National Cancer Policy Forum Workshop Agenda:
Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer

November 10, 2014	
7:45 am	**Registration**
8:00 am	**Welcome from the IOM's National Cancer Policy Forum: Michael Caligiuri, James Cancer Hospital and Solove Research Institute, OSU Comprehensive Cancer Center** **Overview of the Workshop: Adrian Senderowicz, Ignyta, Inc.**
8:15 am	**Session 1 Challenges in developing clinical biomarker tests** ***Moderator: Samir Khleif, Georgia Regents University Cancer Center*** *Lessons learned from single analyte tests* **Bruce Johnson, Dana Farber Cancer Institute** *New challenges with next gen sequencing* **Mia Levy, Vanderbilt University** *Challenges in analytical validation of NGS tests for clinical trials* **Mickey Williams, NCI** *Tests for circulating tumor DNA* **Matthias Holdhoff, MD, Johns Hopkins University** *RNAseq Tests* **Neil Hayes, University of North Carolina-Chapel Hill** **Group Discussion**
10:30 am	**Break**
10:45 am	**Session 2A: Evidentiary Standards: Regulatory Science** ***Moderator: Adrian Senderowicz, Ignyta, Inc.*** *Overview of FDA Regulations for Diagnostics* **Adrian Senderowicz, Ignyta, Inc.** *Evolving paradigm for Companion Diagnostics and other Diagnostic Tests at FDA* **David Litwack, FDA** *Clinical Utility of Diagnostic Tests* **David Eberhard, University of North Carolina-Chapel Hill** **Group Discussion**
12:15 pm	**Lunch Break**
1:00 pm	**Session 2B: Evidentiary Standards: Reimbursement** ***Moderator: Robert McDonough, Aetna*** *MolDX approach* **Dane Dickson, Palmetto, Teton Cancer Institute** *Payers Perspectives* **Donna Messner, CMTP** **Group Discussion**
2:00 pm	**Session 3A: Generating Evidence: Clinical Trial Designs** ***Moderator: Barbara Conley, NCI*** *LungMap* **Roy Herbst, Yale University**

	Matching Drugs to Mutations for Treating Advanced Cancer **Lilian Siu, Princess Margaret Hospital, Ontario Cancer Institute,** *Evaluation of NGS for companion diagnostics use* **Anne-Marie Martin, GSK** **Group Discussion**
3:20 pm	**Break**
3:30 pm	**Session 3B: Generating Evidence: Other Mechanisms** ***Moderator: Richard Schilsky, ASCO*** *Actionable Genome Consortium* **David Solit, Memorial Sloan-Kettering Cancer Center** *Coverage with evidence development* **Sean Tunis, CMTP** *Facilitated drug access program and registry* **Richard Schilsky, American Society of Clinical Oncology** *Benefits and limitations/challenges of registries/databases* **Garnet Anderson, Fred Hutchinson Cancer Research Center, University of Washington School of Public Health** **Group Discussion**
5:15 pm	**Wrap up Day 1 and Adjourn**
November 11, 2014	
7:30 am	**Registration**
8:00 am	**Session 4: Practice Guidelines & Implementation into Clinical Practice** ***Moderator: Roy Herbst, Yale University*** *Guidelines Development* **Bill Gradishar, Northwestern University** *Treatment Pathways* **Jennifer Malin, Wellpoint** *Adoption of genomics in oncology care* **Kathryn Phillips, UCSF** *Return of sequencing results to patients* **Patricia LoRusso, Yale University** **Group Discussion**
10:00 am	**Break**
10:15am	**Session 5: The business model for test development** ***Moderator: Lisa McShane, NCI*** **Karen Long, Abott Molecular** **Federico Monzon, Invitae** **Group Discussion**
11:30 am	**Workshop Wrap Up**
11:45 am	**Adjourn**