABC transporter genes in models of breast cancer and carcinogenesis. She is also currently an Adjunct Professor of Pediatrics at the George Washington University School of Medicine on the faculty at Children's National Medical Center where she attends in the leukemia clinic.

In her role as Associate Chief of IDB she has supervised eleven Senior Investigators and multiple fellows in the Developmental Chemotherapy Section which became Experimental Therapeutics Section I with a focus on inhibitors of DNA repair, damage response, PARPi resistance and replication stress, including PARPi, Wee1, DNA-PKi, angiogenesis inhibitors, heat shock protein 90 inhibitors and inhibitors of receptor/ligand interactions including dis-regulated cancer stem cell embryonic signaling pathways for hedgehog, notch, wnt and others. She has received 16 NIH Merit Awards for her work on specialized studies in patients with hepatic and renal dysfunction using cancer investigational therapeutics, use of novel imaging techniques for the evaluation of investigational agents in early clinical trials and most recently for assisting the in the implementation of the Investigational Drug Steering Committee (IDSC) which is part of the Clinical Trials Working Group, an NCI initiative for improving NCI-sponsored clinical trials in the US. She serves on the IDSC coordination team as well as starting the angiogenesis task force, and NCI chairing the Clinical Trial Design and Pharmacology Task Forces for Early Clinical Trials.

She serves as the program official/director for the Experimental Therapeutics Clinical Trials Network (ETCTN) which is funded by NCI. She is also Program Director for the Drug Resistance and Sensitivity Network and the Create Access to Targeted Cancer Therapy for Underserved Populations (CATCH-UP.2020). She served on the Scientific Committee for the AACR-NCI-EORTC Molecular Targets Conference and for the Experimental Therapeutics Section for ASCO and AACR. She has presented both nationally and internationally on topics related to early therapeutics development, early phase clinical trial design, biomarker development, the role of anti-angiogenic agents in cancer therapy, clinical trials for patients with hepatic and renal dysfunction.



**Joyce Cheng, PhD**  
**Division of Biometrics V**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Joyce Cheng is a statistical team leader in the Division of Biometrics V for the team supporting the Division of Oncology 3 at FDA. She is also a member of OCE's Project Optimus initiative on dose optimization in oncology. She received her PhD in statistics from Baylor University and has been at FDA since 2015.



**Atik Rahman, PhD**  
**Division Director, Cancer Pharmacology II**  
**Office of Clinical Pharmacology**  
**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

Nam Atiqur Rahman, Ph.D., is the Director of the Division of Cancer Pharmacology II within the Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, US Food and Drug Administration (USFDA). The Division includes clinical pharmacology reviewers who are involved in the development, review, approval, and life cycle management of the drugs and therapeutic biologics for solid tumors. Prior to joining FDA, Dr. Rahman earned his doctorate degree from the Washington State University and completed post-doctoral training in Molecular Pharmacology and Pharmacogenomics at the St-Jude Children's Research Hospital, Memphis, Tennessee.

Dr. Rahman's interest includes immunoncology, dosage optimization, and application of modeling and simulation in cancer drug development. Dr. Rahman's interest also includes the application of

pharmacogenomics to promote personalized medicine for cancer patients. He supports the review staff who facilitates innovation in drug development and drug approval from Clinical Pharmacology perspectives.

Dr. Rahman received over 40 FDA level awards, published 60 articles in peer review journals and authored 6 book chapters. He has given over 50 presentations in national and international meetings, workshops, and symposiums. He is currently a member of American Society of Clinical Oncology.