Getting the Dose Right: Optimizing Dose Selection Strategies in Oncology An FDA-ASCO Virtual Workshop Dates: May 3 and 5, 2022	
	Day 1: May 3, 2022
1:00 – 1:10	**Introduction to Workshop** • R. Donald Harvey, American Society of Clinical Oncology (ASCO) Workshop Co-Chair, Emory School of Medicine • Mirat Shah, FDA Workshop Co-chair, U.S. Food and Drug Administration
1:10 – 1:15	**Opening Remarks** • Richard Pazdur, U.S. Food and Drug Administration
1:15 – 2:45	**Session 1: Challenges to Dose Optimization** **Moderator:** Marc Theoret, U.S. Food and Drug Administration **Keynote Speaker:** **Dose and Schedule Selection in Early Phase Trials in Oncology: A Historical Perspective** • Lillian Siu, Princess Margaret Cancer Centre **Panel Discussion:** • Jim Doroshow, National Cancer Institute • Anne Loeser, Patient-Centered Dosing Initiative • Atik Rahman, U.S. Food and Drug Administration • Kellie Reynolds, U.S. Food and Drug Administration • Eric Rubin, Merck
2:45 – 3:00	**Break**

3:00 – 4:40	**Session 2: Opportunities to Improve Dose Optimization: Maximizing Information and Interpretation of Nonclinical and Early Phase Trial Data** **Moderator and Introductory Comments:** Julie Bullock, Certara **Using Nonclinical Pharmacology Data to Support Clinical Dose Optimization** • Matthew Thompson, U.S. Food and Drug Administration **Goals of First-in-Human Clinical Trials** • Mark Ratain, University of Chicago **Variability in Early Phase Clinical Trials: Intrinsic and Extrinsic Factors** • Lanre Okusanya, U.S. Food and Drug Administration **Panel Discussion:** • Sheila Johnson, Breast Cancer Research Advocate • Lilli Petruzzelli, Genentech • Ishwaria Subbiah, MD Anderson Cancer Center
4:40 – 4:45	**Wrap-up and Adjourn**

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	Day 2: May 5, 2022
1:00 – 1:05	**Welcome to the Workshop** • R. Donald Harvey, ASCO Co-Chair, Emory School of Medicine • Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration

1:05 – 2:00	**Session 3a: Opportunities to Improve Dose Optimization: Designing Trials and Applying Pharmacometrics** **Moderator:** Mirat Shah, FDA Co-Chair, U.S. Food and Drug Administration **Trial Designs to Evaluate Multiple Doses in the Premarket Setting** • Liz Garrett-Mayer, American Society of Clinical Oncology **Pharmacometric Applications and Challenges** • Bernd Meibohm, University of Tennessee **Panel Discussion:** • Akintunde Bello, Bristol Myers Squibb • Jill Feldman, Lung Cancer Patient and Advocate • Gregory Friberg, Amgen • Jonathan Vallejo, U.S. Food and Drug Administration
2:00 – 2:05	**Break**
2:05 – 2:55	**Session 3b: Opportunities to Improve Dose Optimization: Assessing Safety and Tolerability** **Moderator:** Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration **Integrating Safety Information from Beyond the First Treatment Cycle** • Sophie Postel-Vinay, Gustave Roussy **Using Patient Reported Outcomes (PROs) to optimize the dose: Integrating Exposure-Response with PROs** • Vishal Bhatnagar and Jeanne Fourie Zirkelbach, U.S. Food and Drug Administration **Panel Discussion:** • Akintunde Bello, Bristol Myers Squibb • Jill Feldman, Lung Cancer Patient and Advocate • Gregory Friberg, Amgen • Jonathan Vallejo, U.S. Food and Drug Administration

2:55 – 3:10	**Break**
3:10 – 4:40	**Session 4: The Path Forward to Optimizing Dose Selection in Oncology** **Moderator:** R. Donald Harvey, ASCO Co-Chair, Emory School of Medicine **Panel Discussion:** • Percy Ivy, National Cancer Institute • Olga Kholmanskikh, European Medicines Agency, Federal Agency for Medicines and Health Products (FAMHP) - Belgium • Shing Lee, Columbia University • Jeffrey Peppercorn, Massachusetts General Hospital • Atik Rahman, U.S. Food and Drug Administration • Mace Rothenberg, Independent Board Member at Tango Therapeutics, Surrozen, and Aulos Bioscience • Mirat Shah, U.S. Food and Drug Administration • Peggy Zuckerman, Patient Advocate - KidneyCAN, Kidney Cancer Association, and SWOG Cancer Research Network
4:40 – 4:45	**Wrap-up and Adjourn**