*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 2

### 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 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.

## Session 3: Case Studies for Developing Combination Therapies

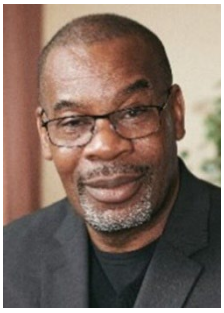
**Michael Matiland, MD (Moderator)**
**Medical Lead, Intellia Therapeutics, Inc.**
**Physician Scientist, ASCO Cancer Research Committee**

Michael Maitland, MD, PhD, is a physician scientist on the ASCO Cancer Research Committee. For 20 years, as a board-certified physician in both Medical Oncology and Clinical Pharmacology Dr. Maitland led academic research programs with continuous NIH funding to employ new technologies to improve the development of safe and effective treatments for cancer. His clinical focus was on the conduct of early phase clinical trials and care of patients with metastatic solid tumors. Past national service responsibilities included Director of the American Board of Clinical Pharmacology, and member of the National Cancer Institute Investigational Drug Steering Committee.
Recently, Dr. Maitland has been the Medical Lead for NTLA-2001 at Intellia Therapeutics, a clinical stage biotechnology company in Cambridge, MA that develops therapeutics based on gene-editing tools. He continues to maintain academic roles as Professor of Medicine at the University of Virginia and as a member of the University of Virginia Comprehensive Cancer Center.

## Case Study 1: Nivolumab and relatlimab

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

Jamie Brewer, MD is a medical oncologist and Clinical Team Lead in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Food and Drug Administration (FDA). Dr. Brewer joined the FDA in 2018 and previously served as a clinical reviewer on the Genitourinary Cancer team. Dr. Brewer serves as the Oncology Center of Excellence (OCE) Scientific Liaison for Cancer Disparities for which she actively engages with FDA colleagues and external stakeholders to promote inclusion and representation of diverse patient populations in clinical trials.



**Akintunde Bello, PhD**
**Bristol Myers Squibb**

Akintunde (Tunde) Bello is Senior Vice President and Head of Clinical Pharmacology, Pharmacometrics, Disposition and Bioanalysis at BMS supporting the therapeutic areas of Oncology, Hematology, Cell Therapy, Immunology, CV and Neuroscience. Tunde has more than 25 years of experience in preclinical and clinical drug development. He started his career at Rhone Poulenc Rorer (Sanofi) in the UK and moved to the US to join BMS in 1998 and spent 5 years working on the development of anti-infective and oncology therapeutics. Following an 11-year stint at Pfizer, as a clinical pharmacology group leader, Tunde rejoined BMS in 2015 to head up clinical pharmacology and pharmacometrics for oncology.

In his current role, Tunde also has quantitative systems pharmacology (QSP), physiologically based PK (PBPK), model based meta-analysis (MBMA), clin pharm analysis and reporting (CPAR) and clin pharm data sciences (DS) functions within his organization. Over the course of his career, Tunde has played key roles in the development, approval and life cycle management of 8 marketed drugs in the oncology, pain

management, inflammation and infectious disease TAs. He oversaw the clinical pharmacology teams that supported the development and approval of multiple sBLAs for nivolumab and ipilimumab, as well as the BLA for elotuzumab. At Pfizer, Tunde managed the clinical pharmacology group and was a core member of the crizotinib (xalkori) development team.

Tunde has a BSc in Medical Laboratory Sciences (Biomedical Sciences) from Portsmouth University (UK), an MSc in Instrumentation and Analytical Sciences from the University of Manchester Institute of Science and Technology (UMIST, UK) and a PhD in Pharmaceutical Sciences from King's College, University of London (UK).
Tunde has authored and co-authored more than 70 peer reviewed abstracts and journal manuscripts, he is a member of the American Society of Clinical Pharmacology and Therapeutics (ASCPT), the International Society of Pharmacometrics (ISoP), the American Association of Pharmaceutical Scientists (AAPS) and the American Society of Clinical Oncology (ASCO).

## Case Study 2: Dabrafenib and trametinib

**LCDR Ruby Leong, PharmD**
**Team Lead, Division of Cancer Pharmacology I**
**Office of Clinical Pharmacology**
**Center for Drug Evaluation and Research**
**U.S. Food and Drug Administration**

Lieutenant Commander (LCDR) Ruby Leong is a team lead in the Division of Cancer Pharmacology I in the Office of Translational Sciences, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). As a clinical pharmacology team lead, she is part of the multidisciplinary team responsible for the approval of safe and effective drugs for cancer. She joined FDA in 2011. Her previous roles included clinical pharmacology reviewer in the Division of Clinical Pharmacology V, and post-doctoral fellow in the Office of Clinical Pharmacology Immediate Office working on pediatrics physiologically-based pharmacokinetic modeling. LCDR Ruby Leong received a Doctorate of Pharmacy from the University of Michigan and completed a post-doctoral industry fellowship in oncology drug development at Rutgers University/Hoffmann-La Roche. She has board certification in oncology pharmacy and practices as a volunteer oncology pharmacist at the Walter Reed National Military Medical Center Hematology/Oncology Pharmacy.

**Shefali Kakar, PhD**
**VP and Global Head, Oncology Therapeutic Area, PK Sciences at Novartis**

Shefali Kakar is the Global Head for Oncology Therapeutic Area, PK Sciences at Novartis. She is responsible for overseeing all aspects of PK Sciences (ADME, PK, PK/PD and clinical pharmacology) for 100+ projects in the Novartis oncology portfolio spanning early discovery to marketed products. Shefali has been passionate about dose for oncology patients throughout her 20+ year career in Pharma. Prior to joining Novartis, Shefali worked at Pfizer and also served as an Adjunct faculty for Clinical Pharmacology at the Brown University. She received her PhD in Pharmacology from U of Michigan.

## Case Study 3: Venetoclax + decitabine/azacytidine/cytarabine

**Lori Ehrlich, MD, PhD**
**Medical Oncologist, Office of Oncologic Drugs**
**Center for Drug Evaluation and Research**
**U.S. Food and Drug Administration**

Dr. Lori Ehrlich is a pediatric hematologist/oncologist serving as a clinical team leader in the FDA's Division of Hematologic Malignancies I in the Office of Oncologic Diseases. She joined the FDA in 2014 and reviews drugs for malignant hematology indications with a focus on acute leukemias and pediatric drug development. Dr. Ehrlich completed her residency and fellowship training as a pediatric hematologist-oncologist at the Children's Hospital of Philadelphia. She received her medical degree and doctorate from the University of Pittsburgh School of Medicine.

**Jalaja Potluri, MD**
**Executive Medical Director, Abbvie**

Dr. Jalaja Potluri is an Executive Medical Director at AbbVie and the Development Leader for myeloid malignancies including VENCLEXTA (venetoclax) and navitoclax. Dr. Potluri is a hematologist and medical oncologist focused on developing transformational treatments for patients with hematological malignancies. She has developed and executed several clinical studies that led to Breakthrough Therapy and Orphan Drug Designations for Venetoclax in AML and global approvals in CLL and AML indications. Prior to joining the VENCLEXTA clinical development team in 2013, Dr. Potluri was a faculty member at the University of Illinois and at the Advocate Health Centers, where she had been involved in national co-operative oncology trials in hematologic malignancies and was the director of the cancer committee. Dr. Potluri completed her M.D. at Nagarjuna University, India, and fellowship training in Hematology and Medical Oncology at the Medical College of Wisconsin. She now leads clinical development team at AbbVie investigating VENCLEXTA and other agents as potential treatment options across multiple tumor types.

**Ahmed Salem, PhD, FCP**
**Senior Director, Clinical Pharmacology, AbbVie**

Ahmed Salem, PhD, FCP is a Senior Director of Clinical Pharmacology at AbbVie and an adjunct Professor at University of Minnesota. Dr. Salem got his PhD in Clinical Pharmacology in 2010 from the University of Minnesota with a focus on Pharmacometrics and a minor in Biostatistics. His research at UMN focused on Pharmacometric Applications in Infectious Diseases. At AbbVie, Dr Salem has led the clinical pharmacology, pharmacometrics and biopharmaceutics strategy of several small and large molecules in oncology, virology, and women's health. He contributed to 14 different FDA and EMA approvals of new drugs, dosage forms and dosage regimens. He has worked on over 180 Phase I, II and III clinical trials. He has over 200 publications with an i-10 index of 114 and H index of 40 and holds seven patents in the USA and EU.

Last year, the American College of Clinical Pharmacology (ACCP) selected Dr Salem as the 2022 recipient of the Tanabe Investigator Award. He was also the 2018 recipient of the High Impact Article Award by the American Association of Pharmaceutical Scientists (AAPS) in addition to other awards and recognition from the IQ-Clinical Pharmacology Leadership Group (CPLG), UMN and AbbVie Inc. Dr. Salem has also been an

invited speaker and chair at multiple conferences such as the American Society for Clinical Pharmacology & Therapeutics (ASCPT), ACCP and Accelerating Anti-Cancer Agent Development & Validation (AAADV). He also recently established a joint industry-academia postdoctoral fellowship in clinical pharmacology and pharmacometrics across AbbVie and University of Minnesota.

## Session 3 Panelists:

**Chris Takimoto, MD, PhD**
**Chief Medical Officer**
**IGM Biosciences**

Chris Takimoto has three decades of experience in oncology and drug development, and he is currently the Chief Medical Officer at IGM Biosciences. He has extensive experience in early phase oncology trials both as an academic investigator and as an industry sponsor. Previously, he served as Senior Vice President in Oncology at Gilead Sciences and he was a member of the Board of Directors for Tizona Therapeutics, a private biotechnology company. Prior to that he was the Chief Medical Officer of Forty Seven, Inc., a clinical stage, public biotechnology company that was acquired by Gilead in 2020, and he has also served as a Vice President for Oncology Experimental Medicine Early Development at Johnson & Johnson/Janssen R&D. He has held faculty positions at the Institute for Drug Development Phase 1 Program at the Cancer therapy and Research Center in San Antonio, TX, the University of Texas Health Science Center San Antonio, the National Cancer Institute, and the Uniformed Services University in Bethesda, MD. He has completed fellowships in Medical Oncology and Clinical Pharmacology, and he is a graduate of the Yale University School of Medicine where he received an MD and a PhD in Pharmacology. He also holds an undergraduate degree in Chemistry from Stanford University.

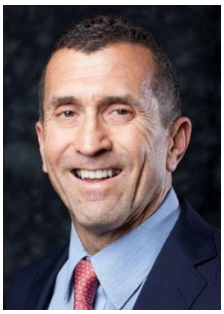
**Olanrewaju (Lanre) Okusanya, PharmD, MS, BCPS**
**Division Director, Cancer Pharmacology I**
**Office of Clinical Pharmacology**
**Center for Drug Evaluation and Research**
**U.S. Food and Drug Administration**

Olanrewaju (Lanre) Okusanya, Pharm.D, MS, BCPS, is the Deputy Division Director for the Division of Cancer Pharmacology I in the Office of Clinical Pharmacology at the U.S Food and Drug Administration. He received his Pharmacy degree from Texas Southern University, completed a Pharmacy Practice Residency at the University of Pittsburgh, and a Pfizer/University at Buffalo Drug Development Fellowship with a Masters in Pharmacometrics from SUNY Buffalo. He has been involved in the review and approval of multiple anti-cancer therapies with an emphasis on drugs to treat malignant and non-malignant hematology diseases including biosimilars and identifying and addressing regulatory issues that arise in oncology drug development from a clinical pharmacology perspective.

Prior to joining the FDA, his work included leveraging pre-clinical and early human data for dose selection, optimizing dosing regimens for patients as well as providing translational and investigational PKPD guidance for the development of novel therapeutics.

**Leslie Seymour, MD, PhD, FRCPC**
**Director, IND Program & Deputy Director, Canadian Cancer Trials Group**
**Professor, Department of Oncology, Queens University**

Professor Lesley Seymour MD, PhD is the Director of the Investigational New Drug Program and the Deputy Director of the Canadian Clinical Trials Group (CCTG). She is a Professor of Oncology at Queens University, Kingston Ontario. She completed specialist training in Internal Medicine and later Clinical Haematology and Medical Oncology as well as a PhD in translational biology (breast cancer). After positions as Senior Consultant in Clinical Haematology and Medical Oncology, she spent two years in the pharmaceutical industry, and then relocated to Canada as the Director of Medical Oncology in Newfoundland before taking up her current role at CCTG. Her primary interests are in early drug development and clinical trial methodology. She is the principal investigator and co-investigator on numerous grants for clinical research and training and served on many provincial, national and international committees, editorial boards, review and grants panels.



**Glenn R Sykes**
**Patient Advocate, ECOG-ACRIN**

Glenn R Sykes, a kidney cancer patient since December 2010, serves as a research advocate on the GU committee of ECOG-ACRIN, a cooperative research organization conducting clinical research across a range of cancers.

Sykes retired in 2019 from the University of Chicago Booth School of Business, where he most recently was the Dean of Students for their MBA Programs.

A native of Philadelphia, Sykes resides there and Miami Beach with his husband, Dirk.

## Session 4: The Path Forward: Optimizing Dose Selection Strategies in Combination Anticancer Therapies

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

See Biography above

## Session 4 Panelists:

**Dean Ho, PhD**
**Provost's Chair Professor**
**Head, Department of Biomedical Engineering**
**Director, The N.1 Institute for Health (N.1)**
**Director, The Institute for Digital Medicine (WisDM)**
**Department of Pharmacology, Yong Loo Lin School of Medicine**
**National University of Singapore**

Professor Dean Ho is currently Provost's Chair Professor, Director of The Institute for Digital Medicine (WisDM) at the Yong Loo Lin School of Medicine; Director of The N.1 Institute for Health (N.1), and Head of the Department of Biomedical Engineering at the National University of Singapore. Prof

Ho and collaborators successfully developed and validated CURATE.AI, a powerful artificial intelligence platform that personalizes human treatment for a broad spectrum of indications ranging from oncology, to digital therapeutics and infectious diseases, among others. His team also developed IDentif.AI to optimise combination therapy design against SARS-CoV-2 and to address antimicrobial resistance. Recently, his team unveiled WisDM Green, a technology platform to sustainably address food security and optimise yield while preserving nutritional content.

Prof. Ho is an elected Fellow of the US National Academy of Inventors (NAI), American Association for the Advancement of Science (AAAS), the American Institute for Medical and Biological Engineering (AIMBE), and the Royal Society of Chemistry. He was also recently named to the HIMSS Future50 Class of 2021 for his internationally-recognised leadership in digital health. Prof. Ho is also a Subgroup Lead in the World Health Organization (WHO) Working Group for the regulation of AI for Health. Prof. Ho is an author (w/Yoann Sapanel and Dr. Agata Blasiak) of the forthcoming book, *Medicine Without Meds*, which is being released internationally. The book serves as a blueprint for a broad community – from business leaders and venture capitalists to healthcare systems – on how to accelerate practice-changing innovation to patients and caregivers. All author proceeds from the book will be benefiting the WisDM Patient Impact Fund at NUS. Prof Ho has appeared on the National Geographic Channel Program “Known Universe,” and Channel News Asia’s “The Hidden Layer: Healthcare Trailblazers". His discoveries have been featured on CNN, The Economist, National Geographic, Forbes, Washington Post, NPR and other international news outlets. Prof. Ho is a recipient of the Tech Heroes from Crisis Pathfinder Award from the Singapore Computer Society, NSF CAREER Award, Wallace H. Coulter Foundation Translational Research Award, and V Foundation for Cancer Research Scholar Award, among others. He has also served as the President of the Board of Directors of the Society for Laboratory Automation and Screening (SLAS), a leading global drug development organization.

**Funda Meric-Bernstam, MD**
**Chair, Department of Investigational Cancer Therapeutics**
**Medical Director, Institute for Personalized Cancer Therapy**
**The Nellie B. Connally Chair in Breast Cancer**
**MD Anderson Cancer Center**

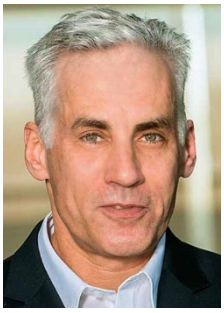
Funda Meric-Bernstam is the Chair of the Department of Investigational Cancer Therapeutics -- the Phase I Program at MD Anderson Cancer Center, the Medical Director of the Institute for Personalized Cancer Therapy (IPCT), and The Nellie B. Connally Chair in Breast Cancer She is a physician-scientist with basic and translational research programs focused on cell signaling, biomarker discovery and molecular therapeutics with specific focus on precision oncology and patient derived models. She is also a clinical trialist with over 25 ongoing clinical trials and extensive experience in novel therapeutics as well as correlative studies from clinical trials, leading a large institutional effort on molecular profiling for clinical trial allocation and biomarker discovery.

**Debbie Pickworth**
**Founder, BRAF Bombers**

I was diagnosed with Stage 4 lung cancer in March of 2013 at the age of 43 years old. I have NSCLC, Adenocarcinoma, with the BRAF V600e mutation. I am a 3rd generation lung cancer patient. My mother and grandmother both died of lung cancer. At the time of diagnosis, there were no treatments in lung cancer for BRAF. My options at the time were chemo. I did 6 rounds of Carboplatin, Alimta and Avastin, then another 6 of Alimta and Avastin. I was able to take a “chemo break” for the next 12 months. In 2015, I had mild

progression and was then able to go on trial for a BRAF combo of Dabrafenib and Trametinib. I stayed on the trial for 2.5 years until side effects removed me from the trial. I then went back on Alimta maintenance for another 12 rounds and again went on another "chemo break". In April of 2020, I again had progression and did 10 rounds of radiation and started back on Alimta maintenance. I currently have stable disease.

I am a wife, mother, and grandmother. I am an Advocate. I enjoy spending time with family and friends, crafting, taking photographs and getting in small vacations whenever I can.



**Eric Rubin, MD**
**SVP & Therapeutic Area Head of Oncology Early Development**
**Merck Research Laboratories**

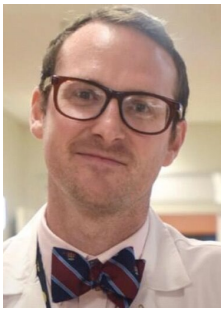
Dr. Rubin has focused on cancer drug development for over 25 years, initially as a faculty member at the Dana-Farber Cancer Institute, then as a senior leader of the Cancer Institute of New Jersey, where he served as the Director of the Investigational Therapeutics Division of that institution. His research efforts focused on mechanisms of resistance to DNA topoisomerase-targeting drugs and his laboratory cloned TOPORS, a novel topoisomerase I- and p53-interacting tumor suppressor gene. In 2008 he was recruited to Merck to lead the clinical oncology development team. Under his leadership, the clinical oncology group underwent a transformational change in an effort to realize the potential of cancer immunotherapy. He led the initial development of the anti-PD-1 antibody pembrolizumab, which was the first anti-PD-1 therapy approved in the U.S., and in the identification of the significant activity of this breakthrough therapeutic across several cancer types. In 2014 Dr. Rubin was asked to head up Oncology Early Development for Merck, and in this role, he oversees development of a promising and expansive early pipeline, as well as translational oncology research activities.

Dr. Rubin has authored over 100 original, peer-reviewed publications and book chapters related to oncology translational research, clinical trials, and drug development. He has served frequently as a member of National Cancer Institute and American Cancer Society study sections, as well as on program committees for the American Association of Cancer Research (AACR) and the American Society of Clinical Oncology. He is a co-chair of the Cancer Steering Committee of the Biomarker Consortium, Foundation of the National Institutes of Health, a member of the Science Policy and Governmental Affairs Committee for AACR and was a member of the National Cancer Moonshot Initiative/Blue Ribbon Panel Working Group on Expanding Clinical Trials.

**Stacy S. Shord, PharmD, BCOP, FCCP**
**Deputy Director, Division of Cancer Pharmacology II**
**Office of Clinical Pharmacology**
**Center for Drug Evaluation and Research**
**U.S. Food and Drug Administration**

Stacy S. Shord, PharmD, BCOP, FCCP, is a Deputy Director in the Division of Cancer Pharmacology II in the Office of Clinical Pharmacology within U.S. Food and Drug Administration. Dr. Shord received her Doctor of Pharmacy from University of Maryland School of Pharmacy. She then completed a Pharmacy Practice residency at the University of Pittsburgh Medical Center, an Oncology Pharmacy Practice residency at UNC Hospitals, and a fellowship in Oncology Pharmacotherapy at the UNC Eshelman School of Pharmacy. Dr. Shord joined the faculty at the University of Illinois at Chicago College of Pharmacy in 2001 as an assistant professor where her research focused on drug metabolism in patients with cancer and hematological diseases. She joined the Food and Drug

Administration in 2009 and served as a primary reviewer and Lead Pharmacologist in the Office of Clinical Pharmacology and an Associate Director of Labeling in the Office of Oncologic Diseases. Special interests include dosage optimization, labeling and pediatric drug development. Dr. Shord earned her Board Certification in Oncology Pharmacy in 2000. She has authored 55 peer-reviewed papers and 10 book chapters. Dr. Shord is a member of ASCPT, ASCO, ACCP and HOPA.



**Garth W Strohbehn, MD, MPhiil**
**Assistant Professor, University of Michigan Rogel Cancer Center**
**Investigator, Veterans Affairs Center for Clinical Management Research**

Garth W Strohbehn MD MPhil is a cancer health services researcher and lung and head/neck medical oncologist with expertise in dose-optimization and scarce resource allocation. His research focuses on developing novel dosing approaches for FDA-approved drugs to enhance access, safety, and value – without sacrificing clinical outcomes. His interdisciplinary health services work centers on the overuse of medical resources, the development and implementation of novel Bayesian trial approaches to optimize dosing, and the societal consequences of excessive dosing from the public payer perspective. He practices within the Veterans Affairs Ann Arbor Health System and is an assistant professor at the University of Michigan Rogel Cancer Center, and investigator in the Veterans Affairs Center for Clinical Management Research.