

Scientific Exchange Workshop CERSI-Sponsored Conference Brings “Big Data” Experts to UMB

By: Malissa Carroll
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Researchers from academia, government, and industry discuss how increasingly large, complex datasets can be harnessed to improve the drug development process.

The University of Maryland, Baltimore (UMB) was teeming with researchers from academia, government, and industry on Feb. 11, as **Eleanor Perfetto, PhD, MS**, professor in the [Department of Pharmaceutical Health Services Research \(PHSR\)](#) at the University of Maryland School of Pharmacy, hosted “Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care?” Designed to examine the use of “big data” and its role in and impact on medical product development, this one-day conference was sponsored by the [University of Maryland Center of Excellence in Regulatory Science and Innovation \(M-CERSI\)](#) and the Food and Drug Administration (FDA), with additional support from the National Pharmaceutical Council.

“Since the 1990s, pharmaceutical companies and government agencies have pursued a wide range of initiatives aimed at database development and data ‘warehousing,’” says **James Polli, PhD**, the Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics at the School of Pharmacy and co-director of M-CERSI. “However, most of their efforts have focused on assembling, merging, and analyzing large medical and pharmacy claims databases for safety, economic, epidemiologic, and market research. Only recently has there emerged an emphasis on ‘big data’ and how this data can be harnessed to improve the drug development process.”

“Big data” is the term used to describe a collection of large, complex datasets that are difficult to process using traditional database management tools or data processing software. In health-related research, big data can take many forms and be used in a wide range of applications.

To-date, there is no universal understanding among health researchers of what big data is or what it can do.

“There seems to be some agreement that big data can be characterized by the volume, velocity, variety, and veracity of data, but this can still include a number of different datasets, such as human genome sequences, cancer cell behaviors, social media interactions, or patient vital signs,” says Perfetto. “Despite this variation, there remains a clear movement among medical product developers and regulators towards using big data to streamline development, efficiently and rapidly identify potential new drug candidates, and produce effective, safe, approved, and reimbursed products more quickly.”

Delivering one of the conference’s kick-off presentations, Thomas Abbott, PhD, head of health care informatics for medical devices and diagnostics at Johnson & Johnson, spoke about the essential role played by big data in the Johnson & Johnson ecosystem, emphasizing how the company uses this data to demonstrate value, drive innovation, gain customer insights, and ensure patient safety.

“There has been an explosion in the use of big data to support decisions by all health care stakeholders,” declared Abbott. “Providers and physicians’ financial incentives have started to align, and they -- along with payers -- are increasingly using their own data to find evidence of better outcomes and value. The pressure is now on device manufacturers to better understand how their products deliver this value in the real world, and to whom.”

The conference also featured three speakers from the FDA -- Lilliam Rosario, PhD, director of the Office of Computational Science; Jeffry Florian, PhD, reviewer in the Division of Pharmacometrics at the Center for Drug Evaluation and Research; and Taha Kass-Hout, MD, MS, chief health informatics officer at the FDA – who highlighted how government agencies are collecting and using big data.

Speaking about how agencies are “rapidly moving towards a modernized, integrated bioinformatics-based review environment,” Rosario highlighted the progress made by the Janus Clinical Trials Repository (CTR) – a big data warehouse developed by the FDA to support automated extraction, transformation, loading, management, and reviewer access to standardized clinical trials data to support the regulatory review of therapeutic biologic and drug products. She noted that reviewers currently using the system have experienced improved productivity and consistency and quality of data.

Similarly, Jane Reese-Coulbourne, MS, ChE, executive director of the Reagan-Udall Foundation, highlighted the Foundation’s Innovation in Medical Evidence and Surveillance (IMEDS) program, which has already benefitted a number of researchers through its emphasis on full transparency, state-of-the-art research laboratory, increased availability of collaboration opportunities, engagement with diverse research participants, and affiliation with the FDA. “This program will help the FDA, regulated industry, and clinicians improve patient care and the safety of medical products by focusing on three areas: methods, evaluation, and education,” she said.

In academia, researchers from the Clinical and Translational Research Informatics Center (CTRIC) at the University of Maryland School of Medicine recently launched an initiative known as the Research HARBOR (Helping Advance Research by Organizing Resources), which brings together data from the University of Maryland Medical System and other local sources to provide health-related information to local researchers.

“The major purpose of the HARBOR is to expose the data, connect collaborators with common tools and services, and promote scientific innovation,” said J. Kathleen Tracy, PhD, associate professor of epidemiology and public health at the School of Medicine and director of CTRIC. “It is an interactive, web-based platform that offers ‘one-stop shopping’ for research support needs. Through a centralized hub, UM researchers and their staff can access our data warehouse, identify and access research support resources, tools, and services, as well as find experts, access regulatory support, learn about educational training opportunities, and more.”

“Leveraging Big Data II: What Does It Mean for Improving Product Development and Health Care?” continued dialogue from an earlier CERSI-sponsored conference held in September 2013, which brought together experts from academia, government, and industry to share their experiences using big data in health outcomes research.

“This conference brought together a number of stakeholders to share information about their interests in big data how they use this data in daily practice,” says Perfetto. “Based on the information that was presented, attendees were able to gain a clearer understanding about who is using big data, how they are using it, and how it could change the way that health care products are developed and used. We also successfully identified a number of opportunities for collaboration among researchers from industry, government, and academia.”

Other speakers for this conference included Aaron Galaznik, MD, senior director of real-world data and analytics at Pfizer, Inc., and Ben Shneiderman, PhD, director of the Human Computer Interaction Lab at the University of Maryland, College Park. The conference also featured an invited reactor panel that included representatives from the National Pharmaceutical Council, Optum Labs, Patient-Centered Outcomes Research Institute, and FDA.