NATIONAL CANCER POLICY FORUM

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

The Drug Development Paradigm in Oncology

NAS Lecture Room
2101 Constitution Ave, NW
Washington, DC 20418
December 12-13, 2016

AGENDA

DECEMBER 12, 2016	
7:30 am	**Registration and Breakfast**
8:00 am	**Welcome and Overview of the Workshop** Richard L. Schilsky, American Society of Clinical Oncology Planning Committee Chair
8:10 am	**Session 1: Vision for a Seamless Cancer Drug Development Paradigm** Moderator: Richard L. Schilsky, American Society of Clinical Oncology • Mark Ratain, University of Chicago • Mace Rothenberg, Pfizer • Janet Woodcock, Food and Drug Administration • Ellen Sigal, Friends of Cancer Research **Panel Discussion**
10:00 am	**Break**
10:15 am	**Session 2: Case Studies and Lessons Learned from Recent Experiences** Moderator: Suzanne Topalian, Johns Hopkins University **Anti-PD1 Immunotherapy** • Eric Rubin, Merck **BRAF Pathway Inhibitors** • Keith Flaherty, Massachusetts General Hospital **T790M EGFR Inhibitors** • Pasi Jänne, Dana-Farber Cancer Institute **Challenges Resulting from Rapid Regulatory Approvals** • Donald Harvey, Emory University **Panel Discussion** – Session speakers and Gideon Blumenthal, Food and Drug Administration
12:15 pm	**Lunch**

1:00 pm	**Session 3: Flexible Drug Development and Decision Making: Accommodating New Insights** Moderator: Mace Rothenberg, Pfizer **Understanding Biological Activity to Inform Drug Development** • Kenneth Anderson, Dana-Farber Cancer Institute • Wolfgang Weber, Memorial Sloan Kettering Cancer Center **Assessing Early Signals of Efficacy to Guide Clinical Development** • David Feltquate, Bristol-Myers Squibb • Richard Finn, UCLA Jonsson Comprehensive Cancer Center **Dose-Finding Considerations and Strategies for Novel Combination Development** • Steven Piantadosi, Cedars-Sinai Medical Center **Panel Discussion** – Speakers plus: • Patricia Keegan, Food and Drug Administration • Hedvig Hricak, Memorial Sloan Kettering Cancer Center
3:15 pm	**Break**
3:30 pm	**Session 4: Continuous Evidence Generation Across the Cancer Therapy Life Cycle** Moderator: Monica Bertagnolli, Dana-Farber Cancer Institute **Clinical Trial Designs to Expedite Drug Development** • Mary Redman, Fred Hutchinson Cancer Research Center • Rajeshwari Sridhara, Food and Drug Administration **The Use of Real World Evidence in Drug Development** • Maria Koehler, Pfizer • Amy Abernethy, Flatiron Health **Panel Discussion** – Speakers plus: • Jeffrey Brown, Harvard Pilgrim Health Care Institute
5:30 pm	**Wrap up Day 1** Richard L. Schilsky, American Society of Clinical Oncology
DECEMBER 13, 2016	
7:30 am	**Registration and Breakfast**
8:00 am	**The National Cancer Moonshot Initiative and Seamless Drug Development** Moderator: Richard L. Schilsky, American Society of Clinical Oncology **Blue Ribbon Panel Recommendations** • Elizabeth Jaffee, Johns Hopkins University

	Q&A
8:30 am	**Session 5: Managing Benefit and Risk in Seamless Cancer Drug Development** Moderator: Rebecca Pentz, Emory School of Medicine **FDA Perspectives on Seamless Drug Development** • Marc Theoret, Food and Drug Administration **Expanding Eligibility Criteria and Access to Experimental Therapies** *ASCO, Friends of Cancer Research, and FDA Working Group to Expand Eligibility Criteria* • Gwynn Ison, Food and Drug Administration *Expanded Access Programs* • Steven Lemery, Food and Drug Administration **Patient Protections and Ethical Considerations** • Steven Joffe, University of Pennsylvania **Data Monitoring Approaches in a Seamless Drug Development Paradigm** • Frank Rockhold, Duke Clinical Research Institute **Benefit Risk Analysis of Decision Making in Oncology** • G.K. Raju, Massachusetts Institute of Technology **Panel Discussion**
11:15 am	**Break**
11:30 am	**Session 6: Stakeholder Perspectives: Goals of the New Paradigm and Priorities for the Path Forward** Moderator: Steven Piantadosi, Cedars-Sinai Medical Center • Howard A. Burris, III, Sarah Cannon Research Institute • Elizabeth Jaffee, Johns Hopkins University • Lynn M. Matrisian, Pancreatic Cancer Action Network • Eric Rubin, Merck • Amy McKee, Food and Drug Administration • Jeffrey Brown, Harvard Pilgrim Health Care Institute • Rebecca Pentz, Emory School of Medicine • Ronald Kline, Centers for Medicare and Medicaid Services
12:45 pm	**Wrap Up of the Workshop** Richard L. Schilsky, American Society of Clinical Oncology Planning Committee Chair
1:00 pm	**Adjourn**