Liquid Biopsies in Oncology Drug and Device Development
Walter E. Washington Convention Center
Washington, DC
July 19, 2016

Background: As a noninvasive method to detect genetic alterations in tumors, analysis of tumor-derived cell-free DNA (cfDNA) in plasma holds much promise for improving cancer diagnosis and monitoring as well as drug development. This technology is advancing quickly, is being incorporated into numerous drug development programs, and is likely to be rapidly incorporated into clinical care.

Purpose: This workshop will provide a public venue to discuss relevant scientific advances in the field of liquid biopsies and the regulatory environment that will support rapid translation of this emerging technology into improved patient care. After reviewing the current state of science in the broader field, the meeting will focus on application of cfDNA technologies for lung cancer as these areas are accelerating rapidly towards clinical use.

MEETING AGENDA	
WELCOME **8:15 AM**	**Welcome and Workshop Objectives** **Workshop Co-chairs:** **Gideon Blumenthal, MD** Clinical Team Leader, Thoracic and Head/Neck Oncology, Office of Hematology and Oncology (OHOP), Center for Drug Evaluation and Research (CDER), FDA **Pasi Jänne, MD, PhD** Director, Lowe Center for Thoracic Oncology; Scientific Director, Belfer Institute for Applied Cancer Science; Senior Physician, Dana-Farber Cancer Institute; and Professor of Medicine, Harvard Medical School **Reena Philip, PhD** Director, Division of Molecular Genetics and Pathology (DMGP), Office of In Vitro Diagnostics and Radiological Health (OIR), Center for Devices and Radiological Health (CDRH), FDA
8:30 – 9:50 AM	**SESSION I: CANCER LIQUID BIOPSIES: STATE OF THE SCIENCE** **Session Chair – Julia Beaver, MD**, Clinical Team Leader Breast and Gynecological Malignancies Group, OHOP/CDER/FDA
8:30 AM	**Overview of session** • ***Julia Beaver, MD****, OHOP/CDER/FDA*
8:35 AM	**The Development of an ARv7 Predictive Biomarker Test on CTC from Analytical Validation to the Demonstration of Clinical Utility** • ***Howard Scher, MD,*** *Chief, Genitourinary Oncology Service; D. Wayne Calloway Chair in Urologic Oncology, Memorial Sloan Kettering Cancer Center*

9:00 AM	**Cell-free DNA: Uses and steps needed for clinical utility** • ***Ben Ho Park, MD, PhD****, Professor of Oncology, Johns Hopkins Sidney Kimmel Cancer Center*
9:25 AM	**Extracellular RNA: a next frontier for liquid biopsy biomarkers** • ***Muneesh Tewari, MD, PhD****, Associate Professor, University of Michigan*
9:50 – 10:10 AM	**BREAK**
10:10 – 11:50 AM	**SESSION II: LIQUID BIOPSIES IN LUNG CANCER DRUG DEVELOPMENT AND CLINICAL USE** **Session chair – Pasi Jänne, MD, PhD,** Dana-Farber Cancer Institute
10:10 AM	**Overview of session** • ***Pasi Jänne, MD, PhD,*** *Dana-Farber Cancer Institute*
10:15 AM	**Plasma Genotyping for Treatment Selection in Advanced NSCLC** • ***Geoffrey Oxnard, MD,*** *Thoracic Oncologist, Dana-Farber Cancer Institute; Assistant Professor of Medicine, Harvard Medical School*
10:35 AM	**Looking toward the future: Liquid biopsies for treatment monitoring, risk stratification, and early detection** • ***Lecia Sequist, MD, MPH,*** *Associate Professor of Medicine, Harvard Medical School, Massachusetts General Hospital Cancer Center*
10:55 AM	**PANEL DISCUSSION** **Moderator: Pasi Jänne, MD, PhD** **Session II speakers and the following additional panelists:** • ***David Shames, PhD****, Principal Scientist, Department of Oncology Biomarker Development, Genentech Inc.* • ***Kenneth Thress, PhD****, Oncology Translational Scientist, AstraZeneca R&D* • ***Victoria Zazulina, MD****, Global Clinical Programme Team Leader, Boehringer Ingelheim*
11:45 AM – 1:00 PM	**LUNCH (on your own)**
1:00 – 1:45 PM	**CASE STUDY: cobas® EGFR Mutation Test v2, a blood-based companion diagnostic for the cancer drug Tarceva (erlotinib)**
	Speakers: • ***Reena Philip, PhD,*** *DMGP/OIR/CDRH/FDA* • ***David Shames, PhD,*** *Genentech, Inc.* • ***Karen Bijwaard, MS, RAC, MB(ASCP)^{CM},*** *Scientific Master Reviewer, DMGP/OIR/CDRH/FDA* • ***Walter Koch, PhD,*** *Vice President, Head of Global Research, Roche Molecular Systems, Inc.* • ***Erin Larkins, CDR, USPHS,*** *Medical Officer, OHOP/CDER/FDA*

1:45 – 3:20 PM	**SESSION III : LIQUID BIOPSY TEST DEVELOPMENT** **Session Chair: Reena Philip, PhD,** DMGP/OIR/CDRH/FDA
1:45 PM	**Overview of session** • ***Reena Philip, PhD,*** *DMGP/OIR/CDRH/FDA*
1:50 PM	**CDRH considerations for liquid biopsy diagnostic development** • ***Abraham Tzou, MD****, Medical Officer, DMGP/OIR/CDRH/FDA*
2:10 PM	**Analytical and clinical validation of liquid biopsy tests** • ***Phil Stephens, PhD****, Chief Scientific Officer, Foundation Medicine, Inc.*
2:30 PM	**PANEL DISCUSSION** **Moderator: Reena Philip, PhD** **Session III speakers and the following additional panelists:** • ***Tera Eerkes, PhD****, Vice President Strategy & Clinical Operations, Resolution Bioscience* • ***AmirAli Talasaz, PhD****, Co-Founder, President, and Chief Operating Officer, Guardant Health* • ***Walter Koch, PhD****, Vice President and Head of Global Research, Roche Molecular Systems* • ***Mark Lee, MD, PhD****, Head of Clinical Development and Medical Affairs, GRAIL, Inc.* • ***Mark Sausen, PhD****, Vice President of Research and Development , Personal Genome Diagnostics*
3:20 – 3:35 PM	**BREAK**
3:35 – 4:55 PM	**SESSION IV: ACCELERATING LIQUID BIOPSY APPLICATIONS TO IMPROVE PATIENT CARE** **Session Chair: Gideon Blumenthal, MD,** OHOP/CDER/FDA
3:35 PM	**Overview of session** • ***Gideon Blumenthal, MD,*** *OHOP/CDER/FDA*
3:45 PM	**STAKEHOLDER PERSPECTIVE PRESENTATIONS** **Stakeholder Perspective: Japanese Regulatory Agency (PMDA)** • ***Sumimasa Nagai, MD, PhD,*** *Clinical expert advisor, Companion Diagnostics Working Group and Office of New Drug V, Pharmaceuticals and Medical Devices Agency, Japan* **Liquid Biopsies: A Patient Perspective** • ***Andrea Ferris,*** *President and Chairman of the Board, LUNGevity Foundation* **The Value of Multisector Collaboration** • ***Gary Kelloff, MD,*** *Special Advisor, National Cancer Institute* **Liquid Biopsies in Oncology: A Payer's Perspective** • ***Robert McDonough, MD, JD,*** *Senior Director for Policy Research and Development, Aetna*

4:25 PM	**PANEL DISCUSSION** **Moderator: Gideon Blumenthal, MD,** OHOP/CDER/FDA **Session IV speakers and the following additional panelists:** • ***Julia Beaver, MD,*** *OHOP/CDER/FDA* • ***Geoffrey Oxnard, MD,*** *Dana-Farber Cancer Institute, Harvard Medical School* • ***Girish Putcha, MD, PhD,*** *Director, Laboratory Science, MolDX, Palmetto GBA*
4:55 PM	**WRAP UP** **Workshop co-chairs**
5:00 PM	**ADJOURN**