University of Maryland Center of Excellence in Regulatory Science and Innovation

Science that speeds health innovation

Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care?

Mark your calendars for Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care, a conference sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Food and Drug Administration (FDA), in collaboration with the National Pharmaceutical Council.

Since the 1990s, efforts have been made to improve database development and data "warehousing" by pharmaceutical companies and government entities. A recent emphasis has been placed on "big data," the term for a collection of data sets so large and complex that they becomes difficult to process using traditional database management tools or data processing applications.

Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care will be held on **Tuesday, February 11, 2014** in Southern Management Corporation Campus Center at the University of Maryland, Baltimore, located at 621 West Lombard Street in Baltimore, MD. It will bring together researchers from the FDA and other government agencies, industry, and academia to continue the M-CERSI dialogue and scientific exchange on big data and its role(s) in and impact on medical product development.

For more information, please visit www.pharmacy.umaryland.edu/bigdata2.

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/bigdata2.

Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care?

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

Make all checks payable to the **University of Maryland, Baltimore Foundation**.

Please provide the following information:

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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 Member (FREE)
☐ Federal Government Employee (FREE)
☐ Employees of the National Pharmaceutical Council – Member Companies (FREE)
☐ Other Participant ($50.00)

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CONFERENCE AGENDA

February 11, 2014

10:00-10:15 a.m.
Welcome and Objectives
James Polli, PhD
Shangraw/Noxell Endowed Chair in Industrial Pharmaceutics
Co-Principal Investigator, Center for Excellence in Regulatory Science and Innovation
University of Maryland School of Pharmacy

Eleanor Perfetto, PhD, MS
Professor of Pharmaceutical Health Services Research
University of Maryland School of Pharmacy

10:15-12:00 p.m.
Moderator: Jennifer Graff, PharmD

Use of Big and Real-World Data by phrma: More than Data Warehousing
Aaron Galaznik, MD
Senior Director, Real-World Data and Analytics
Pfizer, Inc.

Leveraging Real-World Data and Analytics in the Device Industry
Thomas Abbott, PhD
Head, Health Care Informatics
Johnson & Johnson, Medical Devices and Diagnostics

Janus Clinical Trials Repository: An Update and Insights into Future Directions
Lilliam Rosario, PhD
Director, Office of Computational Science
Food and Drug Administration (FDA)

Panel Q&A

12:00-12:20 p.m.
Break (Guests Receive Lunch and Return to Room for Lunch Speaker)

12:20-1:15 p.m.
Introduction of Lunch Speaker
James Polli, PhD
Shangraw/Noxell Endowed Chair in Industrial Pharmaceutics
Co-Principal Investigator, Center for Excellence in Regulatory Science and Innovation
University of Maryland School of Pharmacy

IMEDS: Sentinel and OMOP Programs
Jane Reese-Coulbourne, MS, ChE
Executive Director
Reagan-Udall Foundation, FDA

1:15-2:50 p.m.
Moderator: TBD

Big Data and the "Research Harbor" Concept
Kate Tracy, PhD
Associate Professor of Epidemiology and Public Health
University of Maryland School of Medicine

Big Data and Data Visualization: Extracting Insights from Electronic Health Records
Ben Shneiderman, PhD
Director, Human Computer Interaction Lab
University of Maryland, College Park

FDA Use of Big Data in Modeling and Simulations
Jeffry Florian, PhD
Review, Division of Pharmacometrics
Office of Clinical Pharmacology
Office of Translational Sciences
Center for Drug Evaluation and Research, FDA

Panel Q&A

2:50-3:50 p.m.
Moderator: Eleanor Perfetto, PhD, MS

Invited Reactor Panel with Representatives from the National Pharmaceutical Council, Optum Labs, Patient-Centered Outcomes Research Institute (PCORI), and FDA

3:50-4:00 p.m.
Closing Remarks