Two-Part Webinar Series

Critical Path Initiative

Part 1 December 7, 2009 • Event #09264
Part 2 December 15, 2009 • Event #09266

10:00-11:30 AM EST 8:00-9:30 AM MDT
9:00-10:30 AM CDT 7:00-8:30 AM PDT

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An important goal for the pharmaceutical industry is to have a range of biomarker tests that would signal dangerous side effects like heart failure or liver damage. The Food and Drug Administration (FDA) supports the accelerated evaluation and development of new and better biomarkers that may help predict and monitor the safety of experimental drugs. These biomarkers will be important tools for pharmaceutical companies to bring treatments to market more quickly and to reduce patient risk.

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PART 1 PRESENTERS

Ralph R. Martel, PhD, MBA
Chief Technology Officer, USDS
Critical Path Institute

Federico Goodsaid, PhD
Associate Director for Operations in Genomics
OCP, OTS, CDER, FDA

Karol Thompson, PhD
Division of Applied Pharmacology Research
OTR, OPS, CDER, FDA

Kelci Miclaus, PhD
SAS

WHO SHOULD ATTEND

Mid- and senior-level professionals involved in:

- Safety assessment
- Strategic and collaborative partnerships
- Bioassay validation
- Regulatory affairs
- Investigative toxicology

■ Part 1, December 7, 2009

Standards for Emerging Biomarkers

The draft Companion for the Pharmacogenomics Guidance was originally issued two years ago. There are two major challenges for a Guidance of this type: to define a comprehensive content, and to maintain this content up-to-date. In this section of the webinar we will update the work on this Guidance regarding the expansion of its content as well as updates for its original content.

A systematic approach for assessing laboratory proficiency in conducting whole genome expression microarrays with pharmacogenomic (human) and toxicogenomic (rat) samples will be described that involves mixed tissue RNA reference controls, reference datasets, and metrics.

Standards to ensure high quality results from association studies with a balance between specificity, sensitivity, and reproducibility under current SNP array technologies will be discussed. Topics to be addressed include assessment of genotype calling discordance, typical steps to filter samples and SNPs, and determining genome-wide significance in the era of large-scale genomic studies. Emerging considerations for next-generation sequencing and rare variant analysis will be covered briefly.

FEATURED TOPICS

- Update on the Companion Guidance for the Pharmacogenomics Guidance
- Performance standards for laboratories conducting genome-scale microarray assays
- Best quality control practices for whole genome SNP array analysis

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
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Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

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WEBINAR SERIES

Critical Path Initiative

PART 2 PRESENTERS

Elizabeth Gribble Walker, PhD
Director, Predictive Safety Testing Consortium
Critical Path Institute

PSTC Hepatotoxicity Working Group Chair
Jeff Lawrence, PhD
Director, Biochemical Toxicology and Safety Biomarkers, Amgen, Inc

PSTC Myopathy Working Group Co-chairs
Warren Glaab, PhD
Merck & Co., Inc.
Dave Watson, PhD
Principal Research Scientist, Eli Lilly and Company

PSTC Nephrotoxicity Working Group Co-chairs
Frank Sistare, PhD
Executive Director, Laboratory Sciences & Investigative Toxicology Safety Assessment
Merck & Co., Inc.
Frank Dieterle, PhD
Head, External Affairs and Safety Biomarkers, iTox, Novartis AG, Switzerland

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■ Part 2, December 15, 2009

C-Path's Predictive Safety Testing Consortium Status: Updates on Novel Kidney, Liver, and Skeletal Muscle Safety Biomarkers

The Predictive Safety Testing Consortium (PSTC), a collaborative research endeavor managed by the Critical Path Institute, is identifying and qualifying biomarkers for specific uses that will expedite and/or improve the accuracy of preclinical drug safety evaluation, improve understanding of mechanisms of toxicity, and provide potential early indicators of clinical safety in drug development.

The consortium is organized into working groups that are focused on biomarkers for particular target organ toxicities. Existing and prospectively conducted study data and knowledge are pooled to enable the comparison of novel biomarker performance to existing accepted endpoints for a particular toxicity. All work is conducted in close dialogue with scientists at the regulatory agencies, and is ultimately submitted for formal regulatory evaluation and opinion regarding qualification.

FEATURED TOPICS

- Biomarker qualification and data submission processes
- Safety assessment and monitoring needs in kidney, liver, and skeletal muscle toxicities
- Specific novel biomarkers proposed by the PSTC for qualification but not commonly utilized in regulated drug studies

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Critical Path Initiative

Part 1 – Event #09264 – December 7, 2009 • Part 2 – Event #09266 • December 15, 2009
10:00 AM-11:30 AM EST

Technical Requirements for Audience Members

Browser
Microsoft® Internet Explorer 5.2 or higher
Netscape® Navigator 7

Computer
166Mhz Pentium-based PC with Microsoft® Windows® 98, NT, ME, XP or 2000
Sun JVM 1.4* for Microsoft JVM (all versions supported by Microsoft Windows OS shown above)
Sun SPARCstation with Solaris 8 or 9
Audience: 64 MB RAM

**If you need to install Java Virtual Machine (JVM) on your system, please download it from the Sun Microsystems website.*

Internet Connection Speed
56k or faster

Display
800x600 pixel resolution or greater (1024x768 pixels recommended)

Attendees using Macintosh OS
Microsoft IE 5.2
Macintosh OS 10.2X

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LEARNING OBJECTIVES Part 1, Event 09264, December 7

At the conclusion of Part 1 of this webinar series, participants should be able to:

- Explain the recommendations in the Companion Guidance
- Describe how to design a proficiency testing scheme for laboratories conducting microarray
- Outline sources of variability in the analysis of GWAS data

LEARNING OBJECTIVES Part 2, Event 09266, December 15

At the conclusion of Part 2 of this webinar series, participants should be able to:

- Explain the biomarker qualification process at the FDA and EMEA
- Articulate the safety assessment and monitoring needs in kidney, liver, and skeletal muscle toxicities in both preclinical and clinical settings
- Outline the body of evidence that comprises a biomarker qualification data submission
- Discuss the value of specific novel biomarkers proposed by the PSTC for qualification but not commonly utilized in regulated drug studies

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WEBINAR SERIES

CONTACT INFORMATION: ***Questions about this Webinar?*** Contact Wendy Moyer at the DIA office in Horsham, PA by telephone +1.215.293.5810, fax +1.215.442.6199, or email Wendy.Moyer@diahome.org.

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- ❑ # 09264 Standards for Emerging Biomarkers – December 7, 2009 – 10:00 AM-11:30 AM EST
- ❑ # 09266 C-Path's Predictive Safety Testing Consortium Status – December 15, 2009 – 10:00 AM-11:30 AM EST

INDIVIDUAL REGISTRATION FEES*	#09264 DECEMBER 7	#09266 DECEMBER 15
Standard Member	US $250 ❑	US $250 ❑
Standard Nonmember	US $295 ❑	US $295 ❑
Discounted Fees		
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