FDA-ASCO: Geriatric Oncology Workshop Monday, November 6, 2017 FDA Silver Spring, MD Campus	
8:00 – 8:15	**Opening Remarks** Janet Woodcock, Director, Center for Drug Evaluation and Research, 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 real world patients** Moderator: Harvey Cohen, Duke University Speakers: • Supriya Mohile, University of Rochester Medical Center • Tania Small, Novartis • Hans Wildier, University Hospitals Leuven Panelists: • Julia Beaver, U.S. Food and Drug Administration • Jan Buckner, Mayo Institute • Beverly Canin, patient advocate • Worta McCaskill-Stevens, NCI • 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 • 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 • William Pierce, U.S. Food and Drug Administration • 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 • Anne Pritchett, PhRMA • Richard Schilsky, American Society of Clinical Oncology • Margaret Sedenquist, Patient Advocate Question and Answer
4:15 – 4:30	**Closing Remarks**