

FDA-ASCO: Geriatric Oncology Workshop
Monday, November 6, 2017
FDA Silver Spring, MD Campus

8:00 – 8:15	Opening Remarks
	Janet Woodcock, U.S. Food and Drug Administration
8:15 – 8:45	Welcome and Introduction to Workshop
	<ul style="list-style-type: none"> • Arti Hurria, City of Hope • Laura Levit, American Society of Clinical Oncology • Harpreet Singh, U.S. Food and Drug Administration
8:45 – 10:15	Session 1: Designing clinical trials for older adults with cancer
	Moderator: Harvey Cohen, Duke University
	Speakers: <ul style="list-style-type: none"> • Supriya Mohile, University of Rochester Medical Center • Tania Small, Novartis • Hans Wildiers, University Hospitals Leuven
	Panelists: <ul style="list-style-type: none"> • Julia Beaver, U.S. Food and Drug Administration • Jan Buckner, Mayo Institute • Beverly Canin, patient advocate • Wortia McCaskill-Stevens, National Cancer Institute • Rajeshwari Sridhara, U.S. Food and Drug Administration
	Question and Answer
10:15 – 10:30	Break
10:30 – 12:00	Session 2: Increasing the enrollment of older adults on FDA registration trials to reflect the proportion with the disease: Strategies and challenges
	Moderator: Heidi Klepin, Comprehensive Cancer Center of Wake Forest University
	Speakers: <ul style="list-style-type: none"> • Bindu Kanapuru, U.S. Food and Drug Administration • Lou Fehrenbacher, Kaiser Permanente • Michaela Popa Mckiver, Bristol-Myers Squibb • Eric Rubin, Merck
	Panelists: <ul style="list-style-type: none"> • Jo-Ellen De Luca, patient advocate • Judith Hopkins, Novant Health • Iman Martin, National Cancer Institute

	<ul style="list-style-type: none"> Hyman Muss, UNC Lineberger Comprehensive Cancer Center <p>Question and Answer</p>
12:00 – 1:00	Lunch
1:00 – 2:30	<p>Session 3: Leveraging research designs for real-world patients: Real-world evidence</p> <p>Moderator: Harpreet Singh, U.S. Food and Drug Administration</p> <p>Speakers:</p> <ul style="list-style-type: none"> Sean Khozin, U.S. Food and Drug Administration Gary Lyman, Fred Hutchinson Cancer Research Center Robert Miller, CancerLinQ <p>Panelists:</p> <ul style="list-style-type: none"> Cynthia Chauhan, FDA Patient Representative Program William Dale, City of Hope Gracie Lieberman, Genentech Yu-Ning Wong, Janssen Scientific Affairs, LLC <p>Question and Answer</p>
2:30 – 2:45	Break
2:45 – 4:15	<p>Session 4: Lessons from pediatrics, payers, and the European Medicines Agency</p> <p>Moderator: Arti Hurria, City of Hope</p> <p>Speakers:</p> <ul style="list-style-type: none"> Peter Adamson, Children’s Oncology Group Susan L. Weiner, Children’s Cause for Cancer Advocacy Donna Messner, Center for Medical Technology Policy Frans Opdam, Netherlands Cancer Institute <p>Panelists:</p> <ul style="list-style-type: none"> Joseph Chin, Centers for Medicare and Medicaid Services Rick Pazdur, U.S. Food and Drug Administration Richard Schilsky, American Society of Clinical Oncology Margaret Sedenquist, Patient Advocate <p>Question and Answer</p>
4:15 – 4:30	<p>Closing Remarks</p> <p>Arti Hurria, City of Hope</p>
4:30	Adjourn