

Optimizing Dosages for Oncology Drug Products: Quantitative Approaches to Select Dosages for Clinical Trials

Thursday, February 15, 8am-5pm ET; Friday, February 16, 8am-1pm ET
Grand Hyatt Washington

Workshop Co-Chairs (Alphabetically by Last Name)

Jiang Liu, PhD, U.S. Food and Drug Administration, Session 1A



Jiang Liu, PhD, is the Associate Director for Therapeutic Reviews of the Division of Pharmacometrics, Office of Clinical Pharmacology, Center of Drug Evaluation and Research, at the U.S. Food and Drug Administration. Dr. Liu received his PhD in pharmaceutical sciences and master's in statistics from the University of Florida. He joined the FDA as a pharmacometrics reviewer more than 14 years ago. Dr. Liu had also served as a QT-IRT scientific lead for three years and a pharmacometrics team leader for four years before taking his current role. He is overseeing pharmacometrics review activities focusing on oncology, immunology, rare diseases, etc.

Patricia M. LoRusso, DO, PhD (hc), FAACR, Yale Cancer Center, Moderator of Session 1B



Patricia M. LoRusso, DO, PhD (hc), FAACR, serves as the Amy and Joseph Perella Professor of Medicine at the Yale School of Medicine, and Associate Cancer Center Director for Experimental Therapeutics at Yale Cancer Center. Dr. LoRusso also serves as President-elect of the American Association for Cancer Research. She has more than 25 years of expertise in medical oncology, drug development, and early phase clinical trials. Prior to her appointment at the Yale School of Medicine, she served in numerous leadership roles at Wayne State University's Barbara Ann Karmanos Cancer Institute, including as director of the Phase I Clinical Trials Program and director of the Eisenberg Center for Translational Therapeutics. Dr. LoRusso received her BS from Marygrove College and her DO from Michigan State University, as well as an honorary PhD from Michigan State University.

Stacy S. Shord, PharmD, U.S. Food and Drug Administration, Moderator of Session 3A



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 where she served as a 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 more than 50 peer-reviewed papers and 10 book chapters. Dr. Shord is a member of ASCPT, ASCO, ACCP and HOPA.

Speakers and Panelists (Alphabetically by Last Name)

Vishal Bhatnagar, MD, U.S. Food and Drug Administration, Session 2B



Vishal Bhatnagar, MD, 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.

Youwei Bi, PhD, U.S. Food and Drug Administration, Session 3A



Youwei Bi, PhD, is the Team Lead at the Division of Pharmacometrics, Office of Clinical Pharmacology, Center of Drug Evaluation and Research, FDA. He received his PhD in Clinical Pharmaceutical Sciences and Master's in Biostatistics from the University of Iowa. He has been reviewing oncology, immunology, and dermatology drug products at FDA since 2016. His primary responsibilities include reviewing IND and NDA applications, assessing the drug dosing at the individual and population levels, and evaluating the application of quantitative methods to support regulatory review, labeling and policy development.

Jamie Brewer, MD, U.S. Food and Drug Administration, Session 1B



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. In her current role, she participates in the scientific and regulatory review of drugs and biologics under development for the treatment of melanoma and gastrointestinal malignancies. Dr. Brewer also 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. Dr. Brewer is an active contributor to OCE initiatives such as Project Equity and Project Community. She is also a participant in multiple internal and external scientific working groups. Dr. Brewer completed her residency and a joint fellowship in Medical Oncology and Clinical Pharmacology and Pharmacogenomics at The University of Chicago. She completed her undergraduate training at Northwestern University and earned her medical degree from The University of Illinois at Chicago.

Cong Chen, PhD, Merck, Session 3B



Cong Chen, PhD, is Scientific AVP in Early Development Statistics at Merck & Co., Inc., providing fit-for-purpose decision-making strategies and novel statistical approaches for early and early-to-late transitional oncology programs, and supporting oncology external collaborations, competitive intelligence, and high-profile due diligence projects. Prior to taking the role, he led the statistical support for the development of Keytruda (pembrolizumab) and played a key role in accelerating its regulatory approvals. Dr. Chen is an elected Fellow of American Statistical Association (2016), an Associate Editor of *Statistics in Biopharmaceutical Research*, a member of *Cancer Clinical Research*

Editorial Board and a leader of the DIA Innovative Design Working Group. He has published over 100 papers and 10 book chapters on innovative design and analysis methods of clinical trials.

Joyce Cheng, PhD, U.S. Food and Drug Administration, Session 3B



Joyce Cheng is a statistical team leader in the Division of Biometrics V for one of the teams supporting the Division of Oncology 1 at FDA. She is also a member of OCE's Project Optimus initiative on dosage optimization in oncology. She received her PhD in statistics from Baylor University and has been at FDA since 2015.

Mallorie Fiero, PhD, U.S. Food and Drug Administration, Session 2B



Mallorie Fiero, PhD, is a Supervisory Mathematical Statistician in FDA's Center for Drug Evaluation and Research (CDER) Office of Biostatistics. She currently supports the Division of Oncology 1 in the Office of Oncologic Diseases covering breast, gynecologic and genitourinary cancers. Dr. Fiero's specialized statistical expertise in evaluating patient-reported outcomes in cancer trials. She is heavily involved in patient-focused drug development activities both externally and internally within the Oncology Center of Excellence and CDER. Mallorie received her BS in Statistics from UCLA and a PhD in Biostatistics from the University of Arizona.

William Douglas Figg Sr., PharmD, MBA, National Cancer Institute, Session 3A



W. Douglas Figg, PharmD, MBA, received a BS in Pharmacy from Samford University and a doctoral of pharmacy degree from Auburn University. He completed a clinical internship at the University of Alabama at Birmingham Hospital and a fellowship in Drug Development at the University of North Carolina at Chapel Hill. He also received an MBA from a combined Columbia University and the London Business School program. He holds honorary degrees from Georgetown College and the Philadelphia College of Osteopathic Medicine. Dr. Figg joined the National Cancer Institute, the National Institutes of Health, in 1992. He is Chief of the GU Malignancy Branch and the Clinical Pharmacology Program.

He is also co-director of the Office of Translational Resources and Associate Director of the Center for Cancer Research. Dr. Figg has over 850 peer-reviewed publications. Dr. Figg is an adjunct professor of Medicine at Columbia University in New York and adjunct professor of surgery at the Uniformed Services University in Bethesda, Maryland. Dr. Figg's research is focused on drug development of novel anticancer agents, prostate cancer, pharmacogenetics, and pharmacokinetics.

Manju George, MVSc, PhD, COLONTOWN, Session 2A



Manju George MVSc PhD is a stage IIIb rectal cancer 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 lonelier. 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. She has been at it since 2017 and it has been quite the learning experience. She loves to share her viewpoints on X/Twitter (as @manjuggm) and through the @CRCTrialsChat she hosts.

Bruno Gomes, DVM, PhD, Roche, Session 1B



Bruno Gomes, DVM, PhD, is the Head of Early Clinical Development Oncology at Roche. Bruno has 20 years of experience in oncology drug development in the pharma industry, from big pharma, mid-size companies to biotech/startups, with deep expertise in translational medicine and in moving preclinical drugs into the clinic. He led discovery and translational groups and conducted translational research for small molecules and biologics, before heading the Oncology Biomarker activities - including Biomarker, Companion Diagnostics, Pathology and Clinical Imaging - at Roche Pharma Research and Early Development. As the Head of Early Clinical Development Oncology, he now oversees and leads the clinical portfolio strategy and execution across several therapeutic modalities and mechanisms of action. He is a Doctor in Veterinary Medicine and holds a PhD in Immunology.

Nicole Gormley, MD, U.S. Food and Drug Administration, Session 2B



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.

Manish Gupta, PhD, Genmab, Session 1A



Manish Gupta, PhD, FCP, is currently the Senior Vice President and Global Head of Translational & Quantitative Sciences at Genmab. In this role, Dr. Gupta leads a dynamic R&D department at Genmab spanning clinical pharmacology and quantitative sciences, translational data sciences, bioanalytical sciences, translational research, and precision medicine functions, utilizing cutting-edge technologies to accelerate the translation of groundbreaking research into life-changing therapies. Dr. Gupta received his graduate degree from BITS, Pilani, India, and a PhD from the University of Tennessee Health Science Center. Subsequently, He completed a postdoctoral fellowship at the Children's Hospital of Philadelphia. Prior to Genmab, Dr. Gupta worked in similar roles at Bristol-Myers Squibb, Genentech, and Pfizer. Dr. Gupta has been involved in the clinical development of several successful oncology products, including Avastin, Rituximab, Herceptin, Pertuzumab, Kadcyła, Nivolumab, Ipilimumab, Elotuzumab, Tisotumab vedotin, and Epcoritamab. In addition, he has been involved in the pre-clinical clinical development of more than 100 oncology compounds.

Alexia Iasonos, PhD, Memorial Sloan Kettering Cancer Center, Session 2B



Alexia Iasonos, PhD, has led clinical collaborations with investigators in oncology for the past two decades, both at an academic cancer center and in the pharmaceutical industry. She has worked on collecting and analyzing safety and efficacy data of new interventional treatments, as well as designing, monitoring, and reporting clinical trials. Her methodological research focuses on model-based Phase I and Phase II designs, and her current interests are focused on developing efficient ways and institutional guidelines that can improve early drug development. Dr. Iasonos is an elected Fellow of the Society of Clinical Trials, and she is currently serving as the deputy editor of the Journal of Clinical Oncology. At Memorial Sloan Kettering, she is the chair of the Data Safety Monitoring Board and a member of the Protocol Performance Monitoring Committee.

Jin Y. Jin, PhD, Genentech, Session 3A



Jin Yan Jin, PhD, is Executive Director and Senior Fellow in Clinical Pharmacology at Genentech. As Global Head of Modeling and Simulation (M&S), she oversees clinical M&S and data programming for all modalities in all therapeutic areas. As Head of Clin Pharm-Ophthalmology/Neuroscience, she also oversees overall clinical pharmacology strategy in these TAs. Before joining Genentech, she worked at Eli Lilly in metabolism and neuroscience areas after PhD and post-doc in Pharmaceutical Sciences from the State University of New York at Buffalo. Dr. Jin is recognized for her scientific passion of using wide range of quantitative approaches leveraging diverse data sources to impact development of different modalities across therapeutic areas. She has strong scientific presence with 100+ publications, 40+ oral presentations worldwide, invited panelist on diverse topics, and moderated many scientific conferences, workshops and sessions. Her recent society leadership roles include as the President (2018) and Board of Director (2014-19) of the International Society of Pharmacometrics; chair of the 2015 ACoP meeting; co-chair of the 2018 FDA-ISoP MIDD in Oncology Public Workshop under PDUFA VI; member of Editorial Board for *CPT:PSP* journal; and member of various committees for the American Society of Clinical Pharmacology and Therapeutics. She was recognized as ISoP Fellow in 2020 and received the ISoP Leadership award in 2023.

Brian Koffman, MDCM (retired), MEd, *CLL Society, Session 1B*



Brian Koffman, MDCM (retired), MEd, is a doctor, educator, and clinical professor turned patient and has dedicated himself to teaching and helping the CLL community since his own chronic lymphocytic leukemia (CLL) diagnosis in 2005. Dr. Koffman's dual status as a retired physician and patient provides a unique experience and understanding which allows him to provide clear explanations of complex issues and to advocate for patients and to inform healthcare providers. Besides his medical degree, Dr. Koffman has a Master of Science in Medical Education and loves to teach. Dr. Koffman is a retired family doctor and clinical professor at the Keck School of Medicine, USC. Dr. Koffman co-founded and serves as the Chief Medical Officer and Executive Vice President of the nonprofit CLL Society Inc. that is dedicated to the unmet needs of the CLL community in support, education, advocacy and research. He also has a widely followed blog. He has shared online and across the world his tough battle with his chronic lymphocytic leukemia including a failed bone marrow transplant, and his success with early phase trials, including two Phase 1 trials, first with PCI-32765 that later became ibrutinib followed by an experimental CAR-T, JCAR-014 and most recently he was the first CLL patient in the USA to enter his trial of a bispecific T-cell engager (BITE), epcoritamab.

Mehdi Lahmar, MD, PhD, *Boehringer Ingelheim, Session 3B*



Mehdi Lahmar, MD, PhD, joined Boehringer Ingelheim in Germany as a Clinical Program Lead in Oncology in November 2019 and is currently Evidence Lead for the MDM2-p53 antagonist program; with trials that required dose optimization in continuous dialogue with FDA. He was previously Head of Project Development at Gamamabs, where he coordinated preclinical and clinical stage candidates in immune-oncology as well as interfacing with number of external stakeholders. He contributed to the advancement of drug candidates from Phase I to later stages of development. Prior to Gamamabs, Mehdi worked as project and team lead for number of drug development programs in different therapeutic areas (infectious diseases, immunology and oncology) at Vivalis and Valneva. He received his PhD in Biotechnological Therapeutics from Paris Diderot University in 2008 and his Medical Degree from Tunis Medical School in 2003 and trained in number of French Hospitals among which the European Hospital George Pompidou and Tenon Hospital in Paris.

Qi Liu, PhD, MStat, *U.S. Food and Drug Administration*



Qi Liu, PhD, MStat, is the Associate Director for Innovation & Partnership in the Office of Clinical Pharmacology (OCP)/ Office of Translational Sciences, CDER, FDA. She has helped develop OCP's portfolio on machine learning/artificial intelligence, real world evidence and digital health technologies, collaborating with internal and external experts. She led OCP's Physiological Based Pharmacokinetic Modeling and Simulation Oversight Board and co-leading Biologics Oversight Board. She was a co-lead initiating the Real-Time Oncology Review and Assessment Aid Pilot Programs. During her career at the FDA, she also contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support drug development. She worked on working groups for FDA guidance documents and Manual of Policies & Procedures development. She is an Associate Editor of Clinical Translational Science and on the editorial board of five scientific journals. Before joining FDA, Dr. Liu was a senior pharmacokineticist at Merck & Co. Inc. She obtained her PhD degree in Pharmaceutics and a concurrent Master's degree in Statistics from the University of Florida in 2004. In addition, she has a Master's degree in Pharmaceutics and a Bachelors' degree in Clinical Pharmacy from West China University of Medical Sciences.

Rajanikanth Madabushi, PhD, U.S. Food and Drug Administration



Rajanikanth “Raj” Madabushi, PhD, has over 15 years of regulatory experience as a Pharmacometrics Reviewer and Clinical Pharmacology Team Lead in the Office of Clinical Pharmacology, OTS/CDER/FDA. He currently serves as the Associate Director, Guidance and Scientific Policy in the Immediate Office of Clinical Pharmacology. Dr. Madabushi plays an instrumental role in FDA’s PDUFA MIDD initiatives and is the CDER Point-of-Contact for the MIDD Paired Meeting Program. Dr. Madabushi is also involved in global harmonization activities as the Rapporteur for ICH M12 Expert Working Group – Drug Interaction Studies

Julia Maues, Patient Centered Dosing Initiative, Session 3A



Julia Maues was diagnosed with breast cancer while pregnant in 2013. Shortly after delivering a healthy baby boy, she found out that the cancer had already spread to her bones, liver, and brain. After many treatment setbacks, her cancer began to respond to treatment, and she turned this tragic reality into a drive to improve the lives of people living with this disease. Julia’s main focus is working with researchers, clinicians, and other stakeholders to ensure research is patient-centered, innovative, accessible, and inclusive. She is a co-founder of GRASP – Guiding Researchers and Advocates to Scientific Partnerships, an organization that connects and fosters collaborations between researchers and patient advocates. Julia is also a founding member of the Patient-Centered Dosing Initiative, a patient-led movement building a framework to help physicians and patients select the optimal dosage for the patient based upon their unique physical, circumstantial, and psychological factors. Julia is a member of the Metastatic Breast Cancer Alliance, Living Beyond Breast Cancer’s (LBBC) Hear My Voice program, a Komen Advocate in Science, a member of SABCS’s conference planning committee, a DoD Congressionally Directed Breast Cancer Research Program reviewer, an ASCO guidelines panelist, and a founding member of the #InclusionPledge to end disparities in breast cancer for Black women.

Olanrewaju Okusanya, PharmD, MS, U.S. Food and Drug Administration, Moderator of Session 2A



Olanrewaju “Lanre” Okusanya, PharmD, MS, is the Deputy 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 drugs to treat malignant and non-malignant hematology diseases including biosimilars, identifying and addressing regulatory issues that arise in oncology drug development and 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.

Geoff Oxnard, MD, *Loxo@Lilly, Moderator of Session 3B*

Geoff Oxnard, MD, joined Loxo@Lilly in 2023 to lead early and late-stage clinical development for thoracic cancers, having previously led clinical development at Foundation Medicine, Inc. He is a globally recognized clinical and translational cancer researcher following nearly 10 years on faculty at the Dana-Farber Cancer Institute and Harvard Medical School. He continues to see patients as a thoracic oncologist at Boston Medical Center. Dr. Oxnard has broad experience in drug and biomarker development, having served as PI institutional and pharma sponsored studies as well as ambitious NCI initiatives (ALCHEMIST). He has published extensively on sensitivity and resistance to targeted therapies in molecularly defined lung cancer populations. His recent research focused on genomic analysis of plasma cell-free DNA as a diagnostic to assist in treatment planning, response monitoring, and cancer detection.

Ralph E. Parchment, PhD, *Frederick National Laboratory, Session 1A*

Ralph E. Parchment, PhD, currently serves as a Senior Managing Director for Laboratory & Operations Support of the NCI Division of Cancer Treatment & Diagnosis at the NCI Frederick National Laboratory for Cancer Research, a Federally Funded Research and Development Center operated by Leidos Biomedical Research, Inc. In this role, Dr. Parchment directs a translational laboratory-based program that assesses molecular pharmacodynamics of experimental cancer drugs during early clinical trials, including Phase 0 studies, and fit-for-purpose nonclinical studies to support novel drug development.

Gabby Patilea-Vrana, PhD, *Pfizer, Session 2A*

Gabby Patilea-Vrana, PhD, is currently a Senior Clinical Pharmacologist at Pfizer, where she is the Clinical Pharmacology lead on antibody-drug conjugate and antibody-based oncology programs. Prior to joining Pfizer, Gabby earned her PhD in Pharmaceutics at the University of Washington in 2019 and worked with Dr. Jashvant Unadkat. Gabby earned her BS in Bioengineering in 2013 also from University of Washington. In her current role, Gabby utilizes a variety of traditional and novel modeling and simulation tools to perform translational PK and PK/PD analysis to support FIH dose selection for early stage programs and integrated exposure-response analysis to support RP2D selection. Her focus is on utilizing and developing fit-for-purpose tools to characterize benefit-risk profiles in support of dose selection.

Alex Phipps, PhD, *AstraZeneca, Session 1A*

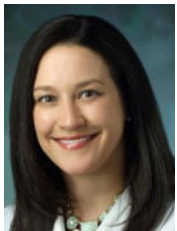
Alex Phipps, PhD, leads the Clinical Pharmacology and Pharmacometrics group in Oncology at AstraZeneca. He holds a BSc in Biochemistry from the University of Liverpool and a PhD from the University of Manchester. Alex has 27 years' experience in the Pharmaceutical Industry, starting as a biochemist and enzyme kineticist before assuming a hybrid clinical pharmacologist/modelling role at Pfizer in the early 2000's. Moving to Roche in 2011, Alex specialised in Oncology, leading the Clinical Pharmacology and systems modelling team. He joined AstraZeneca in 2021. His passion is for using model-based approaches to optimising dose and decision making in drug development, regardless of modality of the medicine. Over the years Alex and his team have led the Clinical Pharmacology contribution to the filing of many medicines and he is a frequent publisher of work in either manuscript or presentation form.

Debbie Pickworth, *BRAF Bombers & American Lung Association, Session 3B*



Debbie Pickworth was diagnosed with Stage 4 lung cancer in March of 2013 at the age of 43 years old. She has NSCLC Adenocarcinoma with the BRAF V600E mutation, and is a 3rd generation lung cancer patient. Her mother and grandmother both died of lung cancer. At the time of diagnosis, there were no BRAF-targeted treatments for lung cancer and standard options at the time were chemo, including carboplatin, pemetrexed and bevacizumab. In 2015, Ms. Pickworth joined a phase 1 trial for a BRAF combo of dabrafenib, trametinib, and the AKT inhibitor GSK2141795, which she stayed on for 2.5 years until side effects were intolerable. She then went back to on and off treatment with pemetrexed and radiation, and has been off treatment for 18 months with stable disease. Ms. Pickworth is also very active in the patient advocacy community, having started the organization BRAF Bombers for patients with BRAF-positive lung cancer, and actively serving with other organization such as the American Lung Association, Lung Force Detroit Walk, Imerman Angels, LiveLung.org, and reviewing research grants with the Department of Defense.

Cara Rabik, MD, PhD, *U.S. Food and Drug Administration, Session 3A*



Cara Rabik, MD, PhD, is a pediatric hematologist-oncologist who has been a clinical reviewer in the Division of Hematologic Malignancies I at the FDA in 2020. Cara completed her MD/PhD at the University of Chicago Pritzker School of Medicine prior to pursuing pediatric residency at the C.S. Mott Children's Hospital at the University of Michigan. She then completed her pediatric hematology-oncology training at the combined Johns Hopkins University / National Institutes of Health fellowship program. Following completion of fellowship, she was a faculty member in the Section of Hematologic Malignancies in the Division of Pediatric Oncology at the Johns Hopkins University School of Medicine. During that time, she was selected as an ASH/EHA Translational Research Training in Hematology scholar and received multiple research grants. At the FDA, Cara is a member of the Project Optimus Dosage Optimization Initiative and the Oncology Center of Excellence Pediatric Review Committee, in addition to serving as the Oncology Center of Excellence vice-liaison to the American Society of Hematology.

Nam Atiqur Rahman, PhD, *U.S. Food and Drug Administration, Session 2A*



Nam Atiqur "Atik" Rahman, PhD, is the Director of the Division of Cancer Pharmacology II within the Office of Clinical Pharmacology, OTS, CDER, US Food and Drug Administration. 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. Dr. Rahman's current interest includes immuno-oncology, application of modeling and simulation and dosage optimization in cancer drug development. Currently, Dr. Rahman is the co-chair of the Project Optimus initiatives of the Oncology Center of Excellence focusing on dose optimization of cancer drugs for US approval.

Amit Roy, PhD, Pumas AI, Session 1B



Amit Roy, PhD serves as the Head of Scientific & Strategic Consulting at Pumas AI. An engineer by training, Amit brings more than 25 years of experience in drug development and advanced pharmacometrics. He has extensive experience integrating MIDD into drug development across several therapeutic areas, including cardiovascular diseases, hematology, immunology, oncology, and virology. He has extensive experience in interacting with global regulatory agencies such as US FDA, EMA, PMDA, not only for regular submissions, but also for innovative topics such as Project Optimus. Amit served as the Executive Director and Head of Pharmacometrics at Bristol-Myers Squibb (BMS)

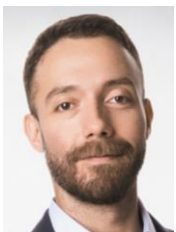
for 18 years prior to joining PumasAI. He is well published and recognized as one of the world leaders in the field of Pharmacometrics. He obtained BS from University of Michigan, PhD in Chemical and Biochemical Engineering from Rutgers University.

Mirat Shah, MD, MHS, U.S. Food and Drug Administration, Session 3B



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 at FDA. 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 is focused on improving the tolerability of cancer therapies through dosage optimization, and she is the Clinical Lead for FDA Oncology Center of Excellence's Project Optimus, an initiative to reform the oncology drug dosing paradigm. She is also committed to providing education in regulatory science to internal and external stakeholders. She enjoys hiking and birding in her spare time.

Anthony Sireci, MD, Loxo@Lilly, Session 2B



Anthony "Nino" Sireci, MD, is the Senior Vice President, Diagnostics Development at Loxo Oncology at Lilly. Dr. Sireci is a board certified Clinical Pathologist and a practicing molecular pathologist. Prior to joining Loxo, he was an Assistant Professor of Pathology and Cell Biology at Columbia University and a medical director in the Laboratory of Personalized Genomic Medicine at Columbia Medical Center. He is an active member of the Association for Molecular Pathology (AMP) where he serves on the organizations' Strategy Committee and was the former vice chair for new codes and pricing on the Economic Affairs Committee. He is also a member of the Pathology Coding Caucus in the College of

American Pathologists (CAP) and the Molecular Pathology Advisory Group in the American Medical Association (AMA). Dr. Sireci received a BA in chemistry from New York University, an MD from the Johns Hopkins University School of Medicine and a Masters in Biostatistics from the Mailman School of Public Health at Columbia University. He completed his residency training in Clinical Pathology in the New York Presbyterian Hospital-Columbia, where he also served as chief resident.

Lillian Siu, MD, Princess Margaret Cancer Centre, Session 2A



Lillian Siu, MD, 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, Co-Director of the Bras and Family Drug Development Program, and Clinical Lead for the Tumor Immunotherapy Program at Princess Margaret Cancer Centre, and holds the BMO Chair in Precision Genomics (2016-2026). Dr. Siu served on the Board of Directors for the American Society of Clinical Oncology (ASCO) during 2012-2016 and was Chair of the ASCO Conquer Cancer Foundation Grants Selection Committee in 2019; she served on the American Association for Cancer Research (AACR) Board of Directors during 2017-2020. Dr. Siu's research focuses on new anticancer drug development, particularly with respect to phase I trials and head and neck malignancies. She is the co-Contact PI of a phase I UM1 grant sponsored by the U.S. National Cancer Institute. In addition to early phase clinical trials, she leads genomics initiatives and immuno-oncology trials at the Princess Margaret Cancer Centre. She was awarded the TAT 2020 Honorary Award for contributions in the development of anticancer drugs. In 2023, Dr. Siu was recognized for her educational efforts by the ASCO International Women Who Conquer Cancer Mentorship Award. Dr. Siu has published over 400 peer-reviewed manuscripts, and she is currently the co-Editor-in-Chief for AACR's newest journal *Cancer Research Communications*, and is on the editorial board for *Cell* and *Cancer Cell*.

Marc Theoret, MD, U.S. Food and Drug Administration



Marc Theoret, MD, is a medical oncologist and Deputy Director in the Oncology Center of Excellence (OCE), FDA, and Acting Supervisory Associate Director 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 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 a 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 of the OCE, he served as the Acting Deputy Office Director in OOD. In these roles, 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.

Matthew Thompson, PhD, MPH, U.S. Food and Drug Administration, Session 1A



Matthew Thompson, PhD, MPH, is a Supervisory Pharmacologist in the Division of Hematology Oncology Toxicology supporting the Division of Oncology 3 in the Office of Oncologic Diseases at the US Food and Drug Administration. 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.

Jonathon Vallejo, PhD, U.S. Food and Drug Administration, Session 1B



Jonathan Vallejo, PhD, is a supervisory mathematical statistician in Division of Biometrics IX at FDA. Jonathon earned his PhD in statistics from Baylor University and joined FDA in 2016. His teams support the Division of Hematologic Malignancies I and Division of Hematologic Malignancies II, which includes review of protocols and applications in leukemias, lymphomas, and related diseases. Jonathon is involved in regulatory initiatives involving trial design and dose optimization. In addition, Jonathon's research interests include biomarkers, meta-analysis, and adaptive designs.

Scott A. Van Wart, PhD, Enhanced Pharmacodynamics, Session 3A



Scott A. Van Wart, PhD, is the co-founder and Chief Scientific Officer (CSO) of Enhanced Pharmacodynamics (ePD), a CRO which assists clients with the design and implementation of model-informed drug development strategies across various therapeutic areas including oncology. Dr. Van Wart has over 25 years of experience helping pharma and biotech companies leverage advanced pharmacometric and systems pharmacology techniques to guide dose selection and provide timely decision-making results during clinical development. Scott has also previously served as an Adjunct Professor at the State University of New York at Buffalo.

Timothy Yap, MBBS, PhD, MD Anderson Cancer Center, Moderator of Session 2B



Timothy Yap, MBBS, PhD, is a Medical Oncologist and Physician-Scientist based at the University of Texas MD Anderson Cancer Center. He is a Professor in the Department for Investigational Cancer Therapeutics (Phase I Program). Dr. Yap is Vice President and Head of Clinical Development in the Therapeutics Discovery Division. He is also the Associate Director of Translational Research in the Khalifa Institute for Personalized Cancer Therapy. Dr. Yap's main research focuses on the first-in-human and combinatorial development of molecularly targeted agents and immunotherapies, and their acceleration through clinical studies using novel predictive and pharmacodynamic biomarkers.

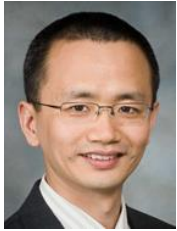
His main interests include the targeting of the DNA damage response (DDR) with novel therapeutics, such as ATR, PARP1, WEE1, POLQ, USP1, PKMYT1, PARG, CHK1, ATM and DNA-PK inhibitors, next generation CDK2, CDK4 and CDK7-selective inhibitors, YAP/TEAD inhibitors, Werner helicase inhibitors, SMARCA2 degraders, as well as the development of novel immunotherapeutics. Prior to his current position, Dr. Yap was a Consultant Medical Oncologist at The Royal Marsden Hospital in London, UK and National Institute for Health Research BRC Clinician Scientist at The Institute of Cancer Research, London, UK.

Jingyu Yu, PhD, U.S. Food and Drug Administration, Session 2A



Jingyu "Jerry" Yu, PhD, is currently a lead Pharmacokineticist in Division of Pharmacometrics, Office of Clinical Pharmacology at US FDA. He joined FDA as a reviewer after graduating from the college of Pharmacy in University of Michigan in 2011. His team supports MIDD related regulatory reviews and research in multiple therapeutical areas. He represents US FDA on scientific issues related to pharmacometrics for concurrent review of oncology products among international partners.

Ying Yuan, PhD, MD Anderson Cancer Center, Session 1B



Ying Yuan, PhD, is Bettyann Asche Murray Distinguished Professor and Deputy Chair in the Department of Biostatistics at University of Texas MD Anderson Cancer Center. Dr. Yuan is an internationally renowned researcher in innovative Bayesian adaptive designs, with over 150 statistical methodology papers published on early phase trials, seamless trials, biomarker-guided trials, and basket and platform trials. The designs and software developed by Dr. Yuan's lab (www.trialdesign.org) have been widely used in medical research institutes and pharmaceutical companies. The BOIN design, developed by Dr. Yuan's team, is a groundbreaking oncology dose-finding design that has been recognized by the FDA as a fit-for-purpose drug development tool. Dr. Yuan was elected as the American Statistical Association Fellow, and is the leading author of two books, "Bayesian Designs for Phase I-II Clinical Trials" and "Model-Assisted Bayesian Designs for Dose Finding and Optimization," both published by Chapman & Hall/CRC.

Hao Zhu, PhD, U.S. Food and Drug Administration, Moderator of Session 1A



Hao Zhu, PhD, is the director of the Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Science, Center of Drug Evaluation and Research, U.S. Food and Drug Administration. Dr. Zhu received his PhD in pharmaceutical sciences and Master in statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 16 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than 6 years and a QT-IRT scientific lead for 2 years. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.