

## **Strategic Discussion on Biomarkers for Breast Cancer**

**Fred Hutchinson Cancer Research Center  
Seattle, Washington**

1:00 PM – 6:30 PM, Sunday September 14, 2008

### **Draft Agenda**

**Speakers are suggestions.**

- |                |   |
|----------------|---|
| 1:00 - 1:10 pm | <b>Welcome</b>  |
| 1:10 - 1:50 pm | <b>Overview of a Successful Clinical Application of a Breast Cancer Biomarker</b><br><br><b>Oncotype DX: From Research, to Clinical Validation, to Commercialization</b><br>Steve Shak, MD, Genomic Health, Inc<br><br>What was the process they went through to bring the marker to the market?<br>What were the major barriers and how did they overcome them?<br>What types of specimens they have used to study and validate Oncotype DX?<br>What lessons can be drawn from the speakers' experience?<br>What advice do the speakers have for others developing biomarkers? |
| 1:50 – 2:30 pm | <b>Clinical Issues of Breast Cancer</b><br>Seema Khan, MD, Northwestern Memorial Hospital, RHL<br>Compressive Cancer Center (confirmed)<br><br>What are clinical issues that we need to develop biomarkers for?   |
| 2:30 – 2:50 pm | <b>Study Design and the need for Repositories</b><br>Margaret Sullivan Pepe<br>Fred Hutchinson Cancer Research Center (confirmed)   |
| 2:50 - 5:30 pm | <b>Epigenetic Markers in Breast Cancer</b><br><br>This session will explore the potential of methylation markers for breast cancer detection and for predicting progression from DCIS or LCIS to invasive cancer.<br><br>Speakers will address  |

What clinical problems their markers or a panel of markers for?  
Specific biomarkers will be discussed and specific clinical problems will be presented.

What are performance of these markers, including utility, specificity, and sensitivity?

What are barriers for moving their markers forward? (Specific difficulties will be addressed, such as need of more markers, lack of proper technology, difficult to get specimens, and need of more cases, controls, or populations.)

Are the assay commercialized and would the commercial participation be necessary or required?

What would be the potential IP issues?

Where are the differences and synergies in various methylation approaches?

Is the universal methylation platform feasible in the future that builds on various discoveries or methylome?

### **Methylation Screen of Ductal Lavage Fluid to Identify Breast Cancer**

Sara Sukumar, PhD, Johns Hopkins University (confirmed)

### **DNA Methylation Assays using Plasma from Women with Breast Cancer**

Paul Cairns, PhD, Fox Chase Cancer Center (confirmed)

### **Differential Distribution of DNA Methylation within the RASSF1A CpG Island in Breast Cancer**

or

### **Mapping Geographic Zones of Cancer Risk with Epigenetic Markers**

Pearly Yan, Ohio State (confirmed)

### **DNA Methylation in Benign Breast Epithelium Tissue in Relation to Age and Breast Cancer Risk**

David Euhus or Cheryl Lewis University of Texas Southwestern Medical Center (confirmed)

### **Global Approach to Identifying Methylation Markers**

Adi Gazdar, M.D., Southwestern Medical Center (confirmed)

5:30 - 6:30 pm

### **Discussion**

Discussant 1: **Technology**

Discussant 2: **Clinical Questions**

**Discussant 3: Fit-for-Purpose: describe which technology for what purpose can be taken up for further evaluation**

Jeffrey Marks, Duke University Medical Center  
Laura J. Esserman, University of California at San Francisco  
Adi Gazdar, M.D., Southwestern Medical Center

What are advantage and barriers to use body fluids (sera, ductal lavage, or nipple aspirate) for early detection with methylation markers or is this premature?

What are advantage and barriers of methylation markers using tissues? Are these markers ready for validation? If so how would they be used?

What similarities exist in the different methylation panels presented? Can a new panel be developed based on their individual panels?

What are the most significant impediments for moving these markers forward to clinical validation? What can be done to remove these impediments?

6:30 PM

**Adjourn**