Registry Assessment of Peripheral Interventional Devices (RAPID)

Phase I Deliverables

July 14, 2016

This document defines the RAPID project and artifacts that together constitute the package of deliverables for Phase I.

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Executive Summary

The Registry Assessment of Peripheral Interventional Devices **(RAPID)** project emerged from the **P**redictable **A**nd **S**u**S**tainable **I**mplementation **O**f **N**ational (**PASSION**) **R**egistries for **C**ardiovascular **D**evices program of the **M**edical **D**evice **E**pidemiology **N**etwork (**MDEpiNet**), a public- private partnership supported by the U.S. FDA to advance the nation's approaches to the evaluation of medical devices. It is one project in a series initiated to advance and demonstrate the interoperable flow of data and information across electronic health information systems as a precursor to the National Evaluation System for Health Technology (NEST) articulated by Drs. Shuren and Califf[1]. The MDEpiNet RAPID project is designed to advance the foundational elements of a total product lifecycle (TPLC) approach for the evaluation of medical devices used to treat and manage peripheral artery disease.

RAPID is focused on devices for peripheral arterial intervention as an archetype of the envisioned TPLC ecosystem. Standard data elements related to the care and treatment of patients with peripheral artery disease are being developed for use with data elements from the **G**lobal **U**nique **D**evice **I**dentification **D**atabase (**GUDID**) database to create a structured dataset that supports pre- and post-market assessment, quality improvement, and safety surveillance of peripheral interventional devices (Phase I). Subsequent phases will validate the potential of the data elements for implementation in various healthcare information systems such that structured, interoperable data is collected at the point of care and is available for use by patient registries, clinical research and medical device evaluation initiatives. Additionally, the **RAPID** data elements will inform the development of a global case report form and data collection instruments needed in the interim. As such, this work facilitates peripheral interventional device development, addresses regulatory needs, and creates efficiencies that will reduce overall time and costs and support quality improvement efforts across the medical device lifecycle.

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[1] Shuren J and Califf RM, Need for a national evaluation system for health technology. JAMA – published online July 11, 2016. doi:10.1001/jama.2016.8708.

RAPID Leadership

Co-Chairs:
Pablo Morales, U.S. Food and Drug Administration (FDA)
Robert Thatcher, 4C Medical Technologies
Jack Cronenwett, Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI)

MDEpiNet Key Advisors:
Mitchell Krucoff, Duke Clinical Research Institute (DCRI)
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Working Group Chairs:
W. Schuyler Jones, Duke Clinical Research Institute (DCRI)
Terrie Reed, U.S. Food and Drug Administration (FDA)
James Tcheng, Duke Clinical Research Institute (DCRI)

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Rebecca Wilgus, Duke Clinical Research Institute (DCRI)
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Mary Williams, Duke Clinical Research Institute (DCRI)

RAPID Stakeholder and Working Group Member Organizations

3 Major US Professional 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

7 U.S. Government 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
- Health Jump
- Boston Biomedical Associates
- Novella Clinical, Quintiles

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

Background

The importance of creating an interoperable infrastructure to support medical device evaluation and surveillance across the total product lifecycle is widely recognized and many efforts are currently in progress[2,3]

Structured clinical data elements are an essential component of an interoperable infrastructure in which clinically based data sources (procedure documentation systems, electronic health record systems, patient registries) can be linked or leveraged with claims data, patient reported outcomes data, and data from other sources needed to aggregate and analyze multi-sourced data sets required to generate evidence across the total product life cycle for medical devices.

Collectively, this evidence is necessary to reduce time to market for new devices, extend indications for use, inform device design and modification, define best practices for selection and use of medical devices, and support aggregate analysis of clinical and economic outcomes (including risks and benefits) across device types for real-world patient populations. It facilitates rapid identification of problematic devices as well as accurate and timely dissemination of information about device performance to clinicians, patients, and manufacturers[1].

Although great strides have been made in some areas, in peripheral artery disease (PAD) much work remains. A recent systematic review of treatment strategies for patients with PAD concluded that insufficient evidence exists to support many treatment options over others[4]. Factors contributing to the heterogeneity of treatment include but are not limited to:

- The large array of treatments and devices used (both on- and off-label) to treat and manage PAD
- The variety of medical specialties performing PAD procedures, including vascular surgeons, interventional cardiologists and interventional radiologists, each of whom bring specific competencies and approaches to managing patients with PAD

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[2] Krucoff MW, Sedrakyan A, Normand SL. Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks. JAMA 2015: 314:1691-1962.

[3] Krucoff, MW, Normand SL, Edwards F, Lystig, T. Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research. A Report from the Medical Device Registry Taskforce & the Medical Devices Epidemiology Network. Http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm459368.pdf   Accessed July 18, 2016.

[4] Jones WS, Schmit KM, Vemulapalli S, Subherwal S, Patel MR, Hasselblad V, Heidenfelder BL, Chobot MM, Posey R, Wing L, Sanders GD, Dolor RJ. Treatment Strategies for Patients With Peripheral Artery Disease. Comparative Effectiveness Review No. 118. (Prepared by the Duke Evidence-based Practice Center under Contract No. 290-2007-10066-I.) AHRQ Publication No. 13-EHC090-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2013. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

- The relatively few large comparative effectiveness studies that stratify patients by risk and/or disease severity or treatment/device type
- The existence of multiple registries focused on PAD defined according to physician specialty rather than reflecting the entirety of the patient population and care practices
- Lack of structured data that links specific devices (unique device identifiers) with the patients in which they are used/implanted

In order to improve many aspects of PAD device evaluation, the RAPID project was initiated. The goal of the first phase was to specify a minimal set of core data elements (CDEs) for registry assessment of peripheral interventional devices, including Unique Device Identifier (UDI)[5] data of relevant devices, and to explore opportunities for peripheral vascular registries to capture and use structured device identification data from the US FDA's AccessGUDID database (http://accessgudid.nlm.nih.gov).

Approach

Core data elements describing the patient with peripheral artery disease were identified and defined. A minimal set of metadata was developed to support implementation of the core data elements at many points across the device lifecycle. Priority was given to data elements that are currently being collected by PAD interventional registries and clinical trials conducted by device manufactures.   A clinical working group aggregated and anonymized data elements from 8 registry and device company CRFs, yielding a total of 3090 data elements. Just over half of these data elements were deemed specific to peripheral artery disease treatment. Through a series of intensive web conferences and face to face meetings over several months, a multi-stakeholder work group reached consensus on the selection of 90 key data elements, prioritized based on their presence in existing data sources, applicability to most PAD devices, and applicability for use across total product life cycle (TPLC).

Following the selection of this minimal set of CDEs, an informatics working group convened to develop sufficient metadata for each of the data elements to be implemented in a variety of systems and used with many data models (OMOP, Sentinel, PCORnet, I2B2, CIMI and others) to support workflows such as:
- Federated/distributed research networks (like Sentinel & PCORnet)
- EDC systems/trial-specific databases
- Multi-source, multi-data type research (or device evaluation) repositories
- Point of care clinical, procedural, and EHR systems with downstream flows to QI Registries and other systems used for outcomes analysis
- Data collections systems not otherwise set to receive or exchange data w/ EHR systems

This approach leverages ongoing data collection efforts and extends the use of existing PAD datasets for collective, aggregate analysis. Furthermore, implementation of the RAPID core dataset in EHRs and

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[5] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/

other clinical systems is an important step toward collecting data important to device evaluation at the point of care delivery to facilitate use by quality registries, regulators, manufacturers and other stakeholders for a variety of purposes.

The RAPID core data set will be validated in future phases by extracting data from existing sources, aggregating it into a multi-sourced analysis dataset that can be used to support a variety of pre- and post-market research, quality improvement and safety surveillance efforts.

Deliverables

In addition to developing the RAPID Core CDEs, value sets and related metadata, the team created several additional artifacts that guided the work of developing the CDEs, will be useful in framing the context of the data elements as the project moves into Phases II and III, and documented recommendations and lessons learned about the adoption of Global Unique Device Identifiers (GUDID) by registries and industry partners. Each of these work products will be described in detail.

Core Data Element Spreadsheet (RAPID Core Data Elements_20JUL2016FinalPhase1.xls)

This spreadsheet is the central deliverable of RAPID Phase I and contains a standardized set of data elements, definitions, and value sets that can be implemented in a variety of health technology platforms and/or serve as the basis for a global case report form (CRF) for pre- and post-market evaluation of peripheral arterial intervention devices, .

The CDEs are presented in a spreadsheet that is organized into four tabs: Main List, FDA Device Problem Codes, Medications and Devices.

- **Main List -** This tab contains the core data elements, value sets and core metadata for each. The intent was to provide just enough metadata to support implementation of these data elements in information technology systems
- **FDA Device Problems Codes** – This tab includes a list of the FDA Device Problem Codes, names, and definitions that are relevant to peripheral arterial vascular intervention devices. This list serves as the value set for data element "Device Failure." Due to the length and breadth of this value set the team chose to display it in a separate tab rather than to embed it within the CDEs as was done with all of the other value sets.
- **Medications** – When the CDEs are leveraged for any future registry, evaluation, or research project, it is intended that medication administration data will be pulled from medical record documentation systems to support specific projects. As such, they did not need to be replicated within the set of CDEs. The team found it useful nonetheless to identify a minimum, representative set of medications uniquely relevant to the evaluation of peripheral arterial vascular intervention devices. These medications are identified on the Medication tab of the CDE spreadsheet.
- **Devices** – This final tab of the spreadsheet contains the UDI data elements as well as representative examples of device types used in the treatment of peripheral artery disease.

Use Cases (RAPID UseCases_pre-mrkt_post-mrkt_RCT_FinalforPhase1.pdf)

To guide the work of the team endeavoring to reach consensus on the CDEs and to provide some boundaries on the scope of the CDEs, the team wrote three use cases: Pre-Market Approval Use Case, Post-Market Approval Use Case, and Randomized Clinical Trial (RCT) Use Case. These use cases represent, at a high level, examples of contexts in which the CDEs *could* be successfully leveraged; they do not represent any existing registry or project under development.

Workflow Diagrams (RAPID_Info_WrkFlw_14JUL2016FinalforPhase1.pdf)

With an eye toward subsequent phases of the RAPID project, the team created three workflow diagrams demonstrating how the CDEs could be integrated into existing data streams:

- **RAPID Data Elements Demonstration Project**: This workflow provides a visual representation of the information collected at the point of care for utilization and reporting across the continuum through device evaluation. The process starts with patient presentation in clinic for a routine visit (top left) and continues through the analysis of their data for device evaluation in an analysis data set (bottom right). The resulting structured dataset supports pre- and post-market surveillance, quality improvement/assurance, and evaluation of clinical outcomes and device performance.
- **National Medical Device Evaluation/Surveillance System**: This workflow represents implementation of RAPID core data elements at a variety of points in the total product life cycle. Starting with Device Manufacturers on the top left and continuing across to the bottom right where devices are associated with individual patients in EHR's & clinical procedure information systems, data from the core data set can be extracted & utilized for device evaluation and safety surveillance.
- **Registry-Embedded Clinical Trial:** This workflow represents implementation of the RAPID core data set as part of a clinical trial that is integrated into a routine, care delivery process. The flow of RAPID Core Data point of care in the top left through analysis in the bottom right is illustrated. Additionally, core data flow from a patient registry into a clinical trial's electronic data capture system where it is used to support research operations such as patient enrollment, randomization, informed consent and study-specific data collection efforts is illustrated.

Global Unique Device Identification (GUDID) Working Group Project Summary (GUDID Integration Workgroup Project Summaryv3FinalforPhase1.pdf)

Medical device registries currently do not have an efficient or consistent mechanism for capturing and storing structured device identification data and there is no existing, recognized codeset that links device records across registries. As such, the RAPID GUDID Working Group was formed to explore and understand the opportunities for using the GUDID for that purpose. The GUDID integration working group sought to promote knowledge sharing across FDA, device manufacturers, clinicians and registries related to extracting and use of data from GUDID and to facilitate the transition from existing non-standardized device identification in device registries to one based upon the Device Identifier (DI) as a standard linking identifier and a key to extracting core standard device identification data elements from the GUDID. Challenges, lessons learned and recommendations are summarized in the **GUDID Working Group Project Summary.**