



**Implementing a National Cancer Clinical Trials System
for the 21st Century, Workshop #2**

Hosted by the **American Society of Clinical Oncology** and
the **Institute of Medicine’s National Cancer Policy Forum**

AGENDA

An ad hoc committee will plan and conduct a public workshop to identify and examine ongoing activities to implement the recommendations put forth in the IOM consensus report, *A National Cancer Clinical Trials System for the 21st Century*.

The goals of the workshop include:

- summarizing current progress;
- identifying remaining gaps; and
- identifying opportunities for closing those gaps within a national clinical trial system.

February 11, 2013

7:30 am	Breakfast and Registration
8:15 am	<p>Welcome from the IOM’s National Cancer Policy Forum</p> <ul style="list-style-type: none"> • John Mendelsohn, MD Anderson Cancer Center Chair, National Cancer Policy Forum <p>Introduction to Workshop</p> <ul style="list-style-type: none"> • Monica Bertagnolli, Alliance for Clinical Trials In Oncology and Dana-Farber Cancer Institute, Workshop Planning Committee Chair
8:25 am	<p>Session 1: Updates from NCI and NCTN Components: Progress To Date <i>Moderator: James Doroshow, NCI</i></p> <p>NCI Updates</p> <ul style="list-style-type: none"> • James Doroshow, NCI Division of Cancer Treatment and Diagnosis <p>Updates from the Cooperative Groups</p> <ul style="list-style-type: none"> • Robert Comis, ECOG-ACRIN Cancer Research Group <p>Updates on CCOPs/NCCCP/NCORP</p> <ul style="list-style-type: none"> • Wortia McCaskill-Stevens, NCI Division of Cancer Prevention <p>Panel Discussion</p> <p>Speakers above plus representatives of community practices in the NCORP:</p> <ul style="list-style-type: none"> • Stephen Grubbs, Helen F. Graham Cancer Center and Christiana Care CCOP • Robin Zon, Michiana Hematology Oncology, PC and Northern Indiana Cancer Research Consortium CCOP
10:00	Break

10:15 am	<p>Session 2: Funding for Cancer Clinical Trials <i>Moderator: John Mendelsohn, MD Anderson Cancer Center</i></p> <p>Metrics on the technical risks of cancer drug development & drug development times</p> <ul style="list-style-type: none"> • Joseph DiMasi, Tufts Center for the Study of Drug Development <p>Funding clinical trials in the academic and community research environment</p> <ul style="list-style-type: none"> • Marc Sabatine, Thrombolysis in Myocardial Infarction Study Group <p>Foundation Perspective</p> <ul style="list-style-type: none"> • Margaret Anderson, FasterCures <p>Panel Discussion</p>
11:45 pm	Lunch
12:30 pm	<p>Session 3: Prioritization of Cancer Trials in a Changing Environment <i>Moderator: George Sledge, Stanford University School of Medicine</i></p> <p>Status report from the CTAC strategic planning subcommittee</p> <ul style="list-style-type: none"> • George Sledge, Stanford University School of Medicine • Robert Diasio, Mayo Clinic Cancer Center <p>An International Perspective from the UK Network on Prioritization of Trials:</p> <ul style="list-style-type: none"> • Richard Kaplan, UK National Cancer Research Network & Medical Research Council <p>Panel Discussion</p>
1:45 pm	<p>Session 4: The NCTN as a Platform to Implement Precision Medicine <i>Moderator: Barbara Conley, NCI Division of Cancer Treatment and Diagnosis</i></p> <p>Resources Needed for a Trial Employing Genomic Profiling for Eligibility</p> <ul style="list-style-type: none"> • Levi Garraway, Dana-Farber Cancer Institute <p>Information from “Exceptional Responders” and the Implementation of Basket Trials</p> <ul style="list-style-type: none"> • David Solit, Memorial Sloan-Kettering Cancer Center <p>Challenges in Real World Implementation of Genomic Profiling for Eligibility in Broad, National Clinical Trials</p> <ul style="list-style-type: none"> • Vincent Miller, Foundation Medicine <p>IDE Requirements for Diagnostic Tests used in Clinical Trials</p> <ul style="list-style-type: none"> • John Jessup, NCI Center for Cancer Research <p>Panel Discussion</p>
3:45 pm	Break

4:00 pm	<p>Panel Discussion (to include questions from the whole day) <i>Moderator: Michael Caligiuri, Ohio State University Comprehensive Cancer Center</i></p> <p>Panelists:</p> <p><u>Cooperative Group Chairs</u></p> <ul style="list-style-type: none"> • Charles Blanke, SWOG • Robert Comis, ECOG-ACRIN • Peter Adamson, Children’s Oncology Group • Walter Curran, NRG Oncology Group <p><u>NCI</u></p> <ul style="list-style-type: none"> • James Doroshow, NCI Division of Cancer Treatment and Diagnosis <p><u>FDA</u></p> <ul style="list-style-type: none"> • Richard Pazdur, FDA Office of Hematology and Oncology Products <p><u>Advocates</u></p> <ul style="list-style-type: none"> • Nancy Roach, Fight Colorectal Cancer • Patrick Gavin, Patrick Gavin R.Ph. Consulting LLC
5:30 pm	Wrap up Day 1 and Adjourn
February 12, 2013	
7:30 am	Breakfast and Registration
8:00 am	<p>Session 5: Accelerating Innovation Through Effective Partnerships <i>Moderator: Monica Bertagnoli, Alliance and DFCI</i></p> <p>Comprehensive Cancer Center Perspectives</p> <ul style="list-style-type: none"> • Edward Benz, Dana-Farber Cancer Institute <p>Industry Perspective</p> <ul style="list-style-type: none"> • Renaud Capdeville, Novartis Oncology <p>International Perspective: NEWDIGS Initiative, MIT Center for Biomedical Innovation</p> <ul style="list-style-type: none"> • Hans-Georg Eichler, European Medicines Agency <p>Accelerating Innovation in Statistical Design</p> <ul style="list-style-type: none"> • Lisa McShane, NCI Division of Cancer Treatment and Diagnosis <p>Partnering with Advocates</p> <ul style="list-style-type: none"> • Patrick Gavin, Patrick Gavin R.Ph. Consulting LLC <p>Panel Discussion</p>
10:45 am	Break – Box lunches available

11:00 am	<p>Session 6: Regulatory Issues <i>Moderator: Richard L. Schilsky, American Society of Clinical Oncology</i></p> <p>Optimizing Safety Data Collection in Cancer Clinical Trials</p> <ul style="list-style-type: none"> • Richard L. Schilsky, ASCO <p>FDA Perspective on Data Quality Issues</p> <ul style="list-style-type: none"> • Rachel Sherman, FDA Office of Medical Policy <p>The Role of CTEP/NCI in Registration Trials</p> <ul style="list-style-type: none"> • Jeffrey Abrams, NCI Division of Cancer Treatment and Diagnosis <p>FDA/NCI collaboration – Independent Radiologic Review</p> <ul style="list-style-type: none"> • Lori Dodd, NCI Biostatistics Research Branch <p>Pharmaceutical Industry</p> <ul style="list-style-type: none"> • Sandra Horning, Genentech <p>EMA-FDA Harmonization</p> <ul style="list-style-type: none"> • Francesco Pignatti, European Medicines Agency <p>Panel Discussion Speakers plus:</p> <ul style="list-style-type: none"> • Robert Iannone, Merck Research Laboratories • Debasish Roychowdhury, Sanofi Oncology
1:45 pm	Workshop Wrap Up
2:00 pm	Adjourn