

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 • 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: • Supriya Mohile, University of Rochester Medical Center • Tania Small, Novartis • Hans Wildiers, University Hospitals Leuven Panelists: • Julia Beaver, U.S. Food and Drug Administration • Jan Buckner, Mayo Institute • Beverly Canin, patient advocate • Wortá 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: • Bindu Kanapuru, U.S. Food and Drug Administration • Lou Fehrenbacher, Kaiser Permanente • Michaela Popa Mckiver, Bristol-Myers Squibb • Eric Rubin, Merck Panelists: • Jo-Ellen De Luca, patient advocate • Judith Hopkins, Novant Health • Iman Martin, National Cancer Institute

	Hyman Muss, UNC Lineberger Comprehensive Cancer Center Question and Answer
12:00 – 1:00	Lunch
1:00 – 2:30	Session 3: Leveraging research designs for real-world patients: Real-world evidence Moderator: Harpreet Singh, U.S. Food and Drug Administration Speakers: - Sean Khozin, U.S. Food and Drug Administration - Gary Lyman, Fred Hutchinson Cancer Research Center - Robert Miller, CancerLinQ Panelists: - Cynthia Chauhan, FDA Patient Representative Program - William Dale, City of Hope - Gracie Lieberman, Genentech - Yu-Ning Wong, Janssen Scientific Affairs, LLC Question and Answer
2:30 – 2:45	Break
2:45 – 4:15	Session 4: Lessons from pediatrics, payers, and the European Medicines Agency Moderator: Arti Hurria, City of Hope Speakers: - 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 Panelists: - 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 Question and Answer
4:15 – 4:30	Closing Remarks Arti Hurria, City of Hope
4:30	Adjourn