Registry Assessment of Peripheral Interventional Devices (RAPID)

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RAPID Goals

- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices
- Phase II: Develop data extraction interoperability across registries and hospital EHRs that provide patient-level data for core data elements
- Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision.

RAPID Partners

- 3 Major U.S. Societies / Registries
  - American College of Cardiology (ACC)
    - National Cardiovascular Disease Registry (NCDR)
  - Society of Interventional Radiology (SIR)
    - National Interventional Radiology Quality Registry (NIRQR)
  - Society for Vascular Surgery (SVS)
    - Vascular Quality Initiative (VQI)
- 5 International Partners
  - Japan's Pharmaceuticals and Medical Devices Agency (PMDA)
  - Global Medical Device Nomenclature Agency (GMDNA)
  - Australian Vascular Audit
  - German Vascular Society
  - Northern German Association for Vascular Medicine

RAPID Partners

- 7 U.S. Agencies
  - FDA (CDRH pre- and post-market, and CDER)
  - Agency for Healthcare Research and Quality (AHRQ)
  - Centers for Medicare and Medicaid Services (CMS)
  - Department of Defense (DOD) Healthcare Resources
  - Office of the National Coordinator (ONC)
  - National Heart, Lung and Blood Institute (NHLBI)
  - National Library of Medicine (NLM)
- 6 EHR / Registry / Clinical Research Companies
  - Epic
  - M2S
  - MedStreaming
  - Healthjump
  - Boston Biomedical Assoc.
  - Novella Clinical, Quintiles

RAPID Partners

- 12 Device Manufacturers
  - Abbott
  - Aortic Medical Inc.
  - Avinger
  - Boston Scientific
  - Cardiovascular Systems Inc
  - Cook Medical
  - CR Bard
  - Medtronic
  - Spectranetics Corp
  - Terumo
  - Volcano Corp/Phillips Health Technology
  - WL Gore

RAPID Leadership

Co-Chairs

- Pablo Morales
  - Food and Drug Administration (FDA)
- Robert Thatcher
  - 4C Medical Technologies
- Jack Cronenwett
  - Dartmouth-Hitchcock Medical Center

Project Leader

- Rebecca Wilgus
  - Duke Clinical Research Institute (DCRI)

MDEpiNet Key Advisors

- Mitchell Krucoff, DCRI
- Danica Marinac-Dabic, FDA

RAPID Rationale

- Heterogeneity complicates our understanding of PAD treatment
  - Multiple different sized arteries and disease severity
  - Multiple specialties with different training, experience, bias
  - Multiple devices available for treating similar lesions:
    - Angioplasty Balloons: plain, drug coated, cutting, cryoplasty
    - Atherectomy Devices: laser, orbital, excisional
    - Stents: bare metal, covered, drug-eluting
    - Total occlusion crossing devices
- Variation in treatment implies lack of adequate information
- Need data about real-world treatment from multiple sources

RAPID Project Plan

- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices
  - Obtain data elements from existing registries and industry case report forms used for pivotal device approvals.
  - Develop structured comparison report of all relevant data elements to allow selection based on clinical expertise.
  - Select core data elements, develop technical specifications for each element and a method to integrate Unique Device Identifier (UDI) data for precise device specification.

RAPID Project Plan

- Phase II: Develop data extraction interoperability across peripheral arterial registries and hospital EHRs that provide patient-level data for core data elements
  - The ACC, SIR and SVS peripheral intervention registries would incorporate the core data elements.
  - Core data set would be provided to other national registries, such as the International Consortium of Vascular Registries (ICVR).
  - EHR manufacturers would develop smart data elements for the core data set.
  - Structured procedure templates would be developed to incorporate the core data elements.

RAPID Project Plan

- Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision.
  - Device evaluation projects will extract data from different registries or EHR systems that have implemented core data elements
  - Individual projects could add supplementary data
  - Prospective clinical trial, pre-market study
  - Post-market study, surveillance
  - Objective performance criteria creation

- Goal: Total Product Life Cycle evaluation of devices in real world practice.

RAPID Progress

Phase I: Started June, 2015 – Completed, August 1, 2016

Based on intense effort by:

- DCRI Informatics Team –Anne Heath, Mary Williams
- Received and anonymized data elements from:
  - 6 Society-based registry data forms
    - 3 Major US Registries: ACC NCDR, SIR NIRQR, SVS VQI
    - 3 International Registries: Australia, Germany, Japan
  - 7 Device manufacturer case report forms
    - Bard, Boston Scientific, CSI, Cook, Gore, Medtronic, Terumo
- Analyzed 3,904 data elements
- Selected and organized 2,021 variables that were specific to peripheral arterial device evaluation

RAPID Progress

Phase I: Started June, 2015 – Completed, August 1, 2016

Based on intense effort by:

- DCRI Informatics Team –Anne Heath, Mary Williams
- Work Groups (many conference calls, face-to-face meeting)
  - Clinical – Schuyler Jones, MD
    - Select core data elements assembled by DCRI Informatics Team
  - Informatics – James Tcheng, MD
    - Develop technical specifications to support interoperability
  - UDI – Terrie Reed, MSIE
    - Develop method to incorporate GUDID data into core data set

RAPID Phase I Deliverables

- Core Data Elements
  - Main elements, FDA device problem codes, medications, devices
- Use Cases for Core Data Elements
  - Pre- and post-market and randomized clinical trial
- Workflow Diagrams
  - Point of care, total product lifecycle and registry-based clinical trial
- GUDID Project Summary
  - Key learnings about use of GUDID data useful to other projects

RAPID Agenda September 14, 2016

- Phase I summary and discussion
- Lessons learned and common themes from others
- Phase II Plan: Implementing core data elements
  - Registries, EHR, health system and structured reports
- Perspectives on implementation and interactions
  - CMS, BUILD, HSPS, Pew, FDA, Sentinel, Industry
- Phase III Planning: Stakeholder discussion
  - Potential projects, problems and solutions
- International Opportunities and Methodology Considerations