



INSTITUTE OF MEDICINE

Facilitating Collaborations to Develop Combination Investigational Cancer Therapies June 13 and 14, 2011

The Keck Center of the National Academies, Room 100
500 Fifth Street, NW
Washington, DC 20001

DRAFT AGENDA

June 13, 2011

7:30 am	Breakfast and Registration
8:00 am	Welcome from the IOM National Cancer Policy Forum John Mendelsohn, M. D. Anderson Cancer Center, National Cancer Policy Forum Chair
8:05 am	Session 1: Workshop Introduction John Hohneker, Novartis Pharmaceuticals, Workshop Planning Chair <i>Rationale for Developing Combination Targeted Cancer Therapies</i> Jeffrey Engelman, MGH <i>Application of Genomic Tools to Assist in Combination Therapy Development</i> Michael Barrett, TGen <i>Patient Advocate Perspective</i> Jane Perlmutter, Gemini Group <i>Panel Discussion (30 minutes)</i>
9:30 am	Session 2: Scientific Challenges and Opportunities: Preclinical Issues in Codevelopment <i>Moderator: James Zwiebel, National Cancer Institute</i> <ul style="list-style-type: none">• <i>Perspectives from the National Cancer Institute</i><ul style="list-style-type: none">○ James Doroshow, NCI• <i>Perspectives from academia</i><ul style="list-style-type: none">○ David Stern, Yale○ Carl June, University of Pennsylvania• <i>Perspectives from industry</i><ul style="list-style-type: none">○ Kurt Bachman, GlaxoSmithKline

	<p><i>Panel Discussion (45 minutes)</i> Include speakers and</p> <ul style="list-style-type: none"> • Haleh Saber, FDA • Robert Iannone, Merck • Michael Caligiuri, OSU Comprehensive Cancer Center
12:00 pm	Lunch
1:00 pm	<p>Session 3: Scientific Challenges and Opportunities: Clinical Issues in Codevelopment <i>Moderator: Roy Herbst, Yale Cancer Center</i></p> <ul style="list-style-type: none"> • <i>Perspectives from the National Cancer Institute</i> <ul style="list-style-type: none"> ○ Helen Chen, NCI • <i>Perspectives from academia</i> <ul style="list-style-type: none"> ○ Patricia LoRusso, Karmanos • <i>Perspectives from industry</i> <ul style="list-style-type: none"> ○ Stuart Lutzker, Genentech • <i>Perspectives on trial design and statistical issues</i> <ul style="list-style-type: none"> ○ Donald Berry, M. D. Anderson ○ Pending Invitation <p><i>Panel Discussion (45 minutes)</i> Include speakers and</p> <ul style="list-style-type: none"> • Samuel Blackman, GlaxoSmithKline
3:20 pm	Break
3:30 pm	<p>Session 4: The Regulatory Environment and Codevelopment <i>Moderator: Richard Pazdur, Food and Drug Administration</i></p> <p><i>FDA Presentation on Draft Guidance</i> Rachel Sherman, CDER</p> <p><i>Brookings/Friends of Cancer Research Perspective on FDA Submission</i> Ellen Sigal/Jeff Allen (TBD)</p> <p><i>Industry Perspective</i> Ramzi Dagher, Pfizer</p> <p><i>Panel Discussion (40 minutes)</i> Robert Temple, CDER</p>
5:30 pm	Adjourn

June 14, 2011

7:30 am	Breakfast and Registration
8:00 am	Welcome, recap of Day 1
8:10 am	<p>Session 5: Codevelopment in Vaccines, Biologics, and Other Therapeutic Areas <i>Moderator: Renzo Canetta, Bristol-Myers Squibb</i></p> <p><i>Experiences from HIV Drug and Vaccine Development</i></p> <ul style="list-style-type: none">• Gary Nabel, NIAID• Carl Dieffenbach, NIAID <p><i>Preclinical issues</i></p> <ul style="list-style-type: none">• Nils Lonberg, Bristol-Myers Squibb <p><i>Clinical issues</i></p> <ul style="list-style-type: none">• Jeffrey Schlom, National Cancer Institute <p><i>Panel Discussion (30 minutes)</i> Keith Flaherty, Massachusetts General Hospital</p>
10:00 am	Break
10:10 am	<p>Session 6: Pharmaceutical and Biotechnology Industry Collaboration to Codevelop Therapies <i>Moderator: Michaele Christian</i></p> <p><i>Organizational Culture in Pharmaceutical and Biotechnology Companies</i></p> <ul style="list-style-type: none">• Bernard Munos, InnoThink <p><i>Legal Issues</i></p> <ul style="list-style-type: none">• Overview of Antitrust Issues<ul style="list-style-type: none">○ Robert Leibenluft, Hogan Lovells• Overview of Intellectual Property Issues<ul style="list-style-type: none">○ Philip Porter, Hogan Lovells• Overview of NCI's CRADA Intellectual Property Language<ul style="list-style-type: none">○ Jason Cristofaro, NCI• Panel Discussion: Perspectives on Intellectual Property Issues in Collaboration (30 minutes)<ul style="list-style-type: none">○ Industry perspective<ul style="list-style-type: none">▪ Lydia McNally, Novartis○ Research institution/technology transfer perspective<ul style="list-style-type: none">▪ Wesley Blakeslee, Johns Hopkins○ National Cancer Institute perspective<ul style="list-style-type: none">▪ Jason Cristofaro, NCI▪ Sherry Ansher, NCI

11:45 am	Break: please pick up boxed lunch and return to workshop
12:05 pm	<p>Session 6 Continued</p> <p><i>Practical Examples and Possible Models of Collaboration</i></p> <ul style="list-style-type: none"> • Collaborations to develop drugs targeting PI3K <ul style="list-style-type: none"> ○ Lewis Cantley, Beth Israel Hospital/Harvard • BATTLE I/II <ul style="list-style-type: none"> ○ Roy Herbst, Yale Cancer Center • I-SPY 2 Trial <ul style="list-style-type: none"> ○ David Wholley, Biomarkers Consortium <p><i>Panel Discussion (45 minutes)</i> Include speakers and: Vassiliki Papadimitrakopoulou, M. D. Anderson Cancer Center</p>
1:50 pm	<p>Closing Comments/Wrap Up John Hohneker, Novartis Pharmaceuticals</p>
2:00 pm	Adjourn