University of Maryland Center of Excellence in Regulatory Science and Innovation

Science that speeds health innovation

Regulatory Issues in Next-Generation Medicine and Pharmacogenomics

Mark your calendars for Regulatory Issues in Next-Generation Medicine and Pharmacogenomics, a one-day conference co-sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation, the Personalized Medicine Coalition, and the University of Maryland School of Medicine's Program in Personalized and Genomic Medicine.

The Regulatory Issues in Next-Generation Medicine and Pharmacogenomics conference will be held on **Tuesday, September 3, 2013**, at the Southern Management Corporation Campus Center at the University of Maryland, Baltimore, located at 621 West Lombard Street in Baltimore, MD.

This conference will host invited speakers from the Food and Drug Administration, academia, industry, hospital and health care systems, health insurance companies, electronic health record vendors, and other stakeholders to discuss regulatory issues surrounding personalized medicine and pharmacogenomics.

For more information, please visit www.pharmacy.umaryland.edu/nextgenmed.

Registering by mail? Please detach this form and submit it with your check. All participants can also register online at www.pharmacy.umaryland.edu/nextgenmed, which accepts credit cards.

Regulatory Issues in Next-Generation Medicine and Pharmacogenomics

Please make check payable to **UMBF/CERSI** and mail to:

University of Maryland School of Pharmacy
Attn: Sharese Essien
20 Penn Street
HSF II, Room 518
Baltimore, MD 21201

Please provide the following information:

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Name

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Address

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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:

☐ Faculty, Staff, Student from the University of Maryland Baltimore or College Park Campus (FREE)
☐ M-CERSI Industrial Consortia Members (FREE)
☐ Federal Government Employees (FREE)
☐ Other Participant ($50.00)

Regulatory Issues in Next-Generation Medicine and Pharmacogenomics

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9:30-9:40 a.m.

Registration and Welcoming Remarks
E. Albert Reece, MD, PhD, MBA
John Z. and Akiko K. Bowers Distinguished Professor and Dean
University of Maryland School of Medicine

9:40-10:00 a.m.

Introduction
Issam Zineh, PharmD, MPH, FCP, FCCP
Director, Office of Clinical Pharmacology
Office of Translational Sciences
Center for Drug Evaluation and Research
US Food and Drug Administration

10:00-11:45 a.m.

Roundtable 1: Generating Evidence for Uncommon Variants and Very Small Populations

- **Overview and Presentation of Case Study**
  Michael Pacanowski, PharmD, MPH
  Associate Director for Genomics and Targeted Therapy
  Office of Clinical Pharmacology; Office of Translational Sciences
  Center for Drug Evaluation and Research
  US Food and Drug Administration

- **Participant Group Discussions**
  - **Overview of Technologies**
    Mickey Williams, PhD
    SAIC Molecular Characterization Lab Chief
    National Cancer Institute
  - **Clinical Trial Landscape in Oncology**
    Edward Sausville, MD, PhD, FACP
    Deputy Director, University of Maryland Greenebaum Cancer Center
    Professor of Medicine and Associate Director for Clinical Research
    University of Maryland School of Medicine
  - **Novel Statistical Approaches to Strengthen Signals of Efficacy: Bayesian Framework**
    Nicholas Schork, PhD
    Director of Bioinformatics & Biostatistics
    Scripps Translational Science Institute
    The Scripps Research Institute

- **Panel Discussion/Audience Q&A**

11:45-12:50 p.m.

Lunch and Keynote Address
Joshua Sharfstein, MD
Secretary of Health & Mental Hygiene
State of Maryland

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12:50-2:30 p.m.

Roundtable 2: Developing the Genetic Testing Infrastructure

- **Overview and Presentation of Case Study**
  David Litwack, PhD
  Personalized Medicine Staff
  Office of In Vitro Diagnostics and Radiological Health (OIR)
  Center for Devices and Radiological Health (CDRH)
  US Food and Drug Administration

- **Participant Group Discussions**
  - **Clinical Lab Perspective: Interactions and Expectations**
    Penny Keller
    Health Specialist
    Division of Laboratory Services
    Centers for Medicare & Medicaid Services
    Zivana Tezak, PhD
    Associate Director for Science and Technology
    Office of In Vitro Diagnostics and Radiological Health (OIR)
    Center for Devices and Radiological Health (CDRH)
    US Food and Drug Administration
  - **Centralized Lab Perspective**
    Victoria Pratt, PhD
    Associate Professor of Clinical Medical and Molecular Genetics
    Director, Pharmacogenomics Diagnostic Laboratory
    Indiana University School of Medicine

2:30-2:45 p.m.

Break

2:45-4:40 p.m.

Roundtable 3: Practical Issues and Barriers

- **Overview and Presentation of Case Study**
  Alan Shuldiner, MD
  John Whitehurst Professor of Medicine,
  Director, Program in Personalized and Genomic Medicine
  Head, Division of Endocrinology, Diabetes, and Nutrition
  University of Maryland School of Medicine

- **Participant Group Discussions**
  - **Clinical Decision Support**
    Mark Hoffman, PhD
    Director, Translational Bioinformatics
    Children's Mercy Hospital
    Associate Professor, Biomedical and Health Informatics
    Director, Bioinformatics Core
    University of Missouri, Kansas City
  - **Ethical and Legal Challenges**
    Frank Pasquale, JD
    Professor of Law
    University of Maryland School of Law
  - **Patient Perspective**
    Mary Dwight
    Vice President, Government Affairs
    Cystic Fibrosis Foundation
  - **Payer Perspective**
    Steven Gutman, MD
    Strategic Advisor, Myraq

- **Panel Discussion/Audience Q&A**

4:40-5:00 p.m.

Wrap-Up and Concluding Remarks

Alan Shuldiner & Michael Pacanowski
Reception to Follow