University of Maryland/Food and Drug Administration
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Building the National Evaluation System for Medical Devices: Using Real World Evidence to Improve Device Safety and Effectiveness

Harnessing the Digital Revolution for Medical Device Evaluation

Mark your calendars for **Building the National Evaluation System for Medical Devices: Using Real World Evidence to Improve Device Safety and Effectiveness**, a workshop jointly sponsored by the University of Maryland Center of Excellence in Regulatory Science and Innovation and the Food and Drug Administration.

Scheduled for **Thursday, March 24, 2016**, Building the National Evaluation System for Medical Devices: Using Real World Evidence to Improve Device Safety and Effectiveness will provide clinicians, researchers and others from the medical device industry, professional societies, health care delivery systems, patient advocacy groups, and the FDA the opportunity to discuss the scientific progress being made in harnessing evidence generated from the real-world use of medical devices to improve device safety and effectiveness. The role that Unique Device Identification (UDI) plays in improving device evaluation to support more informed clinical and patient decision-making and device innovation will also be discussed.

The symposium will be held at the University of Maryland School of Pharmacy, located at 20 N. Pine Street in Baltimore, from 8:30 a.m. to 4:30 p.m., and is open to public. Registration is required.

For more information, please visit http://www.pharmacy.umaryland.edu/deviceeval/.

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CONFERENCE AGENDA

March 24, 2016

Time	Activity
7:30-8:30 a.m.	**Registration and Breakfast**
8:30-8:35 a.m.	**Welcome** Natalie D. Eddington, PhD, FCP, FAAPS Dean and Professor Executive Director of University Regional Partnerships University of Maryland School of Pharmacy
8:35-8:40 a.m.	**Introductions** Fadia Tohme-Shaya, MPH, PhD Professor and Vice Chair for Academic Affairs Associate Director, Center on Drugs and Public Policy Department of Pharmaceutical Health Services Research University of Maryland School of Pharmacy
8:40-9:00 a.m.	**Keynote: FDA Perspective on a National Medical Device Evaluation System** Jeffrey Shuren, MD, JD Director, Center for Devices and Radiological Health Food and Drug Administration
9:00-10:00 a.m.	**Session 1: Harnessing the Digital Revolution for Medical Device Evaluation** **Moderator:** Gregory Pappas, MD, PhD, Associate Director, National Device Evaluation, CDRH, FDA **Building the National Evaluation System for Medical Devices (NESMD): Work of the Planning Board** Gregory Daniel, PhD, MPH Deputy Director, Duke-Margolis Center for Health Policy Duke University **Tools and Methods for Building the NESMD in a New Era – The Role of MDEpiNet** J. Matthew Brennan, MD, MPH Co-Director, STS Analytical Center Duke Clinical Research Institute Duke University **Unique Device Identification: Building Block for the National Evaluation System** Terrie Reed, MS Senior Advisor for UDI Adoption Office of Surveillance and Biometrics Center for Devices and Radiological Health Food and Drug Administration **Questions**

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Time	Activity
10:00-10:15 a.m.	Break
10:15-12:00 p.m.	**Session 2: Foundations for the National Evaluation System: Where Are We Today?** **Moderator:** Francis B. Palumbo, PhD, JD, Professor and Executive Director, Center on Drugs and Public Policy, University of Maryland School of Pharmacy **Building Coordinated Registry Networks : A Core Strategy to Build the National System** Art Sedrakyan, MD, PhD Professor of Healthcare Policy and Research Professor of Healthcare Policy and Research in Surgery Weill Cornell Medical College **Discussant: The Case for Orthopedics** Andrew N. Pollak, MD Chair, Department of Orthopaedics University of Maryland School of Medicine **Big Data Analytics: Statistical Tools for Utilizing the NESMD** Nelson Lu, PhD Mathematical Statistician Office of Surveillance and Biometrics Center for Devices and Radiological Health Food and Drug Administration **Discussant: Analyzing Device Risk Using Textual Databases** Monifa Vaughn-Cooke, PhD Assistant Professor, Department of Mechanical Engineering University of Maryland, College Park **Using Real-World Evidence for Regulatory Decisions and Practice** Danica Marinac-Dabic, MD, PhD, MMSc Director, Division of Epidemiology Center for Devices and Radiological Health Food and Drug Administration **Discussant: The Case for Interventional Cardiology Devices** Anuj Gupta, MD, FACC, FSCAI Director, Cath Lab Department of Medicine University of Maryland School of Medicine
12:00-1:00 p.m.	Lunch

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12:00-4:15 p.m.	**Scientific Information Tables** **Epidemiology Regulatory Science Program/ MDEpiNet Public Private Partnership, CDRH, FDA** Benjamin Eloff, PhD; Marta Steliac, MS; and Danica Marinac-Dabic, MD, PhD, MMSc Division of Epidemiology CDRH, FDA **Unique Device Identifier (UDI)/MedSun, CDRH, FDA** Linda Sigg, MS, Associate Director for Informatics Terrie Reed, MS, Senior Advisor for UDI Adoption Jill Marion, MS, MBA, PMP, Director, Medical Product Safety Network (MedSun) CDRH, FDA **National Library of Medicine** Steven Emrick, Head, Terminology Quality and User Services Patrick McLaughlin, Support Lead, RxNorm, DailyMed, and AccessGUDID Josh Temple, Applications Developer, AccessGUDID NLM, NIH **PCORnet** W. Schuyler Jones, MD Duke University School of Medicine **University of Maryland School of Pharmacy** Colleen Day, Graduate Program Coordinator Pharmaceutical Health Services Research Kristina San Juan, Graduate Program Coordinator Pharmaceutical Sciences University of Maryland School of Pharmacy **NIH Health Care Systems Research Collaboratory Program** Wendy Weber, ND, PhD, MPH Division of Extramural Research National Institutes of Health
1:00-3:00 p.m.	**Session 3: Nodes in the Network: Making the Learning Health Care System Real** **Moderator:** Fadia Tohme-Shaya, PhD, MPH, Professor and Vice Chair for Academic Affairs, Associate Director, Center on Drugs and Public Policy, University of Maryland School of Pharmacy

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Time	Activity
	Presentations: **Sentinel** Nandini Selvam, PhD, MPH Senior Director, Government and Academic Research HealthCore **PCORnet** W. Schuyler Jones, MD Assistant Professor of Medicine Duke University School of Medicine **MDEpiNet** Danica Marinac-Dabic, MD, PhD, MMSc Director, Division of Epidemiology Center for Devices and Radiological Health Food and Drug Administration **NIH Health Care Systems Research Collaboratory Program** Wendy Weber, ND, PhD, MPH Chief, Clinical Research in Complementary and Integrative Health Branch Division of Extramural Research National Institutes of Health **National Library of Medicine (NLM)** Steven Emrick, Head, Terminology Quality and User Services **NESMD** Gregory Pappas, MD, PhD Associate Director, National Device Evaluation Center for Devices and Radiological Health Food and Drug Administration **Patient Stakeholder** **Panel Discussion with Dr. Fadia Tohme-Shaya and Session 3 Presenters**: How Can Nodes in the Network Bring Together Their Real-World Evidence to Promote the Learning Health Care System and Improve Medical Device Safety and Effectiveness?
3:00-3:15 p.m.	**Break**
3:15-4:15 p.m.	**Session 4: Parallel Discussions (Choose Either Session A OR Session B)**

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Time	Activity
	Session A (Second Floor, Room S201) **Panel:** MDEpiNet Public Private Partnership for Building a National Evaluation System Using Real-World Evidence **Moderator**: Benjamin Eloff, PhD, Division of Epidemiology, CDRH, FDA MDEpiNet is a Public Private Partnership (PPP) that brings together leadership, expertise, and resources to build a national medical device evaluation system by improving and integrating real-world data infrastructure, developing appropriate methodologies, and conducting relevant studies. The MDEpiNet PPP is composed of over 100 national and international organizations including FDA and world-leading academic institutions, national and international patient registries, healthcare organizations, medical device industry partners and patient and consumer groups. MDEpiNet was initially stood up in 2010 and supported by a series of FDA grants. In 2014, MDEpiNet evolved into a true PPP with a Methodology Center at Harvard University, a Science and Infrastructure Center at Weill Cornell Medical College, and a Coordinating Center at Duke University. In this session participants will learn about the components of the MDEpiNet PPP, as well as potential opportunities for getting involved. **Session B (Main Auditorium)** **Roundtable:** Unique Device Identification **Roundtable Facilitators:** • Linda Sigg, Associate Director for Informatics, CDRH, FDA • Terrie Reed, MS, Senior Advisor for UDI Adoption, CDRH, FDA • Jill Marion, MS, MBA, PMP, Director, Medical Product Safety Network (MedSun),CDRH, FDA • Mike Schiller, Senior Director of Supply Chain, Association of the Healthcare Resource and Materials Management (AHRMM) Adoption of a structured device identification system like UDI is expected to produce significant benefits to patient care, device safety, and healthcare efficiencies. Since realizing the value of UDI will require changes to healthcare technology infrastructure and process, successful adoption necessitates a commitment to share knowledge and develop best practices across all stakeholder groups affected by the inclusion of UDI in health information. This session will be used to provide more details about this game changing identification system and allow participants to share information about their own UDI planning and adoption efforts. Participants will be invited to share their perspectives on a new Learning UDI Community (LUC) that is being created to support stakeholders from academia, healthcare, government, medical device industry, and patient advocacy groups who are committed to UDI adoption.

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Time	Activity
4:15-4:30 p.m.	**Closing Remarks** **Wrap-up: Impact and Collaboration** Fadia Tohme-Shaya, PhD, MPH Professor and Vice Chair for Academic Affairs Associate Director, Center on Drugs and Public Policy University of Maryland School of Pharmacy **Next Steps** Gregory Pappas, MD, PhD Associate Director, National Device Evaluation Center for Devices and Radiological Health Food and Drug Administration
4:30 p.m.	**Adjourn**