FDA-AACR-ASCO Public Workshop
Complexities in Personalized Medicine:
Harmonizing Companion Diagnostics Across a Class of Targeted Therapies

Tuesday, March 24, 2015, Mayflower Hotel, Washington, DC

Background: Numerous pharmaceutical companies are developing therapeutic products that use similar or identical biomarkers for therapeutic selection potentially requiring contemporaneous approval of a companion diagnostic device, such as for therapies targeting the PD-1/PD-L1 pathway. Given the current practice of independent and unique test development programs for each therapeutic product sponsor, it is likely that multiple drug-companion diagnostic pairs may enter the market in parallel. The resulting matrix of drugs and companion diagnostics could present a complex challenge for testing and decision making in the clinic and potentially harm patients if inappropriate tests were used to make treatment decisions. This public workshop will foster a collaborative examination of the problem and identify potential solutions to address the problem.

Time	Topic	Speaker/Panelist
8:30 – 8:45	**Welcome and Opening Remarks**	**Elizabeth Mansfield, PhD** Deputy Office Director for Personalized Medicine, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, FDA
SESSION 1: DEFINING THE PROBLEM		
8:45 – 9:15	**Emerging Issues in Companion Diagnostics**	**Reena Philip, PhD** Director, Division of Molecular Genetics and Pathology, OIR, CDRH, FDA
9:20 – 10:20	**Stakeholder Presentations**	*Perspectives*: • **Nancy Roach** Chair, Fight Colorectal Cancer • **Suzanne Topalian, MD** Director, Melanoma Program, Johns Hopkins Kimmel Cancer Center • **Debra Leonard, MD, PhD** Chair, Department of Pathology and Laboratory Medicine, University of Vermont Medical Center and College of Medicine • **Steve Averbuch, MD** Vice President, Development, Oncology & Pharmacodiagnostics, Bristol-Myers Squibb Company • **Doug Ward** Vice President & General Manager, Companion Diagnostics, Ventana Medical Systems, Inc. • **Gideon Blumenthal, MD** Medical Officer, Lung Cancer Team Leader, CDER, FDA • **Girish Putcha, MD, PhD** Director of Laboratory Science, MolDX, Palmetto GBA LLC
10:20 – 10:35	**Break**	
10:35 – 11:50	**Moderated Panel Discussion** **Audience Q&A**	*Moderator:* **Debra Leonard, MD, PhD** *Panel:* **All Session 1 Participants**
11:50 – 13:00	**Lunch** (on own)	
SESSION 2: COMPARING THE TESTS		
13:00 – 13:05	**Introduction**	**Laura van 't Veer, PhD** Chair, Diagnostics Policy Subcommittee, AACR; Associate Director, Applied Genomics, UCSF Helen Diller Family Comprehensive Cancer Center
13:05 – 13:15	**Presentation:** Industry Working Group Proposal on Comparing the Analytical Performance of the PDL-1 tests	**Dave Stanforth***, on behalf of the Working Group* Director, Head of R&D, Companion Diagnostics, Agilent Technologies

13:15 – 13:45	**Moderated Panel Discussion:** Industry Working Group Discussion of Proposal	*Moderator*: **Debra Rasmussen, MBA RAC** Senior Director, Diagnostic Global Regulatory Affairs, Janssen Pharmaceutical *Industry Working Group Participants:* • **Steven Averbuch, MD** Vice President, Development, Oncology & Pharmacodiagnostics, Bristol-Myers Squibb • **Kenneth Emancipator, MD** Executive Medical Director, Merck • **Ian McCaffery, PhD** Oncology Biomarker Development and Companion Diagnostics, Genentech • **Dave Stanforth** • **Jill Walker, PhD** Executive Director, Companion Diagnostic Development, Immuno-Oncology, AstraZeneca • **Doug Ward**
13:45 – 14:30	**Moderated Panel Discussion:** Reactions and Discussion **Q&A with Audience**	*Moderator:* **Laura van 't Veer, PhD** *Perspectives*: • **Fred Hirsch, MD, PhD** Professor of Medicine and Pathology, University of Colorado; Chief Executive Director, International Association for the Study of Lung Cancer (IASLC) • **Elizabeth Hammond, MD** Professor, Pathology, University of Utah; College of American Pathologists (CAP) • **Daniel Hayes, MD, FASCO** Stuart B. Padnos Professor of Breast Cancer Research & Clinical Director, Breast Oncology Program, University of Michigan Comprehensive Cancer Center; President-Elect, ASCO • **Axel Hoos, MD, PhD** Vice President, Oncology R&D at GlaxoSmithKline Pharmaceuticals; Co-chair, Cancer Immunotherapy Consortium • **Kenneth Bloom, MD, FACP** Chief Medical Officer, GE Healthcare In Vitro Diagnostics
14:30 – 14:45	**Break**	
SESSION 3: CLINICAL PRACTICE/EDUCATION		
14:45 – 15:30	**Moderated Panel Discussion:** This panel will focus on the type of information and prior knowledge a clinician needs to provide optimal care.	*Moderator:* **Richard Schilsky, MD, FACP, FASCO** Chief Medical Officer, ASCO *Perspectives:* • **Edward Kim, MD** Chair, Solid Tumor Oncology & Investigational Therapeutics, Levine Cancer Institute - Carolinas HealthCare System • **Stacy Gray, MD, AM** Medical Oncologist, Dana Farber Cancer Institute, Assistant Professor of Medicine, Harvard Medical School • **Elizabeth Hammond, MD** • **Daniel Hayes, MD, FASCO** • **Jamie Von Roenn, MD** Senior Director, Education, Science and Professional Development, ASCO • **Michael Kolodziej, MD** National Medical Director, Oncology Solutions, Aetna • **Jane Perlmutter, PhD** President and Founder, Gemini Group
15:30 – 16:00	**Q&A with Audience**	
16:00 – 16:30	**Discussion/Closing Remarks**	*Workshop Co-Chairs:* • **Elizabeth Mansfield, PhD** • **Richard Schilsky, MD, FACP, FASCO** • **Laura van 't Veer, PhD**