University of Maryland Center of Excellence in Regulatory Science and Innovation

Science that speeds health innovation

Evidentiary Considerations for Integration of Biomarkers in Drug Development

Mark your calendars for **Evidentiary Considerations for Integration of Biomarkers in Drug Development**, a symposium jointly sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation, Critical Path Institute, and the Food and Drug Administration (FDA).

Scheduled for **August 21, 2015**, this one-day symposium will bring together leading scientists and researchers from industry, academia, and the Food and Drug Administration (FDA), providing a unique opportunity for participants to gain perspective on biomarker development and application of biomarkers in preclinical and clinical research. Topics to be covered include:

- An overview of biomarkers in drug development
- Biomarker qualification
- Evidentiary considerations for biomarker utilization in drug development

The symposium will be held at the University of Maryland School of Pharmacy, located at 20 N. Pine Street in Baltimore, from 9:00 a.m. to 5:00 p.m., and is open to public. Registration is required.

For more information, please visit http://www.pharmacy.umaryland.edu/centers/cersievents/biomarkers/.

Registering by mail? Please detach this form and submit it to the address below. All participants can also register online at www.pharmacy.umaryland.edu/centers/cersievents/biomarkers/.

Evidentiary Considerations for Integration of Biomarkers in Drug Development

University of Maryland School of Pharmacy
Attn: Sharese Essien
20 Penn Street
HSF II, Room 503B
Baltimore, MD 21201

Please provide the following information:

_____
Name

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Address

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Phone

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Email

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Title and Company/School/Agency

Please indicate highest degree obtained:

☐ High School ☐ Master's Degree
☐ Bachelor's Degree ☐ Doctorate

Please indicate which category best describes you:

☐ Webinar Registration Only (FREE)
☐ Faculty, Staff, Student from the University of Maryland, Baltimore or College Park Campus (FREE)
☐ M-CERSI Industrial Consortia Member (FREE)
☐ Federal Government Employee (FREE)
☐ Critical Path Institute Staff (FREE)
☐ Other Participant ($50.00)

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CONFERENCE AGENDA

August 21, 2015

Session 1: General Introduction and Overview

Time	Activity
9:00-9:10 a.m.	**Welcome** James Polli, PhD Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics Department of Pharmaceutical Sciences University of Maryland School of Pharmacy Natalie D. Eddington, PhD, FCP, FAAPS Dean and Professor University of Maryland School of Pharmacy
9:10-9:30 a.m.	**Opening Remarks/Charge to Participants** Janet Woodcock, MD Director, Center for Drug Evaluation and Research Food and Drug Administration
9:30-9:55 a.m.	**FDA's Efforts to Encourage Biomarker Development and Qualification** Shashi Amur, PhD Biomarker Qualification Scientific Coordinator Office of Translational Sciences Center for Drug Evaluation and Research Food and Drug Administration
9:55-10:15 a.m.	**Statistical Considerations in Biomarker Development and Qualification** Aloka Chakravarty, PhD Director, Division of Biometrics Office of Biostatistics Center for Drug Evaluation and Research Food and Drug Administration
10:15-10:35 a.m.	**Assay Validation and Reproducibility Considerations for Biomarkers Used in Drug Development** Lisa McShane, PhD Mathematical Statistician Division of Cancer Treatment and Diagnosis National Cancer Institute
10:35-10:55 a.m.	**Q&A and/or Panel Discussion**
10:55-11:05 a.m.	**Coffee Break**

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Session 2: Evidentiary Considerations for Clinical Safety Biomarkers

Time	Activity
11:05-11:20 a.m.	**Mechanisms of Drug Toxicity and Relevance to Pharmaceutical Development** F. Peter Guengerich, PhD Tadashi Inagami Professor of Biochemistry Vanderbilt University
11:20-11:40 a.m.	**A Case Study: Clinical Safety Biomarkers Including Methodological Considerations** John-Michael Sauer, PhD Executive Directory, Predictive Safety Testing Consortium Critical Path Institute
11:40-12:00 p.m.	**Statistical Considerations for Clinical Safety Biomarkers** Robin Mogg, PhD Scientific Director, Statistical Modeling The Janssen Pharmaceutical Companies of Johnson & Johnson
12:00-1:00 p.m.	**Panel Discussion** Michael Lawton Research Fellow Pfizer Paul Watkins, MD Director, Hamner Institutes for Health Sciences University of North Carolina Sue Jane Wang, PhD Associate Director (Pharmacogenomics) Office of Biostatistics Organization Center for Drug Evaluation and Research Food and Drug Administration Christopher Leptak, MD, PhD Medical Officer Office of New Drugs Food and Drug Administration Norman Stockbridge, MD, PhD Director, Division of Cardiovascular and Renal Products Office of Drug Evaluation I Food and Drug Administration
1:00-2:00 p.m.	**Lunch**

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Session 3: Evidentiary Considerations for Biomarker-Based Enrichment of Clinical Study Populations to Increase Efficacy or Safety of Drugs

Time	Activity
2:00-2:15 p.m.	**Biomarker-Based Enrichment of Clinical Study Populations** Scott Patterson, PhD Vice President, Biomarker Sciences Gilead Sciences, Inc.
2:15-2:30 p.m.	**Neuroimaging Enrichment Biomarkers for CNS Diseases** Adam Schwarz, PhD Head of Imaging Eli Lilly and Company
2:30-2:45 p.m.	**Case Study: Polycystic Kidney Disease – From Bench to Bedside** Arlene Chapman, MD Chief of Nephrology Professor of Medicine University of Chicago
2:45-3:00 p.m.	**Statistical Considerations for BQ for Biomarker-Based Enrichment in Clinical Studies** Suzanne Hendrix, PhD President Pentara Corporation
3:00-3:40 p.m.	**Panel Discussion** Aliza Thompson, MD Clinical Team Leader Office of New Drugs Center for Drug Evaluation and Research Food and Drug Administration Aloka Chakravarty, PhD Director, Division of Biometrics Office of Biostatistics Center for Drug Evaluation and Research Food and Drug Administration Vikram Sinha, PhD Director, Division of Pharmacometrics Office of Clinical Pharmacology Food and Drug Administration Richard Meibach, PhD Vice President and Global Head Neuroscience and Ophthalmology Drug Regulatory Affairs
3:40-4:00 p.m.	**Coffee Break**

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August 21, 2015

Session 4: Facilitate d Discussion (FDA/C-Path)

Time	Activity
4:00-5:00 p.m.	**Evidentiary Considerations for Safety Biomarkers and Enrichment Biomarkers** ShaAvhrée Buckman-Garner, MD, PhD, FAAP Director, Office of Translational Sciences Center for Drug Evaluation and Research Food and Drug Administration Martha Brumfield, PhD President and Chief Executive Officer Critical Path Institute