MDEpiNet Registry Assessment of Peripheral Interventional Devices (RAPID) Phase II / III Working Group Meeting

FDA Headquarters, White Oak Campus
Building 31, Great Room
10903 New Hampshire Avenue
Silver Spring, MD 20993
Wednesday, March 20, 2019
07:45-16:00 EDT

Objectives:

- Updates on FDA and NESTcc Directions With Real World Evidence for Medical Devices
- Share RAPID Phase II results of the **S**uperficial femoral and **P**opliteal **E**videnc**E** **D**evelopment (**SPEED**) Objective Performance Criteria
- Develop future directions for retrospective Phase III CDE and prospective Phase IV projects supporting regulatory decisions

07:30-08:00 Continental Breakfast

07:50-8:00 **Welcome, Introductions & Objectives for the Day**
A Brief Overview of the RAPID Program

08:00-09:00 **The Evolving Regulatory Universe:** What's happening now and what's coming next!

- U.S. Food and Drug Administration Update
- National Evaluation System for Health Technologies (NEST) Coordinating Center Update:
- European Union Medical Device Regulation Update:
- International Consortium of Vascular Registries Initiative

Discussion

09:00-10:15 **RAPID Phase II: SPEED OPC Results** and Lessons Learned*

Discussion

10:15– 10:30 BREAK

10:30-12:00 **Using UDI in Real World Evidence to Support Medical Device Evaluation**

- Where are we with UDI: FDA perspective
- Value of UDI/AUDI in PAD: Defining device characteristics (or baseline) to complete what we're missing
- Anatomic Location Data Standard
- GUDID Implementation Demonstration Project
- GMDN as a Dimension of Device Evidence

Discussion

12:00 – 12:45 (Networking / Boxed lunch)

12:45 – 2:00 PM **RAPID Phase III Round Tables**: **Using Real World Evidence to Support Regulatory Decisions**

Challenges and Solutions When Using Real World Evidence

- Survey Results from Industry Partners
- Industry View
- Regulatory View
- Statistical Considerations

Leveraging the VISION CRN Infrastructure for Advanced Device Research and Surveillance

- Industry Perspectives
- Centers for Medicare & Medicaid Services

Patient Level Data from Multiple Data Sources

- RAPID Value to Industry
- Syntactx
- American College of Cardiology/ National Cardiovascular Data Repository Cath PVI Registry
- Others (TBD)

1:45-2:00 Break

2:00 – 3:30 **RAPID Phase IV: Using the RAPID Tools to Support Prospective Studies and Randomized Controlled Clinical Trials (RCT)**

- Value of RAPID Dataset for Pre-Market Studies
- International Interfaces for Nested Prospective Trials (Inter^{2}Nest): A Coronary Recipe for RAPID Global Evidence
- U.S. and International prospective Registry-based trials for medical devices: An industry view
- Prospective Registry-based Trials Using VQI Sites: A RAPID Opportunity
- Leveraging CRN Community of Practice (COP)

3:30 - 4PM **Next Steps & Adjourn**

Value & Resources