Getting the Dose Right: Optimizing Dose Selection Strategies in Oncology
An FDA-ASCO Virtual Workshop
May 3 and 5, 2022

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 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.

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.

Biographies

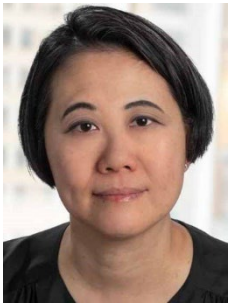
Session 1: Challenges to Dose Optimization

Marc Theoret, MD (Moderator)
Deputy Center Director, Oncology Center of Excellence
U.S. Food and Drug Administration

Dr. Marc Theoret is a medical oncologist and Deputy Director in the Oncology Center of Excellence (OCE), FDA, and Acting Supervisory Associate Director of Oncology Sciences in the Office of Oncologic Diseases (OOD), Center for Drug Evaluation and Research, FDA. Dr. Theoret earned his medical degree from the Penn State College of Medicine. He completed internship and residency training in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston, and fellowship training in Hematology and Oncology at the National Cancer Institute (NCI) in Bethesda. Prior to coming to FDA, he performed basic and translational clinical research in the Surgery Branch, NCI, to investigate novel immunotherapeutic strategies to treat patients with melanoma and other advanced solid tumors.

In 2009, Dr. Theoret came to FDA and served as medical officer in the Division of Biologic Oncology Products and then in the Division of Oncology Products (DOP) 2. He served as the Clinical Team Leader of the Melanoma-Sarcoma team, DOP2, from 2013 to 2017. Subsequently, he served as Associate Director of Immunotherapeutics in the Office of Hematology and Oncology Products (OHOP) as well as an Acting Associate Director of Immuno-oncology Therapeutics in the Oncology Center of Excellence. Prior to his current position as Deputy Director in the OCE, he served as the Acting Deputy Office Director in OOD. In these roles in OHOP / OOD and OCE, Dr. Theoret has led the reviews of numerous breakthrough therapies, new molecular entities, and novel biologics. Dr. Theoret has contributed extensively to initiatives—regulatory, scientific, and policy efforts—in cancer therapeutic development, in particular immuno-oncology therapeutics, and consistently has provided FDA leadership in this field to wide-ranging external stakeholders.

Biographies



Lillian Siu, MD (Keynote Speaker)
BMO Chair in Precision Genomics
Director of Phase I Program
Professor of Medicine, Princess Margaret Cancer Centre
Toronto, Canada

Dr. Siu is a senior medical oncologist at Princess Margaret Cancer Centre since 1998, and has been a Professor of Medicine at the University of Toronto since 2009. She is the Director of the Phase I Program and Co-Director of the Bras and Family Drug Development Program at Princess Margaret Cancer Centre, and holds the BMO Chair in Precision Genomics (2016-2026). She is also the Clinical Lead for the Tumor Immunotherapy Program at Princess Margaret Cancer Centre. Dr. Siu served on the Board of Directors for the American Society of Clinical Oncology (ASCO) for a four-year term (2012-2016). She also served as a member of the Nomination Committee for the American Association for Cancer Research (AACR) (2014-2016) and on the AACR Board of Directors for a three-year term (2017-2020).

Dr. Siu's major research focus is in the area of new anticancer drug development, particularly with respect to phase I trials and head and neck malignancies. She is the Principal Investigator of a phase I cooperative agreement UM1 award sponsored by the United States National Cancer Institute. In addition to her active research in early phase clinical trials, she has been leading genomics initiatives and immuno-oncology trials at the Princess Margaret Cancer Centre. Together, the three programs of drug development, cancer genomics and tumor immunotherapy form a triad of synergy that supports the institution's core vision to deliver precision cancer medicine.

Panelists:

James Doroshow, MD
Deputy Director, Clinical and Translational Research, National Cancer Institute
Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute

Dr. James H. Doroshow has been the Deputy Director for Clinical and Translational Research of the National Cancer Institute since 2011, and the Director of NCI's Division of Cancer Treatment and Diagnosis since 2004. He continues to pursue his own research program as a Senior Investigator in the Developmental Therapeutics Branch of the NCI's intramural Center for Cancer Research. He is the author of over 500 full-length publications in the areas of molecular pharmacology, the role of oxidant stress in tumor cell signal transduction, and novel therapeutic approaches to solid tumors; at the time of his move to his current position, Dr. Doroshow had received over 25

years of peer-reviewed research funding from the NCI. From 1983 to 2004, Dr. Doroshow was the Chairman of the City of Hope Comprehensive Cancer Center's Department of Medical Oncology and Therapeutics Research, and Associate Cancer Center Director for Clinical Investigation. He has served on the Oncologic Drugs Advisory Committee of the U.S. Food and Drug Administration, the Medical Oncology Board of the American Board of Internal Medicine, and as Chair of two NIH study sections: Experimental Therapeutics II and Subcommittee A, Cancer Centers. He is currently a member of both the Forum on Drug Discovery, Development, and Translation and the National Cancer Policy Forum of the National Academy of Medicine of the National Academies of Science. He was the Associate Editor for Oncology of the 25th Edition of the Cecil Textbook of Medicine, and Co-Editor of the 5th and 6th Editions of Abeloff's Clinical Oncology. Dr. Doroshow received his A.B. degree magna cum laude from Harvard College in 1969 and graduated from Harvard Medical School alpha omega alpha in 1973. Following an Internal Medicine residency at the Massachusetts General Hospital, he completed a fellowship in Medical Oncology at the Medicine and Clinical Pharmacology Branches of the National Cancer Institute, NIH.

Anne Loeser
Patient-Centered Dosing Initiative

Anne was diagnosed with early-stage breast cancer at age 39 and with MBC 18 years thereafter. On both occasions her symptoms were misdiagnosed - an experience that subsequently transformed her into a patient advocate, researcher, and author. Anne's book, "The Insider's Guide to Metastatic Breast Cancer" has been portrayed by Mark E. Burkard MD, PhD as "a labor of love in which deep knowledge and years of experience are shared in an organized and accessible format - every drug, every breast cancer subtype, every scan, every site of disease, it's there." The Guide is updated when new treatments are approved and key research findings are announced, so the information therein is always current.

Anne is a member of the Metastatic Breast Cancer Alliance, a research grant reviewer, and a Project LEAD graduate. Her concerns about patients' treatment-related side effects motivated her to establish the Patient-Centered Dosing Initiative (PCDI), a movement made possible through the collaborative efforts of patient advocates and medical professionals who share a passion for improving patients' lives through flexible dosing strategies.

Biographies

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, dose 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 through interaction with the pharmaceuticals. In addition, Dr. Rahman is working with national organizations, such as, American Society for Clinical Oncology, Patient Advocacy Groups, Friends of Cancer Research to modernize the eligibility criteria for entry of patients in clinical trial for drug development.

Dr. Rahman received over 40 FDA level awards, published 55 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.

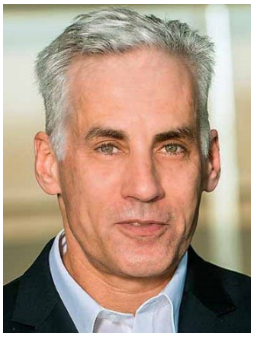
Kellie Reynolds, PharmD
Director, Division of Infectious Disease Pharmacology
Office of Clinical Pharmacology
Center of Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Reynolds is Director of the Division of Infectious Disease Pharmacology in the Office of Clinical Pharmacology, CDER, FDA. She received her B.S. in Biochemistry from Virginia Tech, Pharm.D from Virginia Commonwealth University, and completed a fellowship in Clinical Pharmacokinetics and Drug Development at University of North Carolina. Her work involves application of clinical pharmacology to development of antiviral and anti-infective drugs and drugs developed under the animal

rule. Her interests include dose selection for sub-populations, drug interactions, risk/benefit assessment, and communication. Her work at FDA began in 1994 during a pivotal phase of HIV drug development, allowing her to experience the essential contribution of clinical pharmacology to development of drugs for a life threating disease.

Dr. Reynolds has presented on the study and interpretation of drug interactions and has published peer-reviewed articles that address drug interactions. She is a member of the Drug Interaction Working Group and Drug Interaction Labeling Working Group at FDA and is the FDA topic lead for the International Council for Harmonization Drug Interaction Working Group.

Dr. Reynolds is a past president of the American Society for Clinical Pharmacology and Therapeutics and was an associate editor for *Clinical Pharmacology and Therapeutics*.



Eric Rubin
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.

Session 2: Opportunities to Improve Dose Optimization: Maximizing Information and Interpretation of Nonclinical and Early Phase Trial Data

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 the Senior Vice President and Global Head of Clinical Pharmacology & Translational Medicine at Certara. She has over 17 years of drug development experience and is a recognized drug development scientist with clinical pharmacology and regulatory experience focused in the therapeutic areas of hematology/oncology 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 approaches, pediatrics, dose-finding strategy and streamlining development for breakthrough therapies and accelerated approval.
In her current role, Dr. Bullock supports a global team of clinical pharmacologists, regulatory strategy and drug development scientists who create value for clients across the drug development ecosystem and ultimately accelerate patients' access to medicines.
Prior to her role at Certara Dr. Bullock was the Clinical Pharmacology 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, countless IND related submissions submitted to the hematology/oncology division. Dr. Bullock received her Doctor of Pharmacy from Drake University and completed a clinical pharmacology drug development fellowship with the State University of New York at Buffalo and Novartis Pharmaceuticals.

Presenters:

Matthew Thompson, PhD, MPH
Supervisory Pharmacologist, Division of Hematology Oncology, Toxicology (DHOT)
Office of Oncologic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dr. Thompson is a Supervisory Pharmacologist in the Division of Hematology Oncology Toxicology supporting the Division of Oncology 3 in the Office of Oncologic Diseases, Center for Drug Evaluation and Research at the US Food and Drug Administration. Previously, Dr. Thompson was a Pharmacology/Toxicology reviewer supporting the former Division of Hematology Products. Prior to joining the FDA, Dr. Thompson was a fellow at the National Cancer Institute at the National Institutes of Health. Dr. Thompson received his PhD from the Medical College of Wisconsin and his MPH from the Johns Hopkins Bloomberg School of Public Health

Mark Ratain, MD
Leon O. Jacobson Professor of Medicine
Director, Center for Personalized Therapeutics
Associate Director for Clinical Sciences, Comprehensive Cancer Center
The University of Chicago

Dr. Ratain is a graduate of Harvard College (A.B., 1976) and Yale School of Medicine (M.D., 1980). His postgraduate training was completed at Johns Hopkins Hospital (Internal Medicine, 1980-3) and the University of Chicago Hospitals (Hematology/Oncology, 1983-6). He has been a faculty member in the Department of Medicine at the University of Chicago since 1986 and is currently the Leon O. Jacobson Professor of Medicine, Director of The Center for Personalized Therapeutics and Chief Hospital Pharmacologist. In addition, he serves as the Associate Director for Clinical Sciences in the University's Comprehensive Cancer Center. Dr. Ratain is also one of the cofounders of the Optimal Cancer Care Alliance (previously the Value in Cancer Care Consortium, www.optimalcancercare.org) and currently serves as its Director and Treasurer.

Dr. Ratain's research has included studies of numerous oncology drugs and diagnostics, with a recent focus on dose optimization for both investigational and marketed drugs. He is an international leader in phase I clinical trials, pharmacogenomics, and clinical trial methodology, with over 500 publications. He serves as the first chair of the Steering Committee of the National Institutes of Health Pharmacogenetics Research Network, as well as one of the first co-chairs of the National Cancer Institute Investigational Drug Steering Committee. He has previously served as co-editor of *Pharmacogenetics and Genomics,* and Associate Editor of the *Journal of Clinical Oncology*. He is the recipient of multiple awards, including the Research Achievement Award in Clinical Pharmacology and Translational Research from the American Association of Pharmaceutical Scientists, the Rawls-Palmer Progress in Medicine Award from the American Society for Clinical Pharmacology and Therapeutics, the Translational Research Professorship from the American Society of Clinical Oncology, a Honorary Fellowship from the American College of Clinical Pharmacology, the Award in Clinical Excellence from the Pharmaceutical Research and Manufacturers Association Foundation, and the Arthur H. Rubenstein Mentorship in Academic Award from the Department of Medicine at the University of Chicago.

Biographies

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

Panelists:

Sheila Marie Johnson, MBA
Breast Cancer Research Advocate

Sheila Johnson is a passionate advocate for clinical trials and breast cancer research. She is a 12-year metastatic breast cancer survivor who was diagnosed in December 2009 while active-duty military in the United States Air Force. She is a 25-year Air Force decorated military veteran, receiving four Air Force Meritorious Service Medals, seven Air Force Commendation Medals and four Air Force Achievement Medals. Since her diagnosis, she decided she would speak loudly and openly for not only MBC patients but for black patients.

Sheila has participated in many breast cancer review boards as a consumer reviewer which include Komen Missouri, Patient Centered Outcome Research Institute (PCORI), DOD Breast Cancer Research Program and METAvivor. As a consumer reviewer, having a seat at a table with researchers and stakeholders allows her to share her story and be a part of the grant approval/disapproval process.

Sheila is featured in a Pfizer documentary called A Story Half Told, https://www.storyhalftold.com/meet-sheila-mcglown and she's also featured in the Breast Cancer Wellness Magazine Winter 2018 edition,

http://www.breastcancerwellness.org/mags/bcw1218/HTML5/index.html. She was also featured in "O" Oprah Magazine the September 2020 edition, sharing her story "An Air Force Vet's Hardest Fight Yet."

Her platform and the reason why she became an advocate is to raise awareness about the racial disparities black women face when being diagnosed. Many times, black women are dismissed and told their symptoms don't exist when diagnosed with breast cancer. It's very important for researchers to include black women in the recruitment of clinical trials because black women will use these therapies if approved. Since joining a clinical trial in 2018 she has become a Patients Insight Board Member with Medidata.

Black women have a higher mortality rate than any other race and this has contributed to many different factors (racial disparities, misconceptions about black women and socioeconomics). We as a breast community need to understand why these disparities exist and continue to push to help reduce these devastating statistics. Sheila has a BA and MBA from McKendree University in Lebanon IL. She is also an Advocate in Science Steering committee member and recently being selected as a Komen Scholar in 2021.

"Don't look at me as just a person with MBC but look at me as a woman with lots of love and motivation to join others as a cohesive group to END breast cancer.".

Lilli Petruzzelli, MD, PhD
Senior Vice President, Early Clinical Development for gRED, Genentech Inc.

Lilli Petruzzelli joined Genentech in 2021 as Senior Vice President, Early Clinical Development for gRED where she is responsible for leading clinical development.

Before joining Genentech, Lilli served as the Global Group Vice President, Early Clinical Development at Incyte, and prior to that, she was Global Head, Translational Clinical Oncology and Vice President, Oncology Translational Medicine at Novartis. Along with advancing numerous assets from first-in-human studies through proof-of-concept, she developed strategies that led to the registration of multiple oncology programs including.

Lilli received a Bachelor of Science in Chemistry and Biology from MIT and her MD and PhD from Albert Einstein College of Medicine. She did her internship and residency training in Internal Medicine and her fellowship in Hematology at the Brigham and Women's Hospital and Harvard Medical School in Boston. After completing her post-doctoral training in the lab of Timothy A. Springer at the Center for Blood Research at Harvard Medical School, she was a faculty member in the Department of Hematology/Oncology at the University of Michigan Medical School.

Biographies

Ishwaria Subbiah, MD
Medical Oncologist, University of Texas MD Anderson Cancer Center
Director Faculty and Academic Wellness, Office of the Chief Academic Officer
University of Texas MD Anderson Cancer Center

Dr. Ishwaria Subbiah is a Palliative Care physician and medical oncologist and serves as the Director of Faculty and Academic Wellness in the Office of the Chief Academic Officer (CAO) at the University of Texas MD Anderson Cancer Center.

Dr. Subbiah trained at MD Anderson first as a fellow in developmental therapeutics, then in Medical Oncology and followed by Palliative Medicine prior to joining the faculty. Dr. Subbiah has received several peer-reviewed grants including from the American Cancer Society for her work centered on integrating proactive remote symptom monitoring for patients on early phase trials with a particular emphasis on increasing participation of older adults aged 65 years and above on these trials. She also serves on the Older Adult Oncology guidelines committee of the National Comprehensive Cancer Network (NCCN).

In addition to her academic work, Dr. Subbiah is committed to operationalizing data-driven principles into practice for patients and peers. At MD Anderson, she chairs the Patient Survey Informatics Committee overseeing the institution-wide integration of remote symptom monitoring and patient-reported outcomes into the electronic health record and routine clinical practice. Additionally, in her role as the Director of Faculty and Academic Wellness, her office prioritizes addressing operational inefficiencies in cancer care delivery as a key component of professional wellbeing. To that end, Dr. Subbiah and her team partner with institutional stakeholders to streamline patient care related to treatment decision making and toxicities of therapy to, in turn, impact the workplace wellbeing of the oncology teams.