

Implementing a National Cancer Clinical Trials System for the 21st Century

A Workshop hosted by the

Institute of Medicine's National Cancer Policy Forum and

The American Society of Clinical Oncology

March 21, 2011 Agenda

The Keck Center of the National Academies

Agenda with Audio Links March 21, 2011

7:30 am Breakfast and Registration

8:00 am Welcome and Opening Remarks

- **Richard L. Schilsky**, University of Chicago, Workshop Chair
- **John Mendelsohn**, M. D. Anderson Cancer Center

<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000001.MP3?dl>

8:15 am Panel 1: National Cancer Institute and the Cooperative Groups

Moderator: Richard L. Schilsky, University of Chicago, Workshop Chair

NCI perspective and current activities

- **James Doroshow**, Division of Cancer Treatment and Diagnosis
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000002.MP3?dl>
- **Lori Minasian**, Division of Cancer Prevention
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000003.MP3?dl>

8:45 am Cooperative Group Leadership perspective and current activities

- **Jan Buckner**, North Central Cancer Treatment Group
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000004.MP3?dl>
- **Robert Gray**, Eastern Cooperative Oncology Group Statistical Center
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000005.MP3?dl>

9:15 am Experience from the consolidation of COG

- **Greg Reaman**, Children's National Medical Center, and past chair, COG
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000006.MP3?dl>

9:30 am Roundtable discussion with presenters and Cooperative Group leadership:

<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000007.MP3?dl>

- Peter Adamson, Children's Oncology Group
- Monica Bertagnolli, Cancer and Leukemia Group B
- Robert Comis, Eastern Cooperative Oncology Group
- John J. Crowley, Southwest Oncology Group
- Walter Curran, Radiation Therapy Oncology Group
- Philip DiSaia, Gynecologic Oncology Group
- Heidi Nelson, American College of Surgeons Oncology Group
- David Ota, American College of Surgeons Oncology Group
- Mitchell Schnall, American College of Radiology Imaging Network

- Norman Wolmark, National Surgical Adjuvant Breast and Bowel Project
- Karla Ballman, American College of Surgeons Oncology Group
- John Blessing, Gynecologic Oncology Group Statistical and Data Center
- Joseph Costantino, National Surgical Adjuvant Breast and Bowel Project
- James Dignam, Radiation Therapy Oncology Group; University of Chicago
- Constantine Gatsonis, American College of Radiology Imaging Network
- Sin-Ho Jung, Cancer and Leukemia Group B Statistics Center

11:00 am **Panel 2: Payors**

Moderator: Lee Newcomer, UnitedHealthCare

Opening Remarks

- Insurers
 - **James Cross**, AETNA
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000008.MP3?dl>
 - **Sharon Levine**, Kaiser Permanente
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000009.MP3?dl>
- Centers for Medicare and Medicaid Services
 - **Louis Jacques**
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000010.MP3?dl>
- Charles Rudin, Johns Hopkins
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000011.MP3?dl>
- Process for establishing a new CPT code for patient enrollment in a trial
 - **Karen Hagerty**, Director of Reimbursement Policy, ASCO Cancer Policy and Clinical Affairs Department
<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000012.MP3?dl>

11:45 pm **Panel Discussion**

<http://dl.dropbox.com/u/24012591/Audio%20Part%201/MZ000013.MP3?dl>

1:00 pm **Panel 3: Interactions between industry, the FDA, and the publicly-funded cancer clinical trials system**

Moderator: John Hohneker, Novartis Pharmaceuticals

Opening Remarks

- Pharmaceutical industry
 - **Ira Steinberg**, Sanofi-Aventis US and CEO Roundtable on Cancer Life Sciences Consortium
<http://dl.dropbox.com/u/23609700/MZ000001-%20part%202.MP3?dl>
- Diagnostic industry
 - **Steven Shak**, Genomic Health
<http://dl.dropbox.com/u/23609700/MZ000002-%20part%202.MP3?dl>
- **Richard Pazdur**, CDER
<http://dl.dropbox.com/u/23609700/MZ000003-%20part%202.MP3?dl>
- Informatics vendor
 - **Glen de Vries**, Medidata Solutions
<http://dl.dropbox.com/u/23609700/MZ000004-%20part%202.MP3?dl>

1:30 pm Panel Discussion

Include presenters and:

- **Jerry Menikoff**, OHRP
- **Robert Becker**, CDRH
<http://dl.dropbox.com/u/23609700/MZ000005-%20part%202.MP3?dl>

3:15 pm Panel 4: Clinical trials investigators and Cooperative Group advocates

Moderator: Jan Buckner, North Central Cancer Treatment Group

Opening Remarks

- **Stephen Grubbs**, Community Clinical Oncology Program
<http://dl.dropbox.com/u/23609700/MZ000006-%20part%202.MP3?dl>
- **Michael Katz**, Cooperative Group advocate
<http://dl.dropbox.com/u/23609700/MZ000007-%20part%202.MP3?dl>
- **Michael Caligiuri**, Association of American Cancer Institutes
<http://dl.dropbox.com/u/23609700/MZ000008-%20part%202.MP3?dl>
- **Melanie Thomas**, Medical University of South Carolina, 2009 NCI Clinical Team Leadership Awardee
<http://dl.dropbox.com/u/23609700/MZ000009-%20part%202.MP3?dl>
- **Maria Gonzalez**, NCCCP, St. Joseph Hospital of Orange
<http://dl.dropbox.com/u/23609700/MZ000010-%20part%202.MP3?dl>
- **Shelley Fuld Nasso**, Susan G. Komen for the Cure
<http://dl.dropbox.com/u/23609700/MZ000011-%20part%202.MP3?dl>

4:00 pm Panel Discussion

<http://dl.dropbox.com/u/23609700/MZ000012-%20part%202.MP3?dl>

5:15 pm Closing comments/Wrap up

Richard L. Schilsky

(Audio included in last part of previous link.)

5:30 pm Adjourn