



DEPARTMENT OF VETERANS AFFAIRS
810 Vermont Avenue NW
Washington, DC 20571

Medical Device Registry Summit

GV (Sonny) Montgomery Veterans Auditorium, Room 230
810 Vermont Avenue, NW
Washington, DC 20420

June 4, 2018
8:30 a.m. – 4:30 p.m.

8:30 a.m. Welcome and Introduction of Participants and Organizations

Acting Secretary of VA Robert L. Wilkie

8:45 a.m. – 10 a.m. Session 1: Value for Stakeholders

Objective: To describe value of medical device registries to major stakeholders; identify the gaps; prioritize opportunities

Patient Perspective

Christine Stake, Patient Governor, the ArthritisPower Patient Research Registry

Leveraging the Medical Device Ecosystem

Rachael Fleurence Ph.D., National Evaluation System for Health Technologies

Value Roundtable Discussion

Moderator: SreyRam Kuy, MD

- Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD
- Jeff Shuren, MD, PhD, Director, Center for Devices and Radiological Health
- Centers for Medicare and Medicaid Services Administrator Seema Verma (tentative)
- Secretary of Health and Human Services Alex M. Azar (tentative)
- Secretary of Defense James N. Mattis (tentative)
- American Medical Association, Kathleen Blake, MD

10 a.m. – 11:30 a.m. Session 2: VA Landscape

Objective: Share examples of successful device monitoring at VA, registry infrastructure at VA and present the vision for the future

Moderator: Danica Marinac-Dabic, MD, PhD, MMSC, FISPE – FDA

- ✓ Current Cardiac Device Monitoring in the VA
 - Merritt H. Raitt, MD, Director, National Cardiac Device Surveillance Program, Veterans Health Affairs (VHA)
- ✓ Improving Device Surveillance by Analyzing Passively Collected Electronic Health Record Data
 - Nicholas Giori, MD, PhD, Chief of Orthopedic Surgery, VA Palo Alto Health Care System
- ✓ Medical Device Tracking in Cardiology: The integration of Real Time Locations System into The Clinical Assessment, Reporting, and Tracking System (CART) for Cardiac Catheterization Laboratories
 - Stephen Waldo, MD or Paul Varosy, MD
Director, CART Program
- ✓ Building Future-State Model for VHA Implant Tracking
 - Bruce McIntosh, PharmD, VA National Manager, Product Recall Office, National Center for Patient Safety

Panel Discussion: Speakers + John Rumsfeld, MD, American College of Cardiology

11:30 a.m. – 12:30 p.m. Lunch Break

12:30 p.m. – 2 p.m. Session 3: Infrastructure/Methodology Opportunities for Standing Up a Medical Device Registry – Short and Long-Term

Moderator: Sharon-Lise Normand, PhD (Harvard Medical School/Harvard School of Public Health)

Objective: To identify key national and international efforts in the device space that can be leveraged for the development of a Medical Device Registry; present short- and long-term opportunities

- ✓ Efforts of the Office of the National Coordinator (ONC) for Health Information Technology
 - Don Rucker, MD (ONC)
- ✓ Unique Device Identifier implementation efforts
 - Terrie Reed (FDA)
- ✓ Strategically Coordinated Registry Networks – Linking Registries with other data sources
 - Art Sedrakyan, MD, PhD (Cornell/MDEpiNet)
- ✓ Harmonization Efforts with National/International Registries
 - Danica Marinac-Dabic, MD, PhD, MMSC, FISPE (FDA/Center for Devices and Radiological Health (CDRH))
- ✓ Patient -enabled evidence generation

- Harlan Krumholz, MD (Yale University)
- ✓ Active Surveillance via DELTA in National Registries
 - Fred Resnic, MD (Lahey Clinic)

Panel Discussion: Speakers + Vahan Simonyan, PhD (FDA)

2 p.m. – 3:15 p.m. Session 4: From the Conceptual Framework to the Developmental Efforts and Sustainability

Moderator: Thomas Concannon, PhD (RAND)

Objective: How to begin development of the framework for a Medical Device Registry

- ✓ Who should be at the table: What can we learn from Vascular Quality Initiative?
 - Jack Cronenwett, MD (Dartmouth)
- ✓ How to build in the sustainability: Return of Investment Multi-stakeholder Analysis
 - Greg Pappas, MD, PhD (FDA/CDRH)
- ✓ Privacy/Ethics issues
 - Robert M Portman, JD (Powers, Pyles, Sutter and Verville PC)

Panel Discussion: Speakers + Mike Lauer, MD (National Institute of Health), Elise Berliner, PhD (Agency for Healthcare Research and Quality), Julia Skapik, MD (Cognitive Medical Systems), Kristi Mitchell (Avalere Health)

3:15 p.m. – 4:30 p.m. Panel: Pulling it All Together

Objective: To summarize key points in the next steps toward building a Medical Device Registry

Moderator: Harlan Krumholz, MD (Yale University)

Panel: Bruce McIntosh, PhD (VA)
 Art Sedrakyan, MD (Weill Cornell Medical College)
 Danica Marinac-Dabic, MD, PhD (FDA)
 Rachael Fleurence, PhD (National Evaluation System for Health Technology Coordinating Center)

Closing Remarks

VA Leadership – Dr. Carolyn Clancy

Questions?

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