

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

Held at the FDA White Oak Campus, October 21-22, 2009

If current FDA thinking on integrating biomarkers into clinical development is important to you, *but* you missed the FDA's Workshop in October, *here's your second chance!* The workshop organizer and Chair, Michael Palmer, President, Adaptive Pharmacogenomics, will be giving a *one-day course* based on the FDA Workshop.

Who was at the October 21-22, 2009 workshop?

Janet Woodcock, M.D., Director, CDER, FDA

Lawrence J. Lesko, Ph.D., F.C.P., Director, Office of Clinical Pharmacology, CDER, FDA

Gregory Campbell, Ph.D., Director, Division of Biostatistics, CDRH, FDA

Michael Palmer, President, Adaptive Pharmacogenomics, LLC

some 50 others representing leading pharma companies and US Government agencies

Locations and dates for one day course

New Jersey--Tuesday, February 9 (Morristown)

Boston area--Thursday, February 11 (Cambridge)

San Francisco--Monday, February 15

San Diego--Wednesday, February 17

Contact

Shimon Cohen at shimon.cohen@adaptivepharmacogenomics.com or, by phone, +1-973-387-8655

Cost

\$795 for one registrant from an organization, \$399 for each additional registrant.

Instructor

Michael Palmer, President, Adaptive Pharmacogenomics, LLC, Organizer and Chair of *Workshop on the Impact of Biomarkers on the Complexity and Cost of Drug Development* held at FDA White Oak Campus, October 2009, Principal Investigator on Cooperative Research and Development Agreement (CRADA) with FDA and GlaxoSmithKline for *Development of a General Purpose Software Tool that Optimizes Clinical Study Design with Biomarkers*.

Overview

This one-day course will convey major findings from the *Workshop on the Impact of Biomarkers on the Complexity and Cost of Drug Development*. The workshop culminated a 10 month collaborative effort among several major pharmas, FDA, and MIT to develop case studies and methods for assessing the impact of biomarkers on the complexity and cost of drug development. The workshop program is available at this link: [Workshop Program](#).

One-day course objectives

1. To present the U.S. Food and Drug Administration's current thinking on the potential impact of biomarkers on the complexity and cost of drug development, as it was revealed in the workshop
2. To show how to use the therapeutic area benchmarks developed over the 10 months of the workshop in drug development programs
3. To describe software tools being developed by the FDA for potential use in their evaluations of drug

development programs

Target audience

Pharma, biotech, and diagnostic company Vice-Presidents and Directors with responsibility for clinical research, translational medicine, regulatory affairs, decision analysis, or statistical design and analysis

Course program

8:30 a.m.-10:00

Key discussions at the October 2009 workshop

1. Why the FDA is interested in biomarkers
2. Why industry is interested in biomarkers
3. When and where should biomarkers be integrated into clinical development?

10:00-10:30 Mid-morning break

10:30-11:30 Collaborative exercise

11:30-noon Morning wrap up

noon-1 pm Lunch

1-2:30

Presentation and analysis of oncology and neurodegenerative disease examples developed in the workshop

1. Oncology benchmark
2. Alzheimer's Disease benchmark

2:30-3 Break

3-4:00 Collaborative exercise

4-4:30 Review and critical take-away messages