MDEpiNet Registry Assessment of Peripheral Interventional Devices (RAPID)

Phase II / III Working Group Meeting

Thursday, May 25, 2017
Sheraton Silver Spring
Magnolia Ballroom
Silver Spring, Maryland
07:30-16:30 EDT

Aims:

- Define the methodology for data aggregation, analysis and ownership
- Select the strategy for leveraging national data models and terminologies
- Outline the pathway for data capture, integration, exchange and management
- Reach consensus for the Phase II/III Research Project selection

07:30-08:00 Continental Breakfast

08:00-08:30 **Welcome and Updates**

- Welcome
  Mitchell Krucoff, Duke University / MDEpiNet
- National Evaluation System for Health Technology (NEST)
  William Maisel, US Food and Drug Administration (US FDA) – Center for Devices and Radiological Health (CDRH)
- RAPID Phase II/III Overview
  Jack Cronenwett, Dartmouth-Hitchcock / Society for Vascular Surgery (SVS)

08:30-9:45 **Leveraging National Data Models & Terminologies for Medical Device Evaluation**

Moderator: James Tcheng, Duke University

- BUILD, PCORnet & SENTINEL: Background, Data Model and Data Elements
  Jeffrey Brown, Harvard Pilgrim Healthcare Institute/Harvard School of Medicine
- RAPID Core Data Element Development in LOINC
  Stanley Huff, Intermountain Healthcare / Healthcare Services Platform Consortium
- Lead Discussants
  - Michael Nguyen, US FDA / Center for Drug Evaluation and Research (CDER) / Sentinel Program Lead / CDR, US Public Health Service
  - Gregory Pappas, US FDA / CDRH, Associate Director for National Devices Surveillance
- Group Discussion: Opportunities for RAPID

9:45-10:00 **BREAK**

10:00-11:00 **Inaugural RAPID Phase II/III Research Project**

Moderator: Robert Thatcher, 4C Medical Technologies

- **S**FA-**P**opliteal **E**videnc**E D**evelopment (SPEED): Project Selection and Description
  Pablo Morales, US FDA / CDRH, Medical Officer Division of Cardiovascular Devices
- Status of RAPID CDE Implementation by Registries, EMRs, Industry
  Lead Discussants:
  Jens Jorgensen, Maine Medical Center, Vascular Quality Initiative (VQI)
  Ralph Brindis, University of California, San Francisco / National Cardiovascular Data Registry (NCDR)
  Ahmed Saad, MedStreaming LLC
  Ronnie Bunshaft, Epic Systems Corporation
  Patrick Wang, Medtronic
- Group Discussion

11:00-12:15 **Methods for Data Capture, Integration, Exchange, & Management**

Moderator: Brian McCourt, Duke Clinical Research Institute

- Core and Supplemental Clinical Data
  James Tcheng, Duke University
- UDI Data for Device Identification, Categorization, and Coding
  Behnaz Minaei, US FDA / CDRH, Informatics Analyst
- Current Experience: Successes and Challenges
  Lead Discussants:
  UDI Data Collection
  Barry Daniels, GMDN
  Kin-Wah Fung, National Library of Medicine
  Registry Data Collection:
  Daniel Bertges, University of Vermont, VQI
  Ralph Brindis, NCDR
  EMR Discrete Data Element Collection:
  Ronnie Bunshaft, Epic Systems Corporation
  Ahmed Saad, MedStreaming LLC
  Industry Implementation of UDI:
  Aaron Lottes, Cook Medical
- Group Discussion

12:15-12:30 Break **to get box lunches**

12:30-1:30 **Working Lunch: Funding RAPID Phase II/III**

Moderator: Mitchell Krucoff, Duke Clinical Research Institute

- Cost of Current Industry-Based Device Evaluation
  Brad Martinsen, Cardiovascular Systems, Inc.
- Cost of Current Registry-Based Device Evaluation
  Jack Cronenwett, Dartmouth-Hitchcock / Society for Vascular Surgery (SVS)
- NEST Coordinating Center Funding for Pilot Projects
  Rachael Fleurence, Executive Director, NEST Coordinating Center / Medical Device Innovation Consortium (MDIC)
- Opportunities Provided by RAPID
  Robert Thatcher, 4C Medical Technologies
- Group Discussion

13:30-14:30 **Methods for Data Aggregation, Analysis and Sharing with Industry and FDA**

Moderator: Danica Marinac-Dabic, US FDA / CDRH, Director of the Division of Epidemiology

- Registry Data from VQI
  Daniel Bertges, VQI
- Analyses from SENTINEL
  Jeffrey Brown, Harvard Pilgrim Healthcare Institute / Harvard School of Medicine
- Health Care System Data from BUILD
  James Tcheng, Duke University
- International Analyses and Data from ICOR, ICVR
  Danica Marinac-Dabic, US Food and Drug Administration
- Group Discussion

14:30 – 15:45 **Multi-Stakeholder Benefits from RAPID**

Moderator: Pablo Morales, US FDA / CDRH, Medical Officer

- Perspectives:
  Misti Malone, US FDA / CDRH, Chief Peripheral Interventional Devices Branch
  Daniel Canos, Centers for Medicare & Medicaid Services (CMS)
  Mera Choi, Office for the National Coordinators for Health Information Technology (ONC)
  Josh Smale, Bard Peripheral Vascular
  Joni Creal, Bard Peripheral Vascular
- Group Discussion

15:45 – 16:30 **Planning Next Steps**

Moderators: Mera Choi, Jack Cronenwett, Pablo Morales, Robert Thatcher

- Working Groups, Timeline & Next Meeting

16:30 **Adjourn**