

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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Richard Pazdur, U.S. Food and Drug Administration
1:15-2:45	Session 1: Challenges to Dose Optimization <p>Moderator: Marc Theoret, U.S. Food and Drug Administration</p> <p>Keynote Speaker: Dose and Schedule Selection in Early Phase Trials in Oncology: A Historical Perspective</p> <ul style="list-style-type: none"> • Lillian Siu, Princess Margaret Cancer Centre <p>Panel Discussion:</p> <ul style="list-style-type: none"> • 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

<p>3:00 – 4:40</p>	<p>Session 2: Opportunities to Improve Dose Optimization: Maximizing Information and Interpretation of Nonclinical and Early Phase Trial Data</p> <p>Moderator: Julie Bullock, Certara</p> <p>Using Nonclinical Pharmacology Data to Support Clinical Dose Optimization</p> <ul style="list-style-type: none"> • Matthew Thompson, U.S. Food and Drug Administration <p>Pending</p> <ul style="list-style-type: none"> • R. Donald Harvey, American Society of Clinical Oncology (ASCO) Workshop Co-Chair, Emory School of Medicine • Julie Bullock, Certara <p>Goals of First-in-Human Clinical Trials</p> <ul style="list-style-type: none"> • Mark Ratain, University of Chicago <p>Variability in Early Phase Clinical Trials: Intrinsic and Extrinsic Factors</p> <ul style="list-style-type: none"> • Lanre Okusanya, U.S. Food and Drug Administration <p>Panel Discussion:</p> <ul style="list-style-type: none"> • Sheila Johnson, Breast Cancer Research Advocate • Lilli Petruzzelli, Genentech • Ishwaria Subbiah, MD Anderson Cancer Center
<p>4:40 – 4:45</p>	<p>Wrap-up and Adjourn</p>

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Dates: May 3 and 5, 2022	
Day 2: May 5, 2022	
1:00 – 1:05	Welcome to the Workshop <ul style="list-style-type: none"> • 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 <p>Moderator: Mirat Shah, FDA Co-Chair, U.S. Food and Drug Administration</p> <p>Trial Designs to Evaluate Multiple Doses in the Premarket Setting</p> <ul style="list-style-type: none"> • Liz Garrett-Mayer, American Society of Clinical Oncology <p>Pharmacometric Applications and Challenges</p> <ul style="list-style-type: none"> • Bernd Meibohm, University of Tennessee <p>Panel Discussion:</p> <ul style="list-style-type: none"> • Jonathan Vallejo, U.S. Food and Drug Administration • Gregory Friberg, Amgen • Jill Feldman, Lung Cancer Patient and Advocate • Akintunde Bello, Bristol Myers Squibb
2:00 – 2:05	Break

<p>2:05 – 2:55</p>	<p>Session 3b: Opportunities to Improve Dose Optimization: Assessing Safety and Tolerability</p> <p>Moderator: Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration</p> <p>Integrating Safety Information from Beyond the First Treatment Cycle</p> <ul style="list-style-type: none"> • Sophie Postel-Vinay, Gustave Roussy <p>Using Patient Reported Outcomes (PROs) to optimize the dose: Integrating Exposure-Response with PROs</p> <ul style="list-style-type: none"> • Vishal Bhatnagar and Jeanne Fourie Zirkelbach, U.S. Food and Drug Administration <p>Panel Discussion:</p> <ul style="list-style-type: none"> • Jonathan Vallejo, U.S. Food and Drug Administration • Gregory Friberg, Amgen • Jill Feldman, Lung Cancer Patient and Advocate • Akintunde Bello, Bristol Myers Squibb
<p>2:55 – 3:10</p>	<p>Break</p>
<p>3:10 – 4:40</p>	<p>Session 4: The Path Forward to Optimizing Dose Selection in Oncology</p> <p>Moderator: R. Donald Harvey, ASCO Co-Chair, Emory School of Medicine</p> <p>Panel Discussion:</p> <ul style="list-style-type: none"> • Percy Ivy, National Cancer Institute • Olga Kholmanskikh, European Medicines Agency • 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
<p>4:40 – 4:45</p>	<p>Wrap-up and Adjourn</p>