RAPID: **R**egistry **A**ssessment of **P**eripheral **I**nterventional **D**evices

Peripheral Arterial Disease

- **R**egistry **A**ssessment of **P**eripheral **I**nterventional **D**evices **(RAPID)**
  - Launched June 5, 2015
- Goal
  - Standardize core data elements that could serve as a global case report form for both pre- and post-market assessment of peripheral arterial interventional devices

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Co-Chairs

- **Jack Cronenwett**
  - Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI)
- **Pablo Morales**
  - Food and Drug Administration (FDA)
- **Robert Thatcher**
  - Cardiovascular Systems, Inc. (CSI)

Project Manager

- Rebecca Wilgus
  - Clinical Informatics, Duke Clinical Research Institute (DCRI)

RAPID Partners

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- **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**)
- **Agencies**
  - Food and Drug Administration (**FDA**: pre- and post-market)
  - Japan's Pharmaceuticals and Medical Devices Agency (**PMDA**)
  - Centers for Medicare and Medicaid Services (**CMS**)
  - Office of the National Coordinator (**ONC**)
- **MDEpiNet Coordinating Center**
  - Duke Clinical Research Institute (**DCRI**)

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RAPID Partners

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

Heterogeneity of Treatment

- Variable Patient Conditions
  - Age, gender, diabetes influence outcomes
- Variable Disease Severity
  - Claudication (life style) vs. Critical Ischemia (limb threat)
  - Differing lesion length, occlusion vs. narrowing, calcification
- Variable Disease Location
  - Large (iliac), Medium (SFA, popliteal), Small (tibial) Arteries
- Variable Physician Specialty, Training, Experience
  - Cardiologists, radiologists, surgeons
- Variable Treatment Options
  - Numerous device types, on- and off-label use in practice

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Many Peripheral Interventional Devices

- Angioplasty Balloons
  - Plain, drug coated, cutting, cryoplasty
- Stents
  - Bare metal
    - Self-expanding, balloon expandable
  - Covered
  - Drug-eluting
- Atherectomy devices
  - Laser, mechanical
- Total occlusion crossing devices
- Many not approved for peripheral arterial treatment

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RAPID Project Plan

- **Phase I**: **Identify minimal set of core data elements for registry assessment of infrainguinal arterial devices.**
  - Obtain data elements from existing registries and industry case report forms used for pivotal device approvals.
  - Develop structured comparison report of data elements using DCRI methodology.
  - Define core data elements and definitions, including patient and pathology data, device characteristics, endpoints for safety and effectiveness, and patient reported outcomes.
    - Clinical and Informatics Panels representing all RAPID partners
    - Plan: HL7 balloting, linkage with ONC standards, sharing with EHR manufacturers to allow extraction from multiple sources

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RAPID Project Plan

- **Phase 1a: Develop a method for registries to extract UDI data for relevant PVI devices.**
  - Work with FDA and National Library of Medicine to develop an automated method to periodically extract specific device data from Access GUDID to populate relevant registries.
  - Work with FDA and NLM to assess usefulness of current PVI device categorization and suggest improvements as appropriate.

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RAPID Project Plan

- **Phase II: Develop data extraction interoperability** across peripheral 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.
  - EHR manufacturers would be encouraged to develop smart data elements for the core data set.
  - Core data set would be provided to other national registries, such as the International Consortium of Vascular Registries (ICVR).

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RAPID Project Plan

- **Phase III: Apply a coordinated registries network to studies supporting a regulatory decision.**
  - Projects would extract minimal core data from different registries or other data sources, such as centers using the same EHR system
  - Individual projects may need supplemental data
  - Prospective clinical trial, pre-market study
  - Post-market study, surveillance
  - Objective performance criteria creation
  - Goal: Total Product Life Cycle evaluation in real world practice

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RAPID Progress

- Infrastructure Established
  - DCRI Informatics Team, Project Manager
  - Clinical, Informatics, UDI Work Groups selected
    - Multiple stakeholders represented in each group
- 3 Registry data forms and 4 Industry CRF forms submitted to date, other companies in process
- Full day planning meeting held at FDA on June 5
- Break out during MDEpiNet meeting October 1
- Bi-weekly teleconferences of leadership group
- **DCRI informatics group work** to be presented today