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

Registry **A**ssessment of **P**eripheral **I**nterventional **D**evices (**RAPID**)

- Used to treat infrainguinal arterial occlusive disease

- **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

- **MDEpiNet-Sponsored, Public-Private Partnership**
- Duke Clinical Research Institute **(DCRI)**
  - Coordinating Center

RAPID Partners

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- **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

RAPID: Registry Assessment of Peripheral Interventional Devices

- **7 U.S. Agencies**
  - FDA (**CDRH** pre- and post-market, and **CEDR**)
  - 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

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- **12 Vascular 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

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- **Co-Chairs:**
- Pablo Morales
  - Food and Drug Administration (FDA)
- Robert Thatcher
  - Cardiovascular Systems, Inc. (CSI)
- Jack Cronenwett
  - Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI)
- **Project Manager:**
- Rebecca Wilgus
  - Clinical Informatics, Duke Clinical Research Institute (DCRI)
- **MDEpiNet Key Advisors:**
- Mitchell Krucoff, DCRI
- Danica Marinac-Dabic, FDA

Rationale:

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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

Rationale:

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Heterogeneity of 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**: **Define the 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 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.
- **Duke Clinical Research Center (DCRI)**
  - Clinical Research Informaticists: Anne Heath, Mary Williams

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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: Use a coordinated registries network (CRN) for 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 might need 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.**

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RAPID Progress

Phase I: June, 2015 – April, 2016

- **Developed 3 Work Groups:**
- **Clinical**
  - Select core data elements assembled by DCRI Informatics Team
- **Informatics**
  - Develop technical specifications to support interoperability
- **UDI**
  - Develop method to incorporate GUDID data into core data set
- Multiple stakeholders represented in each group
- Multiple teleconferences with broad participation

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RAPID Progress

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 disease (PAD) device evaluation**

RAPID: Registry Assessment of Peripheral Interventional Devices

RAPID Progress

Clinical Work Group - Schuyler Jones, MD, Chair

- Reviewed and prioritized 2,021 data elements with goal to select 100-125 PAD most relevant variables
- Discussed use cases for RAPID data elements
- Prioritized variables applicable to most devices, for most use cases, across TPLC, already being used by stakeholders
- Organized by Condition, Test, Treatment, Device, Outcome
- Selected 113 candidate variables
- Final selection based on work group meeting tomorrow

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RAPID Progress

Informatics Work Group - James Tcheng, MD, Chair

- Identified minimum meta-data required for each variable to allow interoperability and HL7 balloting
- Developed work product prototype from 8 data elements
- Discussed with ONC and decided to develop data element specifications based on Clinical Information Modeling Initiative (CIMI)
- Identified several data models (PCORNet, Sentinel, OMOP) to evaluate for potential data aggregation in Phase II
- Much ongoing work as core data elements are finalized

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RAPID Progress

- **UDI Work Group** - Terrie Reed, MSIE, Chair
- Identified set of GUDID data elements required for RAPID
  - Company, brand, product number, GMDN term, size, model, etc.
- Documented the method to extract these data from GUDID so that registries, EHRs, others can link device information
- Evaluated usefulness of categories used in Global Medical Device Nomenclature (GMDN)
  - Issues with devices used off-label and non-US approved devices
- Identified relevant device information not included in current GUDID data that requires supplemental dataset
- Capturing UDI at point of use is key for registries, EHRs

RAPID: Registry Assessment of Peripheral Interventional Devices

RAPID Progress

- Meetings June 5, Nov 6, 2015 and April 13, 2016
- Timetable Goals:
- Phase I:
  - July, 2016: Finalize core data element selection
  - Dec, 2016: Finalize meta-data specification
- Phase II:
  - 2016-2017: Incorporation core data elements into registries, EHR systems
- Phase III:
  - 2017: Initiation of device evaluation project
- Details to be finalized during tomorrow's workshop