

Modeling Clinical Development Strategies with Biomarkers at the FDA - Webinar

Overview

The two complementary webinars will show you the U.S. Food and Drug Administration (FDA)-Adaptive Pharmacogenomics (APG) software tool for modeling clinical development strategies that include predictive biomarkers and they will relate experiences with the tool in the FDA's Genomics Group, Office of Clinical Pharmacology. The Tuesday, August 24 webinar will feature the history, motivation, and use of the FDA-APG tool with reference to specific hypothetical case studies from the Genomics Group. The Wednesday, August 25 webinar will feature the specific, measurable inputs and outputs to use in strategy selection identified in the FDA-APG collaboration and the methodology for how to collect and organize this knowledge. At the end of the webinars on August 25, you'll understand what the software does, how to use it, and the experiences of the Genomics Group. Each webinar will end with a question and answer period. You may register for one or both webinars.

To register, please contact:

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Target audience

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

Objectives

1. To relate the experiences of the FDA's Genomics Group with the FDA-APG software tool
2. To describe and discuss with case studies the role of the tool in clinical development strategy selection with predictive biomarkers

Presenters

Federico Goodsaid, PhD. is the Associate Director for Operations in Genomics and Biomarker Qualification Process Coordinator at the U.S. Food and Drug Administration (FDA) and a Principle Investigator of the Cooperative Research and Development Agreement (CRADA) between the FDA, GlaxoSmithKline, and Adaptive Pharmacogenomics. The CRADA was titled "Development of a General Purpose Software Tool that Optimizes Clinical Study Design with Biomarkers"

Michael Palmer, President, Adaptive Pharmacogenomics, LLC, 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" and 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.

Dates, times, presenters for the webinars

Tuesday, August 24 at 11:30 a.m.- 1:00 p.m. Eastern time. Federico Goodsaid and Michael Palmer will present.

Wednesday, August 25 at 11:30 a.m. - 1:00 pm Eastern time. Michael Palmer will speak. Federico Goodsaid will not present on Wednesday.

Cost

\$50 per login per webinar (\$100 per login for both webinars)