

# Workshop on the Impact of Biomarkers on the Complexity and Cost of Drug Development

October 21 – 22, 2009

FDA Campus, White Oak, Maryland

***Organizing Committee: Michael Palmer, President, Adaptive Pharmacogenomics, LLC (Chair), Federico Goodsaid, Ph.D. Associate Director for Operations in Genomics, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA, Mark Trusheim, Visiting Scientist and Executive-in-Residence, MIT Sloan School of Management and President, Co-Bio Consulting.***

The U.S. Food and Drug Administration (FDA), the Massachusetts Institute of Technology (MIT) and industry partners are collaborating in the development of software tools and case studies to assess the impact of biomarkers on the complexity and cost of drug development and the economic viability of stratified medicines and companion diagnostics. The tools and case studies are intended to support personalized medicine decision making. The tools will be publicly available in 2010. This workshop developed from the FDA/Adaptive Pharmacogenomics/GSK Cooperative Research and Development Agreement (CRADA). The CRADA partners are developing software tools to help regulators and industry assess clinical development complexity and cost when biomarkers are part of development.

This collaborative effort between government, industry, and the academic world has four main objectives:

- Inventory and quantify factors critical to the success of innovative pharma products across the innovation chain
- Integrate stakeholder perspectives into quantitative models of the product life cycle, from development through the end of market exclusivity
- Describe the success boundaries for stratified medicine
- Create evidence based, data driven consensus for the key factors surrounding the successful adoption of stratified medicine.

This workshop will focus on case studies in two therapeutic areas: oncology and Alzheimer's disease. These case studies were developed from January to September 2009 by two groups with membership from industry, MIT, and FDA. Discussion will cover the assumptions leading to each case, the analyses of these cases, and the interpretation of these analyses with regard to the four objectives above.

Workshop participants will be encouraged to actively engage in refining and exploring the scientific, clinical and economic models and case studies through therapeutic area break-out groups and a panel discussion with thought leaders on critical success criteria.

## **Participants**

Participants represent the range of stakeholders affected by biomarker enabled drug development, such as drug sponsors, diagnostic sponsors, regulators and payers. Participating organizations to date include the FDA, MIT, BristolMyersSquibb, Eli Lilly, GlaxoSmithKline, IMS, Merck, Merck EMD, Roche, the Van Andel Institute, and Adaptive Pharmacogenomics LLC. Workshop participants will include researchers through the Vice President level. From government, senior executive level policy makers will participate.

Draft Agenda

**Day 1: A unified scientific, clinical and economic model and the critical factors for biomarker utility across the product life cycle**

1 pm – 2 pm

**Welcoming Statement**

**Janet Woodcock, M.D.**

*Director, Center for Drug Evaluation and Research, FDA*

**Project Objectives and Purposes**

**Federico Goodsaid, Ph.D.**

*Associate Director for Operations in Genomics, Office of Clinical Pharmacology and Office of Translational Science, Center for Drug Evaluation and Research (CDER), FDA*  
and

**Mark Trusheim**

*Visiting Scientist and Executive-in-Residence, Applied Economics, MIT Sloan School of Management*

2 pm – 3 pm

**Project Findings: Critical Success Factors for Biomarkers**

**Mark Trusheim**

3:15 pm – 4:45 pm

Panelists:

**Lawrence J. Lesko, Ph.D., F.C.P. (Session Chair)**

*Director, Office of Clinical Pharmacology, CDER*

**Sue-Jane Wang, Ph.D.**

*Associate Director, Adaptive Designs/Pharmacogenomics, Office of Biostatistics, CDER*

**Gregory Campbell, Ph.D.**

*Director, Division of Biostatistics, Center for Devices and Radiation Health, CDRH*

**Jeffrey C. Roche, MD, MPH**

*Medical Officer, Division of Items and Devices, Centers for Medicare and Medicaid Services, CMS*

4:45 pm – 5:15 pm

**Day 1 Wrap Up**

**All workshop participants**

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## **Day 2: Workshop day on the impact of biomarkers on the complexity and cost of drug development**

8:30 am – 9 am

### **Overview of the Day**

**Michael Palmer**

*President, Adaptive Pharmacogenomics, LLC*

9 am – 10:30 am

Break out sessions for oncology and Alzheimer's Disease groups

Facilitators:

**Breon Burgess**

*Finance Lead, Oncology Franchise, Merck*

**Theresa Wood**

*Business Analyst, Program of Translational Medicine, Van Andel Research Institute*

**Sean Hu, MBA, PhD**

*Leader, Personalized Medicine Strategy Consulting, Strategy & Portfolio Analysis, IMS Health*

**Irina Saulea**

*Senior Consultant, Strategy & Portfolio Analysis, IMS Health*

11 am – noon

### **Break-out sessions prepare afternoon presentations**

Oncology

Alzheimer's Disease

Noon – 1:30 pm

Lunch

1:30 pm – 2:30 pm

### **Reconvene plenum for break-out group presentations to address the workshop objectives:**

- Inventory and quantify factors critical to the success of innovative pharma products across the innovation chain
- Integrate stakeholder perspectives into quantitative models of the product life cycle, from development through the end of market exclusivity
- Describe the success boundaries for stratified medicine
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1:30-2:15

Oncology—presentation by breakout group

### **Discussion with FDA clinical reviewers**

2:15-3:00

Alzheimer's Disease—presentation by breakout group

### **Discussion with FDA clinical reviewers**

3:00 pm – 3:30 pm

Break

3:30 pm – 5 pm

### **All--critique**

Conclusion

**Michael Palmer**