

**Second Annual Workshop on Getting the Dose Right:  
Optimizing Dose Selection Strategies in Combination Anticancer Therapies**

**An FDA-ASCO Virtual Workshop**

**September 6-7, 2023**

	<b>Day 1: September 6, 2023</b>
<b>1:00</b>	<p><b>Introduction to the Workshop</b></p> <ul style="list-style-type: none"> <li>• R. Donald Harvey, American Society of Clinical Oncology (ASCO) Co-Chair, Emory School of Medicine</li> <li>• Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration</li> </ul>
<b>1:20</b>	<p><b>Opening Remarks</b></p> <ul style="list-style-type: none"> <li>• Richard Pazdur, U.S. Food and Drug Administration</li> </ul>
<b>1:30</b>	<p><b>Session 1: Current State of Dosage Optimization in Combination Anticancer Therapies</b></p> <p><b>Moderator:</b> Mirat Shah, U.S. Food and Drug Administration</p> <p><b>Keynote Presentation: Challenges and Opportunities to Developing Combination Anticancer Therapies in Oncology</b></p> <ul style="list-style-type: none"> <li>• Pat LoRusso, Yale School of Medicine</li> </ul> <p><b>Lessons from Anesthesiology</b></p> <ul style="list-style-type: none"> <li>• Steven Shafer, Stanford University</li> </ul> <p><b>Panelists:</b></p> <ul style="list-style-type: none"> <li>• Janice Cowden, Patient-Centered Dosing Initiative</li> <li>• Nicole Gormley, U.S. Food and Drug Administration</li> <li>• Alice Tseng, University Health Network</li> <li>• Jennifer Lauchle, Genentech</li> </ul> <p><b>Panel Discussion</b></p>
<b>2:45</b>	<b>Break</b>

<b>3:00</b>	<b>Session 2: The Nuts and Bolts of Combination Dosage Optimization</b>  <b>Moderator:</b> Julie Bullock, Certara  <b>Presenters:</b> <ul style="list-style-type: none"><li>• Mallika Singh, REVOLUTION Medicines</li><li>• Giovanni Abbadessa, Sanofi</li><li>• J. Jack Lee, MD Anderson Cancer Center</li></ul> <b>Panelists:</b> <ul style="list-style-type: none"><li>• Percy Ivy, National Cancer Institute</li><li>• Joyce Cheng, U.S. Food and Drug Administration</li><li>• Atik Rahman, U.S. Food and Drug Administration</li></ul> <b>Panel Discussion</b>
<b>4:30</b>	<b>Wrap-up and Adjourn</b>

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<b>Day 2 September 7</b>	
<b>1:00</b>	<p><b>Welcome to the Workshop</b></p> <ul style="list-style-type: none"> <li>• R. Donald Harvey, ASCO Co-Chair, Emory School of Medicine</li> <li>• Mirat Shah, FDA Co-chair, U.S. Food and Drug Administration</li> </ul>
<b>1:05</b>	<p><b>Session 3: Case Studies for Developing Combination Therapies</b></p> <p><b>Moderator:</b> Michael Maitland, Intellia Therapeutics, Inc.</p> <p><b>Case Study 1: Nivolumab and relatlimab</b></p> <ul style="list-style-type: none"> <li>• Jamie Brewer, U.S. Food and Drug Administration</li> <li>• Akintunde Bello, Bristol Myers Squibb</li> </ul> <p><b>Case Study 2: Dabrafenib and trametinib</b></p> <ul style="list-style-type: none"> <li>• Ruby Leong, U.S. Food and Drug Administration</li> <li>• Eugene Tan, Novartis Pharmaceuticals Corporation</li> </ul> <p><b>Case Study 3: Venetoclax + decitabine/azacytidine/cytarabine</b></p> <ul style="list-style-type: none"> <li>• Lori Ehrlich, U.S. Food and Drug Administration</li> <li>• Raid Ibrahim, AbbVie Inc.</li> </ul> <p><b>Panelists:</b></p> <ul style="list-style-type: none"> <li>• Chris Takimoto, IGM Biosciences</li> <li>• Lanre Okusanya, U.S. Food and Drug Administration</li> <li>• Glenn Sykes, patient advocate</li> </ul> <p><b>Panel Discussion After Each Case Study</b></p>
<b>3:15</b>	<b>Break</b>

<b>3:30</b>	<p><b>Session 4: The Path Forward: Optimizing Dose Selection in Combination Anticancer Therapies</b></p> <p><b>Moderator:</b> R. Donald Harvey, ASCO Workshop Co-Chair, Emory School of Medicine</p> <p><b>Panelists:</b></p> <ul style="list-style-type: none"><li>• Dean Ho, National University of Singapore</li><li>• Funda Meric-Bernstem, MD Anderson Cancer Center</li><li>• Debbie Pickworth, American Lung Association’s Lung Cancer Patient Advisory Group</li><li>• Eric Rubin, Merck</li><li>• Stacy Shord, U.S. Food and Drug Administration</li><li>• Garth Strohbehn, University of Michigan</li></ul> <p><b>Panel Discussion</b></p>
<b>4:30</b>	<b>Wrap-up and Adjourn</b>