Registry Assessment of Peripheral Interventional Devices (RAPID)

Developing a minimum core dataset for total product life cycle device evaluation across multiple data sources: a step toward establishing a National Evaluation System for Health Technology for peripheral intervention devices.

BY JOSE PABLO MORALES, MD; JACK CRONENWETT, MD; AND ROBERT THATCHER, MBA; ON BEHALF OF THE RAPID PROJECT COLLABORATORS

Registry Assessment of Peripheral Interventional Devices (RAPID) is one of the PASSION CV (Predictable and Sustainable Implementation of National CardioVascular) registry projects approved by the Scientific Oversight Committee of the Medical Device Epidemiology Network Public-Private Partnership (MDEpiNet PPP).[1] The PASSION program is intended to contribute pilot projects promoting a more efficient and sustainable national medical device evaluation system for cardiovascular devices, supporting regulatory and best practice decisions throughout the total product life cycle. Primarily, the focus of these approaches is through novel configurations of structured data elements across existing electronic registries, health records, and related health information repositories, or strategically, "coordinated registry networks" (CRNs).[2] Such CRN-based data could accelerate clinical trial timelines, reduce trial-related site work burden, and support both labeling expansion of already approved devices and clearance or approval of new devices in the future.[3]

The current evaluation of medical devices used for peripheral arterial intervention is particularly challenging due to the heterogeneity of the disease process, the availability of multiple devices for treatment, and lack of consensus about the best treatment type. In addition, peripheral interventional devices are produced by multiple manufacturers and used by several medical specialties, including cardiologists, radiologists, and surgeons, each of which brings a different training and experience to influence treatment choice. Furthermore, peripheral interventional devices represent the most rapidly growing device category used to treat Medicare beneficiaries, with recent concerns that they may be overused by some practitioners. Although several distinct society- and industry-based registries have been developed to monitor these procedures, the core data elements are not standardized across registries, making evaluation of device class effect challenging across different data sources.

The goal of RAPID is to standardize core data elements that could allow utilization of data from multiple sources to serve as a global case report form (CRF) for both pre- and postmarket assessment of peripheral arterial interventional devices. One of the project goals is to incorporate the standardized data elements into two major existing registries (Society for Vascular Surgery Vascular Quality Initiative [SVS VQI] and American College of Cardiology National Cardiovascular Disease Registry [ACC NCDR]), as well as into the electronic health record (EHR) system of at least one vendor, in order to subsequently conduct a device evaluation project using these data sources to demonstrate the benefit of interoperable device data collection for both industry and the US Food and Drug

Administration (FDA). With these considerations in mind, RAPID is aligned with the current Center for Devices and Radiological Health (FDA/CDRH) initiative to improve the total product life cycle (TPLC) assessment of medical devices and enhance the use of real-world data for regulatory determinations.[4,5]

RAPID was successfully launched on June 5, 2015, and it was developed following the MDEpiNet philosophy of a public/private partnership as it brought together representatives of the following stakeholders:

- **Professional societies and their registries:** ACC NCDR, SVS VQI, and the Society of Interventional Radiology (SIR) National Interventional Radiology Quality Registry (NIRQR) Japan Endovascular Treatment Conference (JET).
- **International partners:** Japan's Pharmaceuticals and Medical Devices Agency, the Global Medical Device Nomenclature Agency, the Australian Vascular Audit, the German Vascular Society, and the Northern German Association for Vascular Medicine.
- **United States federal agencies:** The FDA, including the CDRH and the Center for Drug Evaluation and Research, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Department of Defense, Healthcare Resources, the Office of the National Coordinator, and the National Institute of Health with representation from the Heart, Lung, and Blood Institute, and the National Library of Medicine.
- **Electronic health record and clinical research companies:** Epic, M2S, MedStreaming, Healthjump, Boston Biomedical Association, and Quintiles (Novella Clinical).
- **Medical device manufacturers:** Abbott Vascular, Aorta Medical, Inc., Avinger, Inc., Boston Scientific Corporation, Cardiovascular Systems, Inc., Cook Medical, Bard Peripheral Vascular, Inc., Medtronic, Spectranetics Corporation, Terumo Interventional Systems, Volcano Corporation/Philips Health Technology, and Gore & Associates.

To successfully manage the enormity of such a project, RAPID was divided into the three phases listed below to allow for a progressive and step-wise approach.

- **Phase 1:** This phase consists of identifying the minimal set of core data elements for registry assessment of peripheral arterial interventional devices, including a method for registries to extract Unique Device Identifier (UDI)[6] data for relevant peripheral arterial vascular intervention devices.
- **Phase 2:** This phase consists of incorporating the standardized data elements into existing registries and EHR systems and demonstrating the ability to extract data for studies from multiple sources.
- **Phase 3:** This phase consists of the use of interoperable data extraction to conduct a prospective device evaluation project in the peripheral arterial treatment space.

The overall project is managed by the Duke Clinical Research Institute (DCRI), which serves as the coordinating center for MDEpiNet. The project manager is Rebecca Wilgus, RN, MSN, of DCRI. It is co-chaired by the authors of this article, with advice from Mitchell Krucoff, MD, of DCRI, and Danica Marinac-Dabic, MD, PhD, of the FDA. Phase 1 has been completed within the 1-year aggressive goal set for this project using the following methods.

First, Anne Heath, BA, from the DCRI informatics team obtained and anonymized data elements from six different professional society-based registry data forms, three from the United States (ACC NCDR, SIR NIRQR, and SVS VQI), and three from international registries (Australia, Germany, and Japan), along with CRFs used by seven device manufacturers (Bard Peripheral Vascular Inc., Boston Scientific Corporation, Cardiovascular Systems, Inc. [CSI], Cook Medical, Gore & Associates, Medtronic, Terumo Interventional Systems). Overall, a total of 3,904 data elements were identified. The data elements were catalogued for uniqueness and specificity in terms of peripheral arterial disease (PAD) device evaluation. A total of 2,021 unique data elements focused on PAD were selected.

Next, a multi-stakeholder clinical work group, under the leadership of W. Schuyler Jones, MD, selected the core data elements. During conference calls and face-to-face meetings, the work group reviewed and prioritized the 2021 data elements specific to PAD device evaluation and selected the minimum core set of clinical data elements. These 100 core data elements were prioritized based on their applicability to most devices, for most use cases, and across TPLC, and organized in categories of condition, test, treatment, device, and outcome. After the clinical work group selected the core clinical data elements, an informatics work group, under the direction of James Tcheng, MD, developed the technical specifications to accomplish syntactic and semantic interoperability and electronic interchange of each RAPID core data element that would be required to exchange and leverage the RAPID dataset with data from other sources (eg, distributed research networks, claims, master death index, the FDA's Global Unique Device Identification Database [GUDID]). The informatics work group also documented workflow models to illustrate the use of the data elements. This work positions the data elements to become the controlled vocabulary for PAD, formal balloting (eg, Health Level Seven International [HL7],

Clinical Information Modeling Initiative [CIMI]), and use in common data model frameworks (eg, SENTINEL,[7] OMOP[8]).

Simultaneously, a UDI integration workgroup was formed under the leadership of Terrie Reed, MS, to develop a generalizable method whereby the registries represented in RAPID, as well as future device registries, could automatically download relevant standardized device identification information from the GUDID[9] into each registry. The GUDID workgroup came to a consensus on a set of common device identifier (DI) data elements that could be downloaded from GUDID:

- Device identifier (of the UDI)
- Company name
- Brand
- Catalog/product number
- Global Medical Device Nomenclature (GMDN) term/Systemized Nomenclature of Medicine (SNOMED) term
- Device description
- Clinically relevant size
- Version or model

As representatives of one of the first groups to test the GUDID data extraction for integration into registries, the workgroup documented the value of UDI integration and identified recommended improvements to both the data submitted to GUDID, as well as the processes for extracting GUDID data. The documentation will inform efforts by coordinated registry networks on the appropriate use of the device identifier of the UDI as the key to link across data sources (eg, EHRs, registries, recall data). The group also evaluated the usefulness of the GMDN terminology for identifying device types, identified relevant device information not included in current GUDID data that will require development of a supplemental dataset, and discussed the exchange of UDI data captured at point of use for reuse in registry data, as this is key for registries and EHRs.

Now that Phase 1 has been accomplished, the data elements are ready to become the controlled vocabulary for PAD interventional device evaluation, for formal balloting via HL7 or CIMI, for use in common data model frameworks via SENTINEL or OMOP, and for continuing with Phase 2.

In summary, RAPID has built a foundation to assess global medical devices currently being used for peripheral artery interventions, by engaging a multi-stakeholder collaboration that is essential to move a project of this magnitude to a successful endpoint. The use of registries for TPLC evaluation of devices in the real-world benefits from harmonization across both society- and industry-based registries, which can be achieved by collecting standardized data elements to enable consistent assessment across specialties and countries. Given the exponential, and sometimes criticized, expansion of peripheral arterial device usage, RAPID has great potential to not only improve device effectiveness and quality, but also to reduce variation in device use by different specialties in different countries. RAPID may also facilitate peripheral arterial device development and help address regulatory needs by providing a common data set that may be used in all pre- and postmarket device trials with the potential to meet respective regulatory requirements for premarket approval or postmarket surveillance. Further, such data could be extracted from multiple sources, including registries, EHRs, payer data, etc. This process may facilitate national and international device approval process and the potential to expand indications for existing devices in the future. ■

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APPENDIX 1

RAPID Leadership Team
Eighteen people from seven organizations

- 4C Medical Technologies
- Centers for Medicare & Medicaid Services (CMS)
- Duke University & Duke Clinical Research Institute
- Mercy Health System
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Society for Vascular Surgery
- US Food and Drug Administration (US FDA)

First Name	Last Name	Organization or Affiliation
Daniel	Canos	Centers for Medicare & Medicaid Services (CMS)
Jack	Cronenwett*	Society for Vascular Surgery Patient Safety Organization
Joe	Drozda	Mercy Health System
Rie	Fukaya	Pharmaceuticals and Medical Devices Agency (PMDA)
Nobuhiro	Handa	Pharmaceuticals and Medical Devices Agency (PMDA)
Schuyler	Jones	Duke Clinical Research Institute
Mitchell	Krucoff	Duke Clinical Research Institute
Misti	Malone	US Food and Drug Administration (US FDA)
Danica	Marinac-Dabic	US Food and Drug Administration (US FDA)
Pablo	Morales*	US Food and Drug Administration (US FDA)
Terrie	Reed	US Food and Drug Administration (US FDA)
Kazuhisa	Nojima	Pharmaceuticals and Medical Devices Agency (PMDA)
Christopher	Ronk	US Food and Drug Administration (US FDA)
Sara	Takahashi	Pharmaceuticals and Medical Devices Agency (PMDA)
Madoka	Murakami	Pharmaceuticals and Medical Devices Agency (PMDA)
James	Tcheng	Duke University
Robert	Thatcher*	4C Medical Technologies
Rebecca	Wilgus	Duke Clinical Research Institute

*RAPID project co-chairs.

APPENDIX 2

RAPID Working Groups Composition
1. Clinical working group: 55 people from 30 organizations

- Abbott Vascular
- American College of Cardiology
- Australian Vascular Audit, ICVR countries
- Bard
- Baylor College of Medicine (BCM)
- Boston Scientific Corporation
- Boston-Biomedical
- Cardiovascular Systems, Inc. (CSI)
- Centers for Medicare & Medicaid Services (CMS)
- Cleveland Clinic/SCAI
- Cook Medical
- CR Bard (Bard Peripheral Vascular, Inc.)
- Duke University/Duke Clinical Research Institute
- Epic
- German Vascular Registry
- Japan Endovascular Treatment Conference (JET)
- Mass General Vascular Center (VasCore)
- Medical University of South Carolina (MUSC)

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- Medstreaming
- Medtronic Aortic and Peripheral Vascular
- Mercy Health System
- Office of the National Coordinator (ONC)
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Saint Joseph Mercy Hospital
- Society for Vascular Surgery
- Society of Interventional Radiology
- University of Virginia Health System
- US Food and Drug Administration (US FDA)
- Veteran's Administration Eastern Colorado Healthcare System
- Volcano Corp/Philips Health Technology

First Name	Last Name	Organization or Affiliation
Ehrin	Armstrong	VA Eastern Colorado Healthcare System
Herbert	Aronow	St. Joseph, Mercy Hospital/SVM/ACC
Sophia	Autrey	Centers for Medicare & Medicaid Services (CMS)
Jeannette	Bankes	Boston Scientific Corporation
Christian	Behrendt	German Vascular Registry
Barry	Beiles	Australian Vascular Audit, ICVR countries
Daniel	Bertges	Society for Vascular Surgery/ University of Vermont Medical Center
Megan	Brandt	Cardiovascular Systems, Inc. (CSI)
Ralph	Brindis	American College of Cardiology
Tom	Brothers	Medical University of South Carolina (MUSC)
Donna	Buckley	US Food and Drug Administration (US FDA)
Joni	Creal	Bard
Jack	Cronenwett	Society for Vascular Surgery/Dartmouth-Hitchcock Medical Center
Sebastian	Debus	German Vascular Registry
Joe	Drozda	Mercy Health System
Jeremy	Durack	Society of Interventional Radiology
Wael	Elseaidy	Medstreaming
Mark	Gosnell	Boston-Biomedical
Melissa	Hasenbank	Medtronic
Anne	Heath	Duke Clinical Research Institute
Elisa	Hebb	Volcano Corp/Philips Health Technology
Kathleen	Hewitt	American College of Cardiology
Mami	Ho	Pharmaceuticals and Medical Devices Agency (PMDA)
Osamu	Iida	Kansai Rosai Hospital, Japan Endovascular Treatment Conference (JET)
Shin	Iwamoto	Pharmaceuticals and Medical Devices Agency (PMDA)
Michael	Jaff	Mass General Vascular Center, VasCore
Schuyler	Jones	Duke Clinical Research Institute
Robert	Lee	US Food and Drug Administration (US FDA)
Robert	Lookstein	Society of Interventional Radiology/Mount Sinai Medical Center
Aaron	Lottes	Cook Medical
Michele	Masters	Medtronic Aortic and Peripheral Vascular
Kristina	McCoy	American College of Cardiology
Michael	McGuffey	Medtronic Aortic and Peripheral Vascular
Joseph	Mills	BCM
Caroline	Morgan	American College of Cardiology
Masato	Nakamura	Toho University Hospital, Japan Endovascular Treatment Conference (JET)

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Mehdi	Shishebor	Cleveland Clinic/SCAI
Josh	Smale	CR Bard (Bard Peripheral Vascular, Inc.)
Sara	Takahashi	Pharmaceuticals and Medical Devices Agency (PMDA)
Erika	Tang	US Food and Drug Administration (US FDA)
James	Tcheng	Duke University
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Hiroyoshi	Yokoi	Fukuoka Sanno Hospital, Japan Endovascular Treatment Conference (JET)
Yoshiaki	Yokoi	Kishiwada Tokushukai Hospital, Japan Endovascular Treatment Conference (JET)
Margo	Zaugg	Abbott Vascular

2. Informatics working group: 36 people from 18 organizations:

- American College of Cardiology–NCDR
- Aorta Medical Inc.
- Boston Biomedical Associates
- Centers for Medicare & Medicaid Services (CMS)
- Cook Medical
- Duke University/Duke Clinical Research Institute (DCRI)
- Epic
- Geisinger Health System
- HealthJump, Inc.
- M2S
- Medstreaming
- Office of the National Coordinator (ONC)
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Society for Vascular Surgery
- Society of Interventional Radiology
- US Food and Drug Administration (US FDA)
- Vanderbilt
- Volcano Corp/Philips Health Technology

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Jeremy	Durack	Society of Interventional Radiology
Wael	Elseaidy	Medstreaming
Brian	Fortier	Aorta Medical Inc.
Rie	Fukaya	Pharmaceuticals and Medical Devices Agency (PMDA)
Jove	Graham	Geisinger Health System
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Brian	McCourt	Duke Clinical Research Institute (DCRI)
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Julia	Skapick	Office of the National Coordinator (ONC)
Albert	Taylor	Office of the National Coordinator (ONC)
James	Tcheng	Duke University
Michael	Thompson	Medstreaming
Emily	Tucker	American College of Cardiology–NCDR
Matteo	Verzola	Epic
Roseann	White	Duke Clinical Research Institute (DCRI)
Ke	Zhang	M2S

3. Global Unique Device Identifiers (GUDID) working group: 39 people from 23 organizations:

- 4C Medical Technologies
- American College of Cardiology
- Bard
- Boston Scientific Corporation
- Cardiovascular Systems, Inc. (CSI)
- Centers for Medicare & Medicaid Services (CMS)
- Cook Medical
- Department of Defense (DoD)/AHRMM
- Duke University/Duke Clinical Research Institute (DCRI)
- Epic
- GMDN Agency
- M2S
- Medtronic
- Mercy Health System
- National Library of Medicine (NLM)
- Society for Interventional Radiology
- Society for Vascular Surgery
- Society of Interventional Radiology
- University of Michigan
- University of Washington Health Sciences Center
- US Food and Drug Administration (US FDA)
- Volcano Corp/Philips Health Technology
- Weill Cornell Medical College and New York Presbyterian

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Carrie	Bosela	Society for Vascular Surgery
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Barry	Daniels	GMDN Agency
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Jeremy	Durack	Society of Interventional Radiology
Jackie	Elkin	Medtronic
Steven	Emrick	National Library of Medicine (NLM)
Hitinder	Gurm	University of Michigan
Melissa	Hasenbank	Medtronic
Elisa	Hebb	Volcano Corp/Philips Health Technology
Larry	Kessler	U. Washington Health Sciences Center
Mitchell	Krucoff	Duke Clinical Research Institute
Carah	Kucharski	Boston Scientific Corporation
Robert	Lookstein	Society of Interventional Radiology/Mount Sinai Medical Center
Jeff	Lord	M2S
Aaron	Lottes	Cook Medical
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Sanjay	Misra	Society for Interventional Radiology
Pablo	Morales	US Food and Drug Administration (US FDA)
Caroline	Morgan	American College of Cardiology
Robert	Perry	Department of Defense (DoD)/AHRMM
Melanie	Raska	Boston Scientific Corporation
Terrie	Reed	US Food and Drug Administration (US FDA)
Elizabeth	Rehfeld	Volcano Corp/Philips Health Technology
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4. Additional RAPID participants

- Agency for Healthcare Research Quality (AHRQ)
- American College of Cardiology
- Avinger
- Bard
- Centers for Medicare & Medicaid Services (CMS)
- Cook Advanced Technologies
- Cook Medical
- Cordis
- CR Bard
- Duke Margolis Center for Health Policy
- Gore & Associates
- Harvard
- Kaiser Permanente
- NHLBI, NIH

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- Novella Clinical, A Quintiles Company
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Quintiles
- Spectranetics Corporation
- Terumo
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