



Leveraging Real World Evidence to Get Better, Faster, Cheaper Medical Devices for Physicians and Patients

Major initiatives:

- **Medical Device Epidemiology Network (MDEpiNet)**
- **Registry Assessment of Peripheral Interventional Devices (RAPID)**
- **SFA-Popliteal Evidence Development (SPEED)**

October 12, 2018 - 1:00 pm U.S. Eastern Time

Renee Mitchell, MT(ASCP), CLS(NCA), Regulatory Affairs, Boston Scientific

Terrie Reed, MSIE, Senior Advisor for UDI Adoption, US Food & Drug Administration

Roseann White, MA, Director of Innovative Clinical Trial Statistics, Duke Clinical Research Institute

Outline

- Background
- MDEpiNet
- RAPID project
- SPEED overview
- SPEED analysis
- Unique Device Identifier
- Vision for the future



Paradigm shift in Healthcare



Purpose

Webinar

- Educate viewers about MDEpiNet, RAPID, and SPEED

MDEpiNet RAPID

- **Better, Faster, Cheaper** devices to patients' bedsides
- FDA, clinician, and manufacturer partners benefit from the use of real world evidence
- Multiple partners = Greater diversity = Better data and results
- Medical device manufacturers can leverage real world data in RAPID Phase III



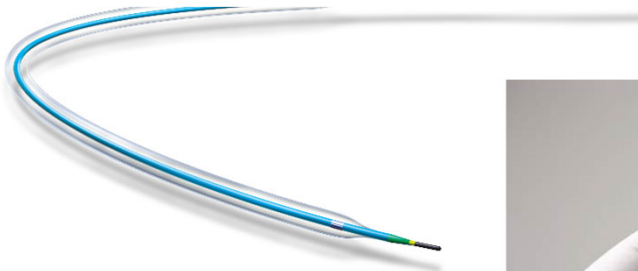
Medical Devices: “The Opportunity”

- Capture “real world evidence” in order to evaluate pre- and post-market safety and effectiveness of medical treatment
- Develop analytical methodologies for device evaluation
- Generate guiding principles and clear data governance
- Build infrastructure to share best practices amongst diverse stakeholders and merge data sources for better interoperability
- Demonstrate more effective capture and reuse of UDI across supply chain, clinical, and analytical systems





Medical Device Epidemiology Network (MDEpiNet)

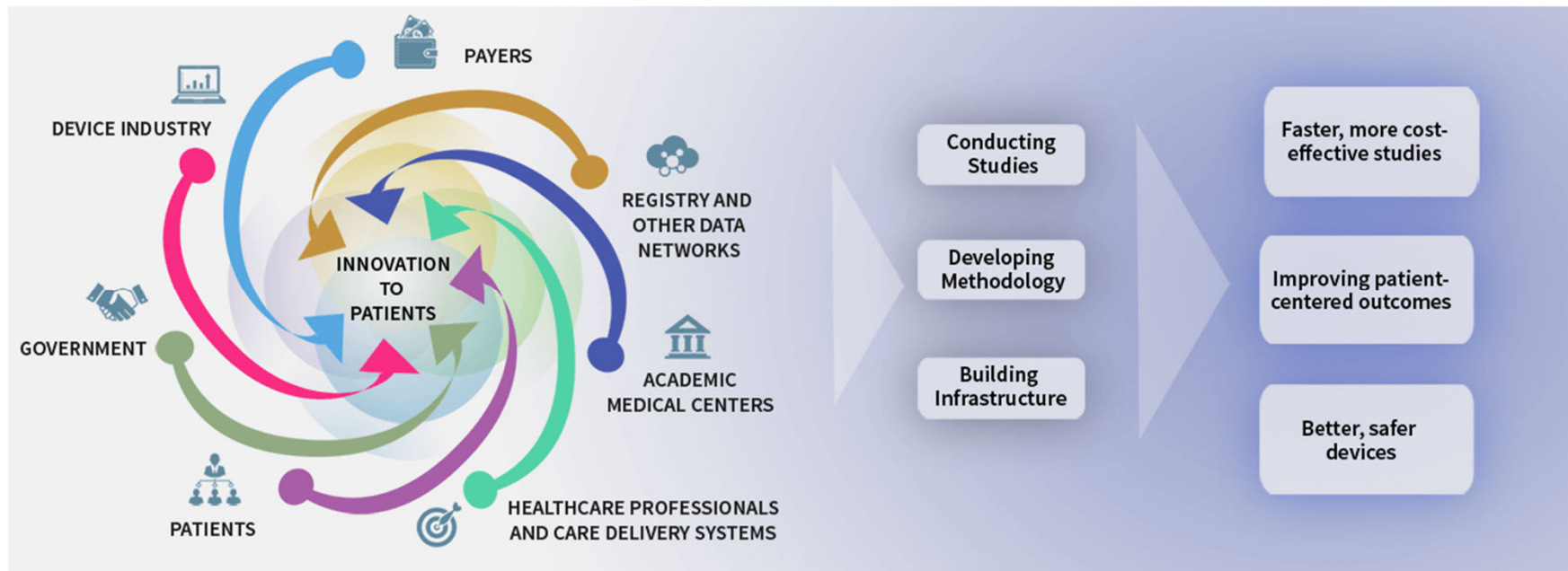


MDEpiNet Initiative

- A public-private partnership, started in 2010, with stakeholders from FDA, private industry, academia, and professional organizations
- **Purpose:** Bring together leadership, expertise, and resources to support a national medical device evaluation system
- **Mission:** Advance national and international infrastructure for patient-centered regulatory science, surveillance and quantitative methodology
- **Goal:** Optimize evidence generation, appraisal, and synthesis for medical device Total Product Lifecycle (TPLC) evaluation



Value of Device Lifecycle and Evaluation



Benefits of MDEpiNet for Patients, Clinicians, Industry, Regulatory Agencies

Better product

- Better devices, faster to bedside for patients
- Improved pre-/post-market balance

Increased information

- Information on device risk/benefit
- Comparative effectiveness, cost-effectiveness
- Historical data (modeling; performance goals and criteria)
- Best practice guidelines
- Increased data sets for greater accuracy

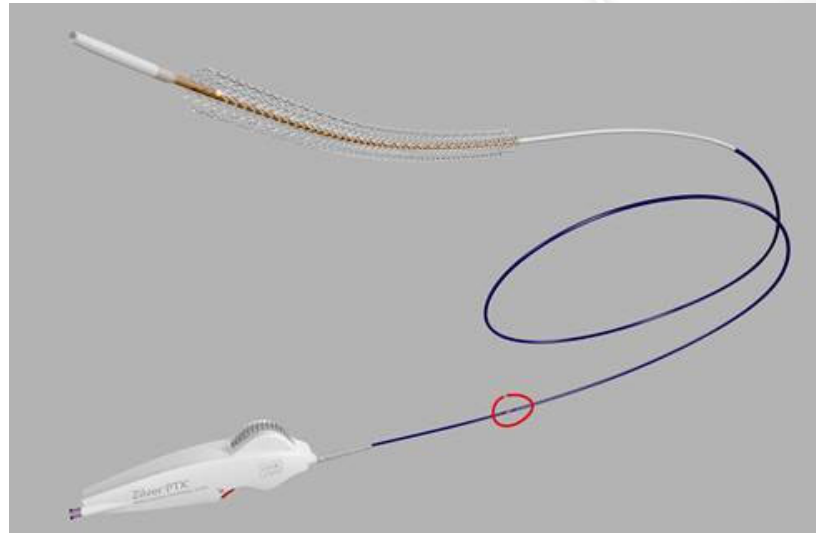
Greater efficiency

- Interoperable collection and exchange of electronic health data
- Reduced regulatory burden
- Leveraging existing data for device evaluation



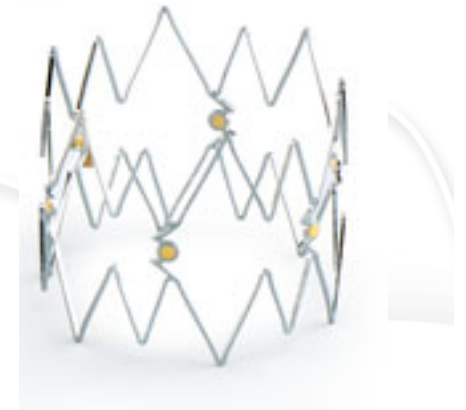


Registry Assessment of Peripheral Interventional Devices (RAPID)



Registry Assessment of Peripheral Interventional Devices (RAPID)

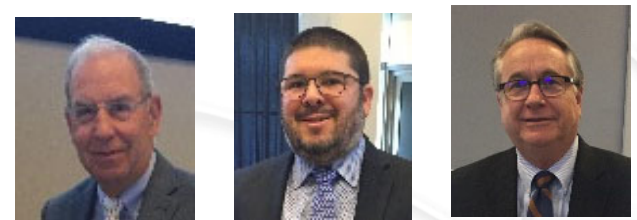
- The MDEpiNet RAPID project is designed to advance the foundational elements of the approach for the evaluation of medical devices used to treat and manage peripheral artery disease.
- RAPID is an archetype of the total product lifecycle ecosystem.
- It is one of a series of projects initiated to advance and demonstrate the interoperable flow of data across electronic health information systems.
- Is fundamental to the basis of the development of the National Evaluation System for Health Technology (NEST).
- A demonstration project of MDIC/NESTcc, a public-private partnership.



RAPID Leadership Team

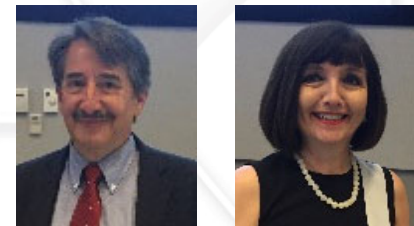
Principal Investigators

- Jack Cronenwett, MD, Society of Vascular Surgery, Vascular Quality Initiative
- Pablo Morales, MD, United States Food and Drug Administration
- Robert Thatcher, MBA, 4C Medical Technologies



Key Advisors

- Mitch Krucoff, MD, Duke Clinical Research Institute
- Danica Marinac-Dabic, MD, Ph.D., MMSC, United States Food and Drug Administration



Project Management and Informatics Support

- Duke Clinical Research Institute
- Weill Cornell Department of Healthcare Policy and Research



RAPID Partners

Medical Societies / Registries

- American College of Cardiology (ACC)
- International Consortium of Vascular Registries (ICVR)
- National Cardiovascular Data Registry (NCDR) – Peripheral Vascular Intervention (PVI)
- National Interventional Radiology Quality Registry (NIRQR)
- Society of Interventional Radiology (SIR)
- Society for Vascular Surgery (SVS)
- Vascular Quality Initiative (VQI) – Peripheral Vascular Intervention (PVI)



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Government Agencies

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Medicare and Medicaid Services (CMS)
- Department of Defense (DOD) Healthcare Resources
- FDA (Center for Devices and Radiological Health (CDRH) and Center for Drug Evaluation and Research (CDER))
- Japan's Pharmaceuticals and Medical Devices Agency (PMDA)
- National Heart, Lung and Blood Institute (NHLBI)
- National Library of Medicine (NLM)
- Office of the National Coordinator (ONC)



RAPID Partners (cont.)

Companies / Organizations

- 4C Medical Technologies, Inc.
- Aorta Medical, Inc.
- Boston Biomedical Association
- Cerner
- Cognitive Medical Systems
- Deloitte Healthcare
- Device Events
- Epic
- First Databank, Inc.
- Global Healthcare Exchange
- Global Medical Device Nomenclature (GMDN)
- Healthjump, Inc.
- MDIC/NESTcc
- MedStreaming/M2S
- INC Research
- IQVIA (formerly Quintiles)
- PCPI
- Pharm3r
- Ultamed Corp



RAPID Funders



RAPID Goals: Phase I

- **Phase I:** Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used.
- Phase II: Demonstrate the value of integrating standardized core data elements, establish a methodology to use RWE to support clinical and regulatory decision-making, and increase data interoperability.
- Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision, including patient-level data from multiple sources.



RAPID Phase I: Delivered

- **Phase I:** Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used – Completed!
- Meta-data of the 100 core data elements include:
 - Data element label (e.g. Modified Rutherford Category; wound grade)
 - Data element definition
 - Value set
 - Definitions of the elements of the value set
 - Reference source

Download RAPID Phase I Core Data Elements at:

http://mdepinet.org/wp-content/uploads/RAPID-Core-Data-Elements_20JUL2016FinalforPhaseI_Rev1.xlsx



RAPID Phase I: Delivered (cont.)

Core Data Elements

- 100 “key core data elements,” including UDI, covering patient characteristics, clinical descriptors, device descriptors, lesion descriptors, etc., as published in Journal of Vascular Surgery

Use Cases for Core Data Elements

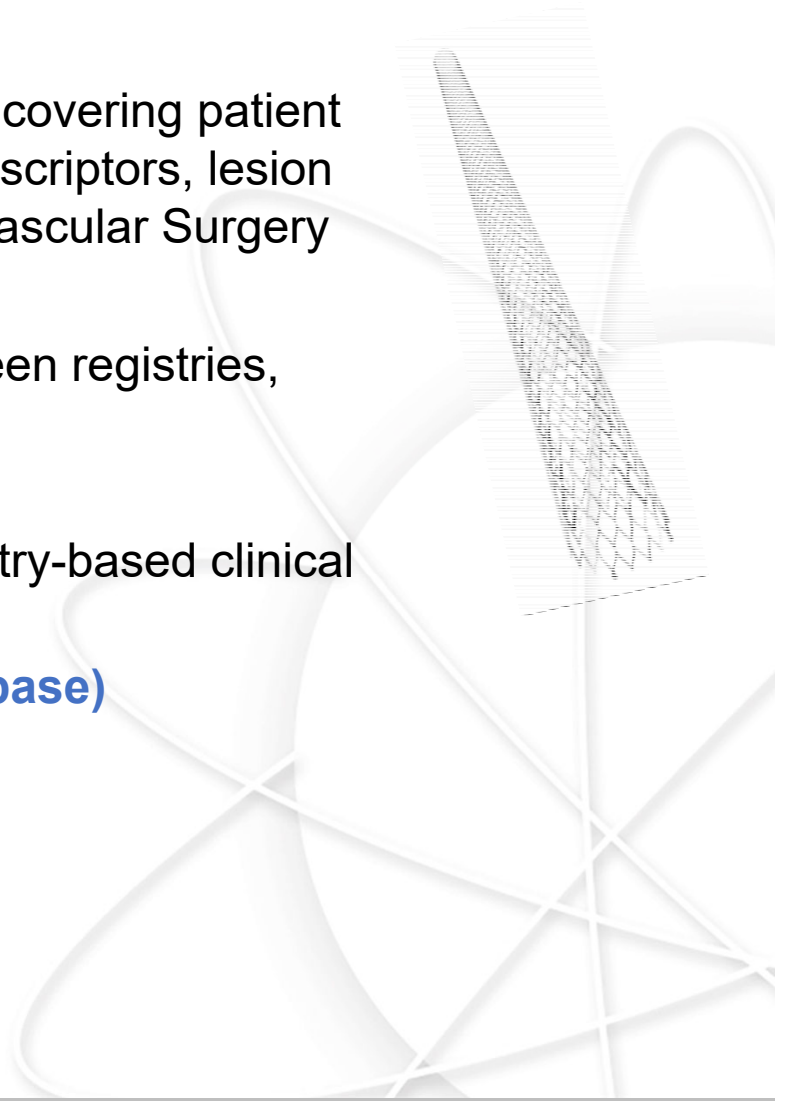
- Infrastructure facilitates interoperability between registries, EHRs, and other data sources

Workflow Diagrams

- Point of care, total product lifecycle and registry-based clinical studies/trials

GUDID (Global Unique Device Identifier Database) Project Summary

- Key learnings about use of GUDID data



Publications and Guidance

Global Reach

SPEED: A New Initiative in Real-World PAD Evidence Evaluation

An overview of the FDA's new multistakeholder project to support real-world evidence evaluation for devices aimed at treating peripheral artery disease.

BY MISTI MALONE, PhD

Endovascular Today
Sept., 2018

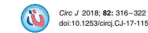
SPECIAL COMMUNICATIONS

Registry Assessment of Peripheral Interventional Devices (RAPID); Registry assessment of peripheral interventional devices core data elements



W. Schuyler Jones, MD;¹ Mitchell W. Krucoff, MD;² Pablo Morales, MD;³ Rebecca W. Wilgus, RN, MSN;⁴ Anne H. Heath, BA;⁵ Mary F. Williams, BS;⁶ James E. Tchong, MD;⁷ J. Danica Marinac-Dabic, MD, PhD;⁸ Misti L. Malone, PhD;⁹ Terrie L. Reed, MS;¹⁰ Rie Fukaya, MMedSc;¹¹ Robert A. Lookstein, MD;¹² Nobuhiro Handa, MD;¹³ Herbert D. Aronow, MD, MPH;¹⁴ Daniel J. Bertges, MD;¹⁵ Michael R. Jaff, DO;¹⁶ Thomas T. Tsai, MD, MSc;¹⁷ Joshua A. Smiale, BS;¹⁸ Margo J. Zaugg, BSN;¹⁹ Robert J. Thatcher, MBA;²⁰ and Jack L. Cronenwett, MD;²¹ Durham, NC; Silver Spring, MD; Tokyo, Japan; New York, NY; Providence, RI; Burlington, VT; Newton, Mass; Denver, Colo; Tempe, Ariz; Santa Clara, Calif; Minneapolis, Minn; and Lebanon, NH

Journal of Vascular Surgery
Feb., 2018



Circ J 2018; 82: 316–322
doi:10.1253/circj.CJ-17-1156

REVIEW

Registry Assessment of Peripheral Interventional Devices (RAPID) — Registry Assessment of Peripheral Interventional Devices Core Data Elements —

W. Schuyler Jones, MD; Mitchell W. Krucoff, MD; Pablo Morales, MD; Rebecca W. Wilgus, RN, MSN; Anne H. Heath, BA; Mary F. Williams, BS; James E. Tchong, MD; J. Danica Marinac-Dabic, MD, PhD; Misti L. Malone, PhD; Terrie L. Reed, MS; Rie Fukaya, MMedSc; Robert Lookstein, MD; Nobuhiro Handa, MD; Herbert D. Aronow, MD, MPH; Daniel J. Bertges, MD; Michael R. Jaff, DO; Thomas T. Tsai, MD, MSc; Joshua A. Smiale, BS; Margo J. Zaugg, BSN; Robert J. Thatcher, MBA; Jack L. Cronenwett, MD; Durham, NC; Silver Spring, Md; Tokyo, Japan; New York, NY; Providence, RI; Burlington, Vt; Newton, Mass; Denver, Colo; Tempe, Ariz; Santa Clara, Calif; Minneapolis, Minn; Lebanon, NH

Circulation Journal (Japan)
Jan., 2018

REGULATORY UPDATE

Current Considerations on Real-World Evidence Use in FDA Regulatory Submissions

Examples and decision making from the Center for Devices and Radiological Health's Peripheral Interventional Devices Branch.

BY ELENI WHATLEY AND MISTI MALONE

Endovascular Today
Oct., 2017

Contains Nonbinding Recommendations

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 31, 2017.

The draft of this document was issued on July 27, 2016

FDA Guidance
Aug., 2017

REGULATORY UPDATE

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

Endovascular Today
Aug., 2016



RAPID Goals: Phase II

- Phase I: Identify minimal set of core data elements for registry assessment of lower extremity arterial devices, including methods to identify specific devices being used.
- **Phase II:** Demonstrate the value of integrating standardized core data elements, establish a methodology to use RWE to support clinical and regulatory decision-making, and increase data interoperability.
- Phase III: Use a coordinated registries network (CRN) for studies supporting a regulatory decision, including patient-level data from multiple sources.



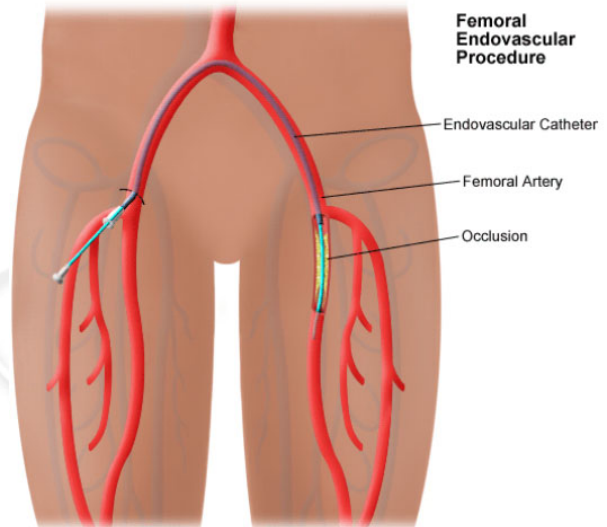
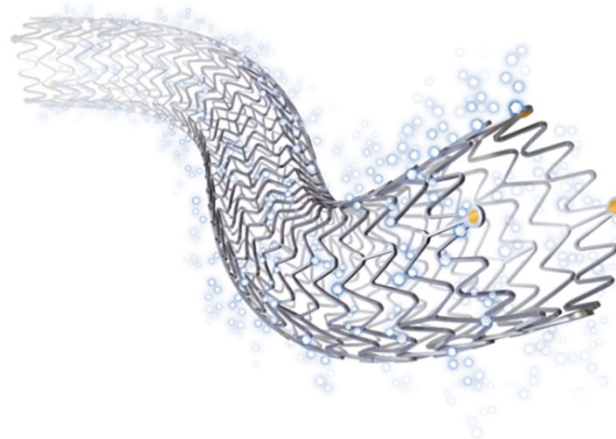
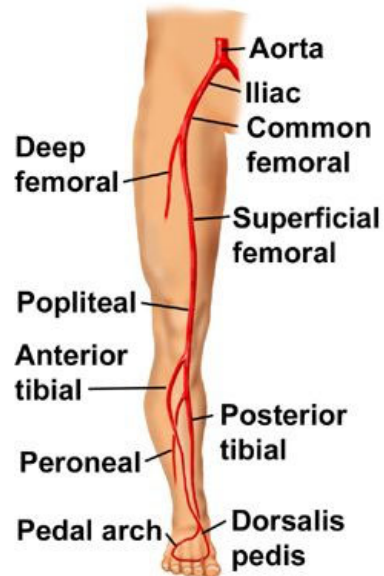
Phase II Stakeholder Working Groups

1. Informatics, Interoperability & Global Unique Identifier (GUDID)
2. Governance, Access, Data Sharing
3. Protocol Development
 - a. Statistics
 - b. Industry
 - c. Clinician
4. Educational Outreach





SFA-Popliteal Evidence Development (SPEED)



http://aicdheart.com/patient_education/heart_HTML_scaleable/heart/fempop.htm

<http://www.yoursurgery.com/ProcedureDetails.cfm?BR=5&Proc=33>

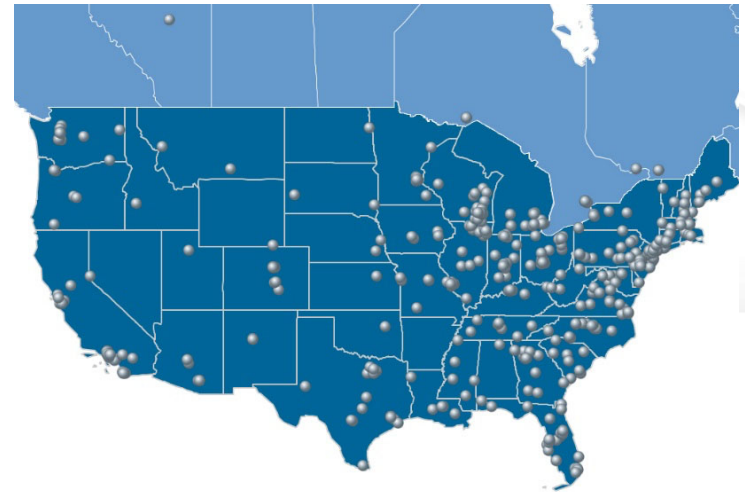
SFA-Popliteal Evidence Development (SPEED)

- RAPID Phase II
- Why SPEED?
 - Multiple devices currently in use, with new drug-coated and other technologies in pipeline
 - Expansion of current labeling for appropriate use
 - Provide additional real world evidence for clinical and regulatory decision making
 - Modernize objective performance criteria (OPC) for SFA-POP devices
- Goals of SPEED:
 - Device-specific data for companies that wish to expand indications for use of current devices
 - Line-by-line data to allow propensity matching to establish non-inferiority of new device compared with contemporary treatment of similar patients and lesions
 - Contemporary OPC for percutaneous/peripheral vascular intervention (PVI) treatment
 - Dynamic OPCs depending on patient, lesion, and treatment type characteristics



What is Vascular Quality Initiative (VQI)?

- VQI Mission: Improve the care of vascular patients.

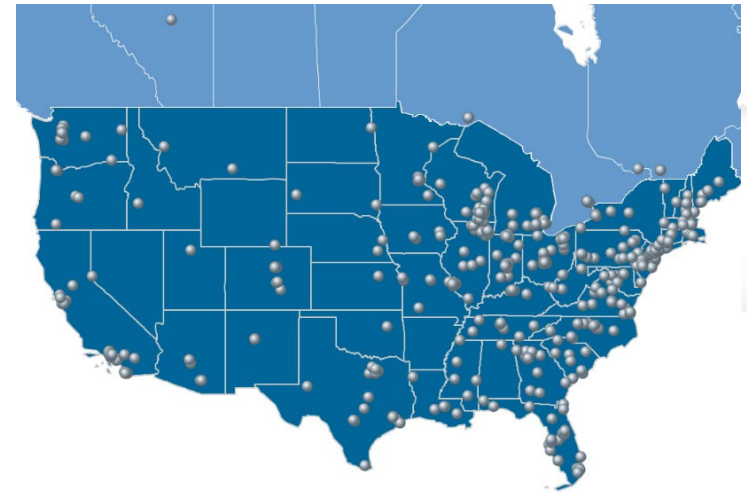


458 Centers, 46 States + Canada



What is Vascular Quality Initiative (VQI)?

- VQI Mission: Improve the care of vascular patients.
- Registry sponsored by the Society for Vascular Surgery
- VQI includes over 450 sites and 450,000 patients

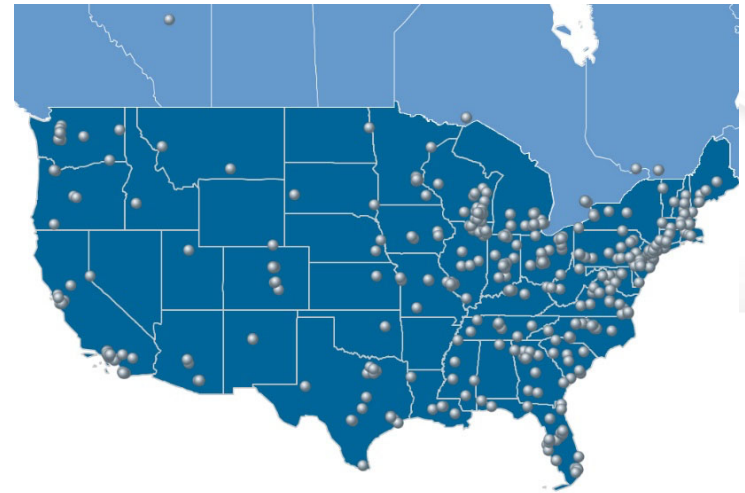


458 Centers, 46 States + Canada



What is Vascular Quality Initiative (VQI)?

- VQI Mission: Improve the care of vascular patients.
- Registry sponsored by the Society for Vascular Surgery
- VQI includes over 450 sites and 450,000 patients
- Incorporated RAPID core data elements into its Peripheral Vascular Intervention (PVI) data
- Data source for RAPID/SPEED



458 Centers, 46 States + Canada



Benefits of Real World Evidence

Better

- Enhance safe, effective, and patient-centric outcomes
- Inform users and patients of real world performance
- Improve relevance over traditional post-market studies

Faster

- Expand indications for new patient populations
- Reduce time to patient access

Cheaper

- Alleviate burden on clinical research enterprise (pre- and post-market)
- Lower cost of clinical evidence generation



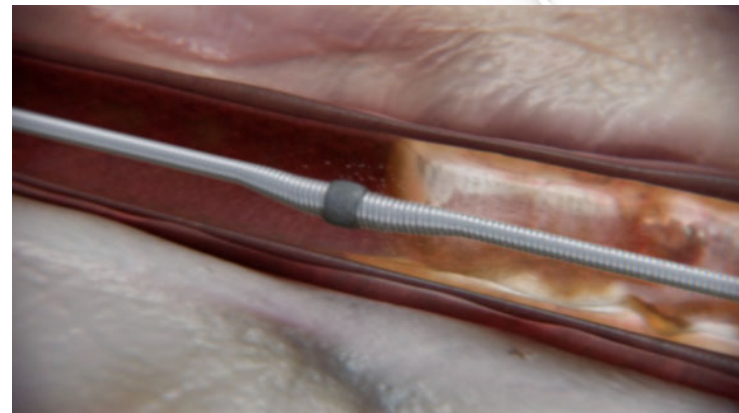
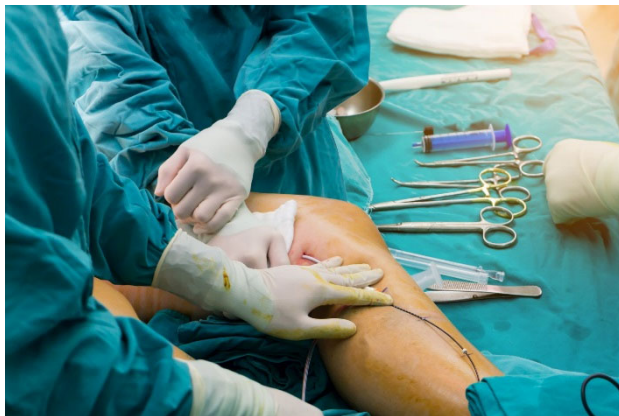
Global Benefits

Harmonization of various registries

- Incorporate RAPID / SPEED common data elements in all registries

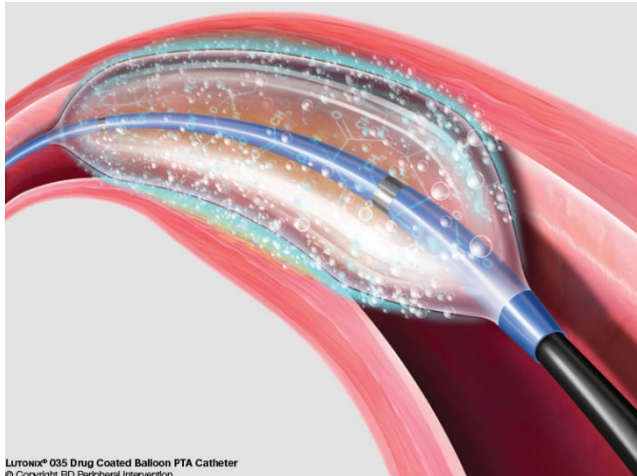
Elimination of small clinical trials with no statistical significance

- Leverage existing patient data to gain regulatory approval
- Reduce time to market

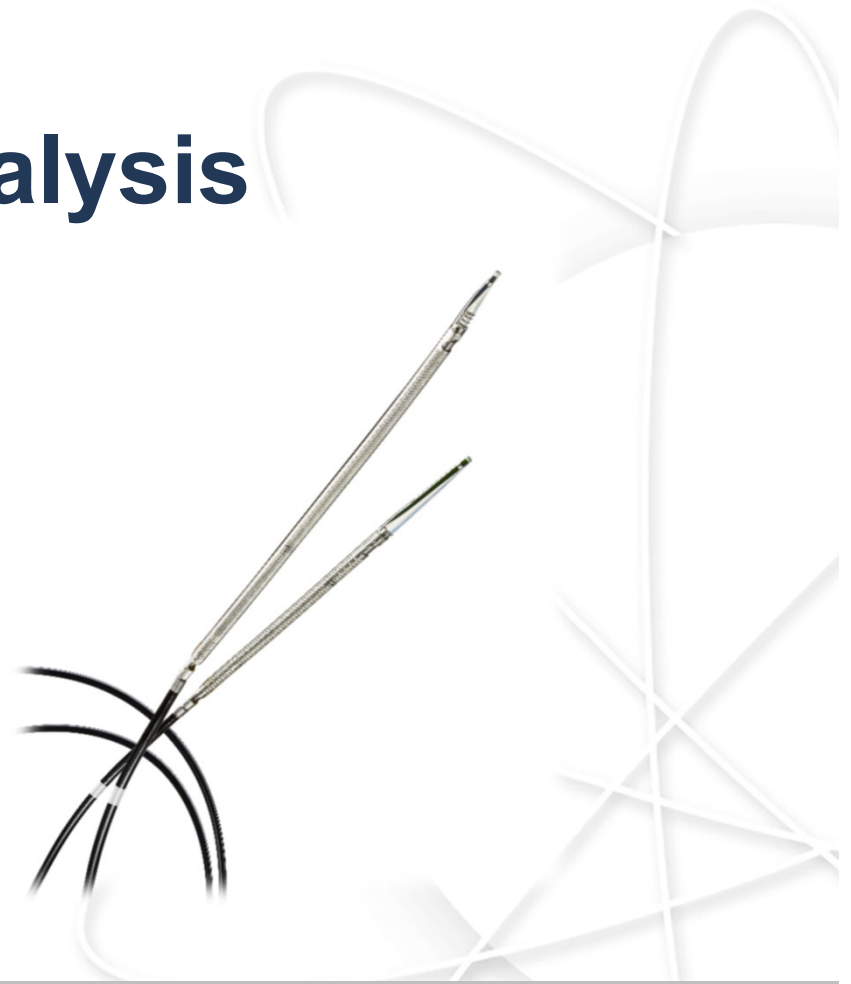




SPEED Analysis



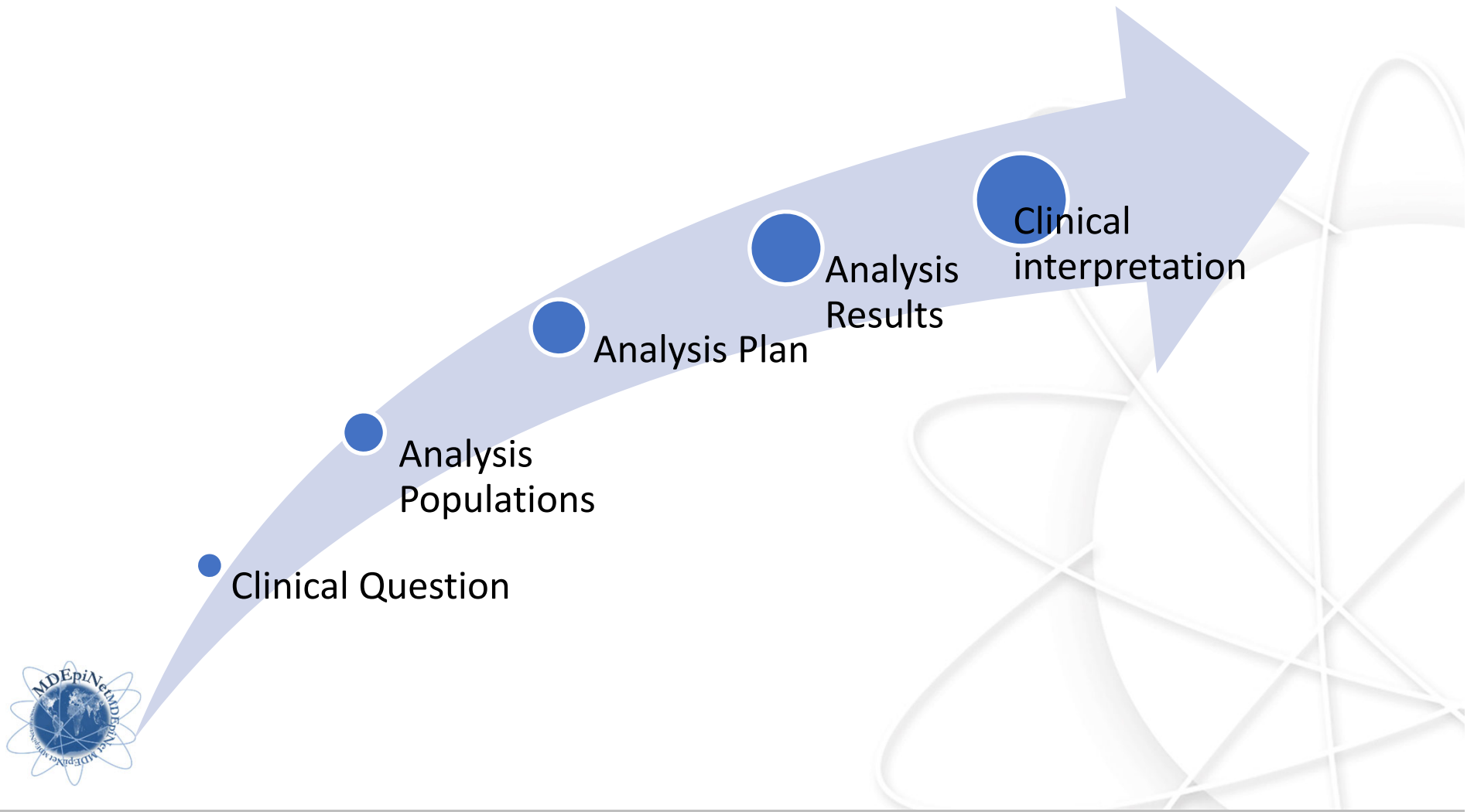
LUNOX® 035 Drug Coated Balloon PTA Catheter
© Copyrighted RFI Percutaneous Intervention



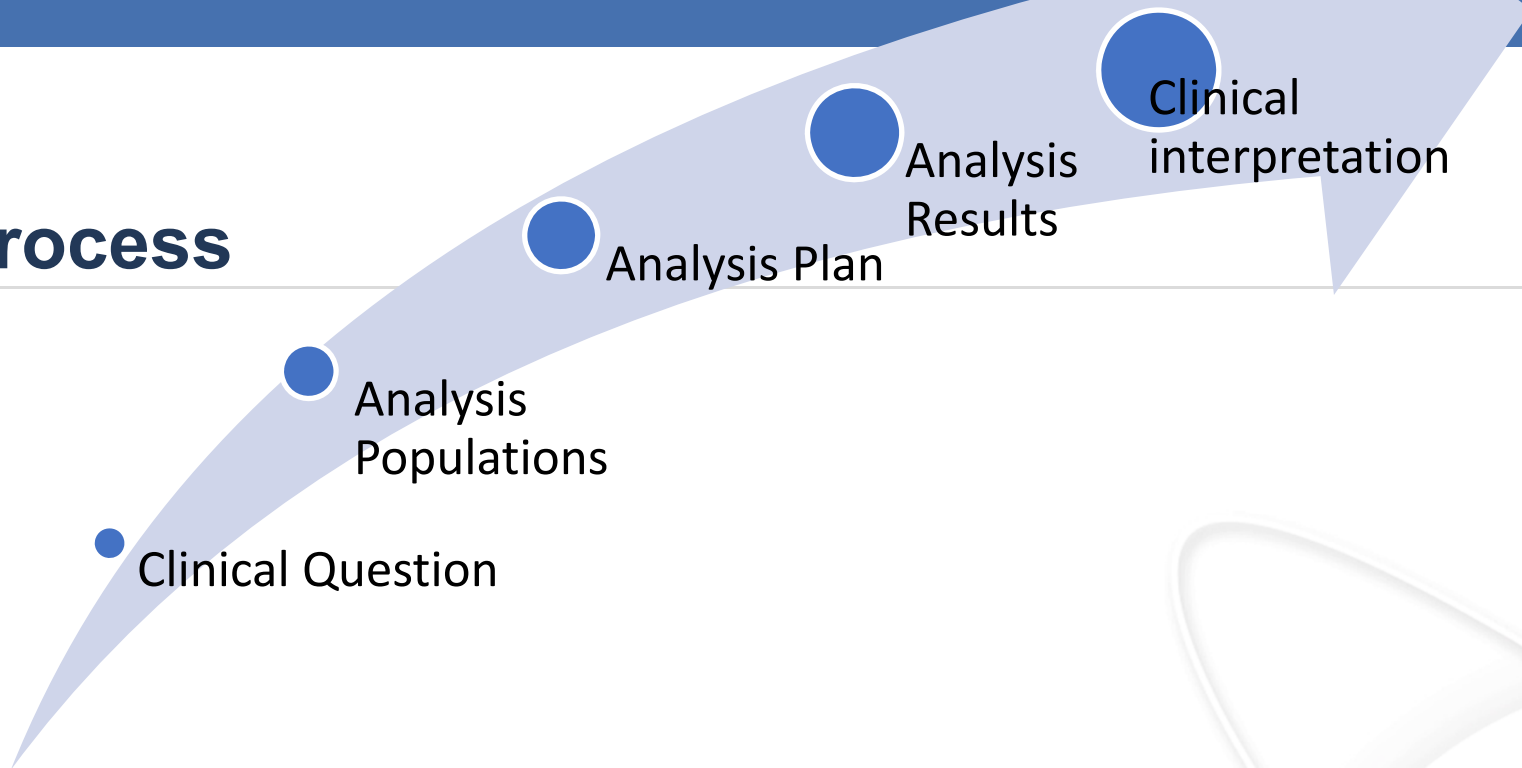
Process



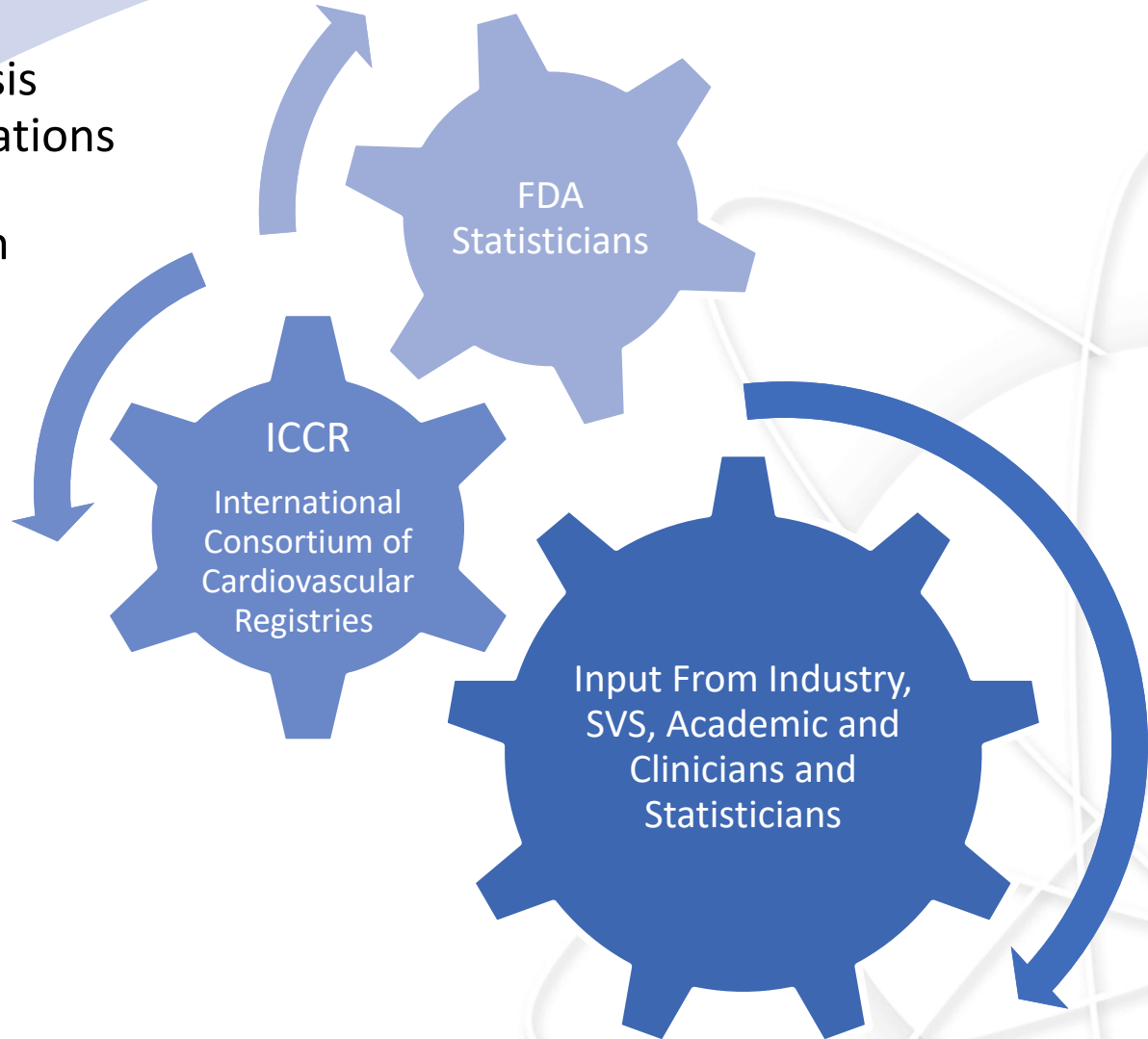
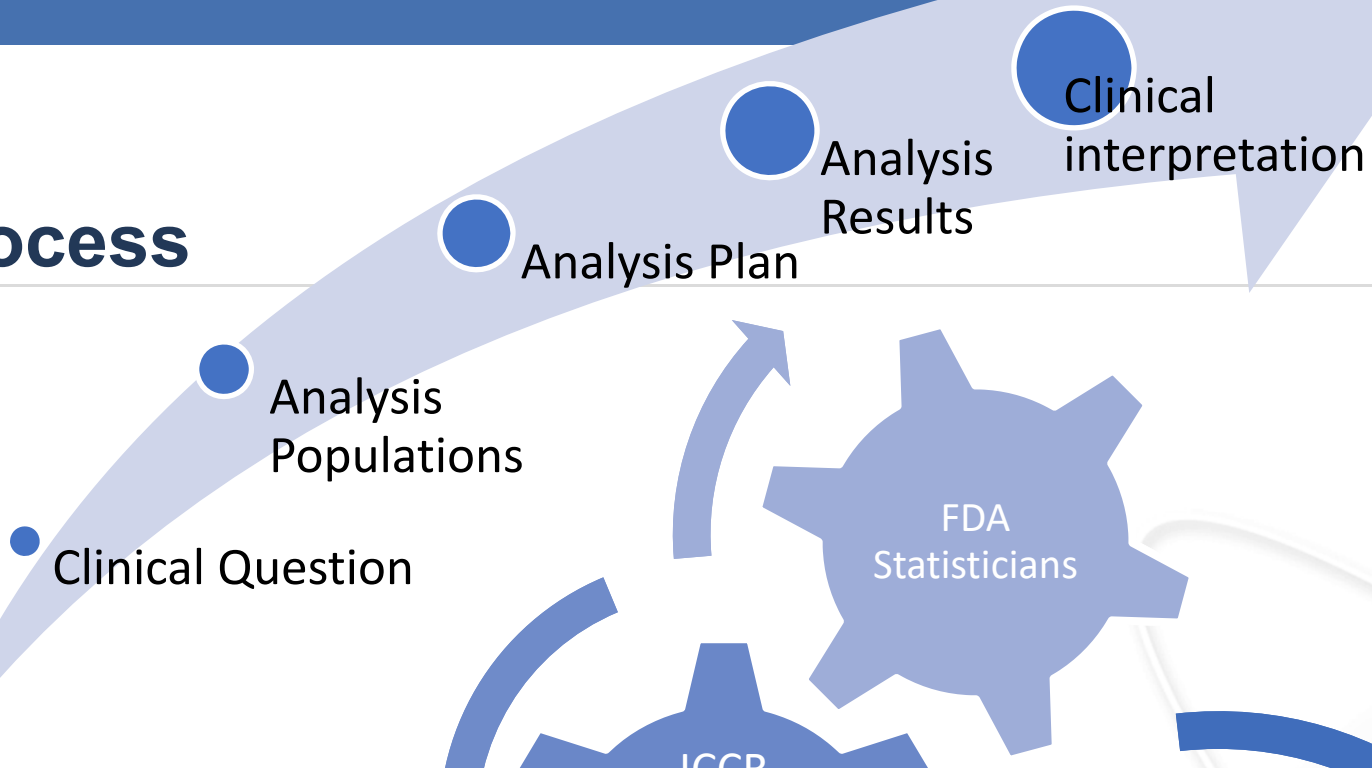
Process



Process



Process



Analysis Team

From Devices and Radiologic Health

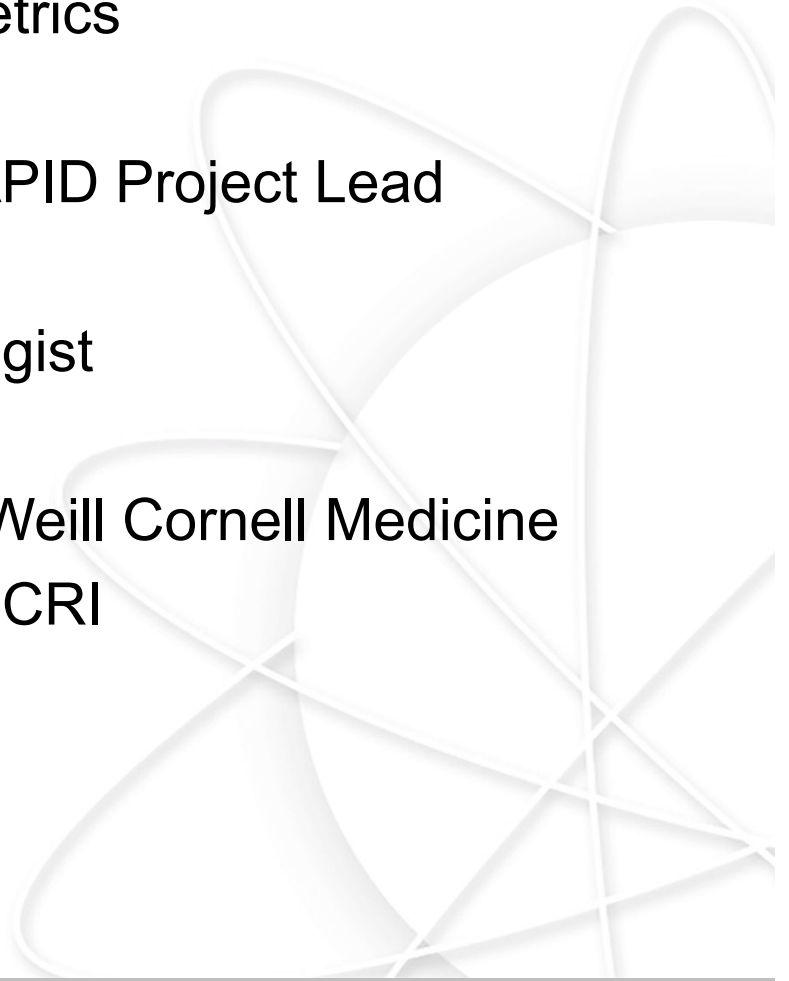
Office of Surveillance and Biometrics

Dept. of Epidemiology

- Yu-Ching Cheng, Epidemiologist, RAPID Project Lead
- Li Wang, Staff Fellow, Advisor
- Jiping Chen, Supervisory Epidemiologist

Additional Support

- Tiyani Sun, Research Data Analyst, Weill Cornell Medicine
- Roseann White, Project Facilitator, DCRI



Advisors

Industry

- Aimin Feng, CR Bard
- Joe Griffin, Intact Vascular
- Terry Lao, Boston Scientific
- Aaron Lottes, Cook Medical
- Justin Recknor, W L Gore
- Alan Saunders, Cook Medical
- Scott Snyder, Cook Medical
- Robert Thatcher, 4C Medical
- Ying Wan, CR Bard
- Jin Wang, Abbott
- Hugo Xi, Abbott

Clinical Practice

- Philip Goodney, Center for the Evaluation of Surgical Care at Dartmouth
- Jens Jorgensen, Maine Medical Center

Professional Organizations

- Rebecca Baker, ACC
- Jim Wadzinski, SVS PSO

Academia

- Haley Abing, Harvard
- Jack Cronenwett, Cornell University
- James Tchong, DCRI
- Roseann White, DCRI

PMDA (Japanese Regulatory Agency)

- Mami Ho, PMDA
- Ono-Mao, PMDA
- Handa-Nobuhiro, PMDA

FDA

- Joshua Chetta, FDA/CDRH/IDE
- Nelson Lu, FDA/CDRH/OSB/DBS
- Misti Malone, FDA/CDRH/ODE/DCD/PIDB
- Danica Marinac-Dabic, FDA/CDRH/OSB/DEPI
- Pablo Morales, FDA/CDRH/ODE/DCD/VSDB
- Subok Park, FDA/CDRH/OSB/DEPI
- Audrey Zhao, FDA/CDRH/OSB/DBS



Objective Performance Criteria (OPC)

- Determine the minimum acceptable success rate for demonstrating device effectiveness, based on the trial population, e.g. provide an OPC calculator



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- Determined after there is a large accumulation of performance data for the type of device



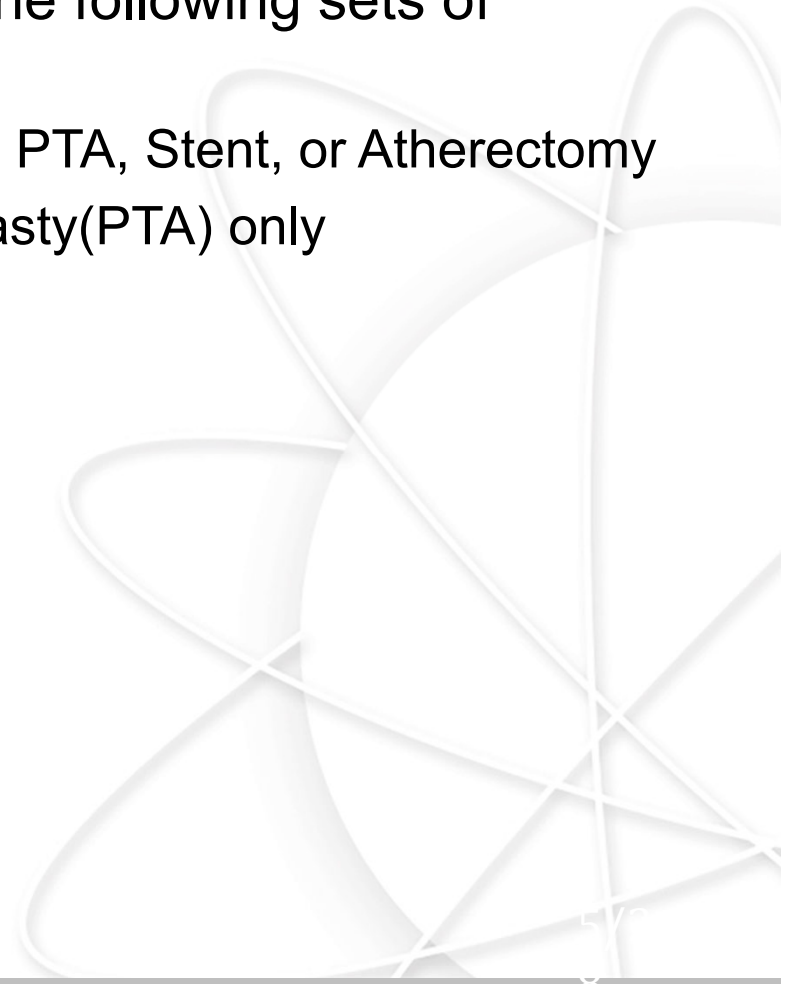
Objective Performance Criteria (OPC)

- Determine the minimum acceptable success rate for demonstrating device effectiveness, based on the trial population, e.g. provide an OPC calculator
- Determined after there is a large accumulation of performance data for the type of device
- Detailed Statistical Analysis Plan (SAP) developed



Analysis Populations

- For each vessel-based subgroup, an objective performance criteria (OPC) will be developed for the following sets of procedures:
 - All patients with any of the following: PTA, Stent, or Atherectomy
 - Percutaneous Transluminal Angioplasty(PTA) only
 - Stent with or without PTA
 - Atherectomy with or without PTA
 - Stent + Atherectomy



Dataset for SPEED Analysis

of patients in transfer from VQI

- 30,899 patients
- 25,077 patients with 1 procedure
- 5,822 patients with more than 1 procedure

of procedures

- 38,344 procedures

of procedures with follow-up information

- 26,389 procedures

of lesions

- 22,362 SFA
- 11,001 POP



Endpoints of interest

- Patient level
 - Mortality, any cause
 - Amputation free survival (AFS)
 - Open surgery
- Limb level
 - Major Amputation
- Lesion level
 - Target lesion revascularization (TLR)
 - Target lesion occlusion
 - Target Vessel Revascularization





Initial Results at MDEpiNet Annual Meeting

RAPID Goals: Phase III

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Unique Device Identifier (UDI) linked to AccessGUDID (Access 'to' Global Unique Device Identification Database)



Unique Device Identifier (UDI) linked to AccessGUDID (Access 'to' Global Unique Device Identification Database)

REPLACEMENT CAP, WHITE FEMALE LUER LOCK¹

100 Quantity	STERILE EO	CE0123
2020-07-31 Expiration Date	SAMPLE	
LOT 0061443956		
REF 474900		
PRODUCT CODE W1000		
GTIN 04022495770332		(0 04022495770332 17)200731(10)0061443956
 B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862 www.bbraun.com	 B. Braun Melsungen AG 34209 Melsungen, Germany	



Unique Device Identifier (UDI) linked to AccessGUDID (Access 'to' Global Unique Device Identification Database)

REPLACEMENT CAP, WHITE FEMALE LUER LOCK¹

100 Quantity **STERILE EO** **CE0123**

2020-07-31
Expiration Date

LOT 0061443956 P5000366-7
REV: 9/15

REF 474900

PRODUCT CODE W1000

GTIN 04022495770332 (0 04022495770332 17)200731(10)0061443956

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
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34209 Melsungen, Germany

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ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

DEVICE: Replacement Cap 04022495770332

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Replacement Cap	Primary DI Number: 04022495770332
Version or Model: 474900	Issuing Agency: GS1
Commercial Distribution Status: In Commercial Distribution	Commercial Distribution End Date:
Catalog Number: 474900	Device Count: 100
Company Name: B. BRAUN MEDICAL INC.	Labeler D-U-N-S® Number: 002397347 *Terms of Use
Device Description: White Replacement Cap	

DEVICE CHARACTERISTICS

DEVICE RECORD STATUS

ALTERNATIVE AND ADDITIONAL IDENTIFIERS

CUSTOMER CONTACT [?]



Unique Device Identifier (UDI) linked to AccessGUDID (Access 'to' Global Unique Device Identification Database)

REPLACEMENT CAP, WHITE FEMALE LUER LOCK¹

100 Quantity **STERILE EO** **CE0123**

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ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

HOME ABOUT NEWS API DOWNLOAD HELP

DEVICE: Replacement Cap **04022495770332**

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Replacement Cap Primary DI Number: 04022495770332
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CLOSE

- + DEVICE CHARACTERISTICS
- + DEVICE RECORD STATUS
- + ALTERNATIVE AND ADDITIONAL IDENTIFIERS
- + CUSTOMER CONTACT [?]



How important is it to identify an Implant?

Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Pepperidge Farm® Announces Voluntary Recall of Four Varieties of Goldfish® Crackers

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For Immediate Release

July 23, 2018

Contact

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Bethridge Toovell
✉
Bethridge_Toovell@PepperidgeFarm.com
☎ 203-846-7136

Announcement

[View Product Photos](#)

Pepperidge Farm has been notified by one of its ingredient suppliers that whey powder in a seasoning that is applied to four varieties of crackers has been the subject of a recall by the whey powder manufacturer due to the potential presence of *Salmonella*. Pepperidge Farm initiated an investigation and, out of an abundance of

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Consumers can make decisions within days

Company Announcement

When a company announces a recall, market withdrawal announcement as a public service. FDA does not endo

Pepperidge Farm® Anno of Four Varieties of Goldfish

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For Immediate Release

July 23, 2018

Contact

Consumers

Customer Service
800-679-1791

Announcement

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Pepperidge Farm has been powder in a seasoning that subject of a recall by the wt *Salmonella*. Pepperidge Fa

From: [Walmart.com Recalls <WMRecalls1@walmart.com>](#)

Date: Wed, Jul 25, 2018 at 12:19 AM

Subject: Pepperidge Farm Recalls Varieties of Goldfish Crackers

Dear Valued Walmart Customer:

Pepperidge Farm has been notified by one of its ingredient suppliers that whey powder in a seasoning that is applied to some varieties of crackers has been the subject of a recall by the whey powder manufacturer due to the potential presence of *Salmonella*. Pepperidge Farm initiated an investigation and, out of an abundance of caution, is voluntarily recalling select varieties of Goldfish crackers.

Pepperidge Farm has asked us to recall the products listed below with the corresponding Best by Dates. Our records reflect that you may have purchased one or more of the items listed below.

Description	UPC	Sell By Dates	Product Images
Pepperidge Farm® Goldfish® Flavor Blasted® Ktra Cheddar Crackers, 6.6 oz. Bag	1410006548	WO 11/25/18	
		WO 12/2/18	
		WO 12/9/18	
		WO 12/16/18	
		WO 1/20/19	
		RU 12/30/18	

Your prompt action to this notice is strongly encouraged. If the affected product is still in your possession, we request that you do not consume it, discard it, and go to any Walmart store for a full refund. At Walmart, we adhere to strict quality assurance controls and work with our suppliers to ensure that we provide you with quality products. The supplier is cooperating fully with the U.S. Food and Drug Administration (FDA) to resolve the issue.

Pepperidge Farm recommends consumers with any questions or concerns about this recall visit www.pepperidgefarm.com/GoldfishUpdate or contact 1-800-679-1791.

Consumers with additional questions may also contact the Walmart Customer Care Center through the contact form at: <http://help.walmart.com/app/grocery>.

We apologize for any inconvenience and look forward to meeting your needs in the future.



UDI in RAPID: Improve decision making with better UDI data

GUDID/Informatics Workgroup Phase III

1. Objective

- a) To improve UDI capture/utilization and broaden its impact
- b) Demonstration Project
 - Use findings and partnerships built in Phase I and Phase II to form a partner-based quality improvement study of UDI workflow
 - Develop process to capture RWE from selected data partners for worldwide regulatory support of device TPLC

2. Methodology

- Clarifying structured data values to be assigned by manufacturers to improve quality of clinically relevant size and device categorization values in GUDID;
- Assessing existing workflows at NESTcc data partners who are committed and show high level of UDI adoption maturity;



UDI in RAPID: Improve decision making with better UDI data (cont.)

Methodology (cont'd)

- Assisting implementation of core RAPID phase I data attributes (including UDI) into EHR or other point of care systems;
- Exploring mechanism for transfer of UDI and other data into a PAD registry; and
- Evaluating impact on data partner workflows and reductions in data capture, data transfer, and feedback to improve value of UDI to multi-stakeholders across the PAD lifecycle.
- **Expected NEST impact:** facilitate development of UDI workflow processes in NEST partners that could be leveraged by other healthcare systems, as well as evidence generation processes that could be utilized across the medical device industry

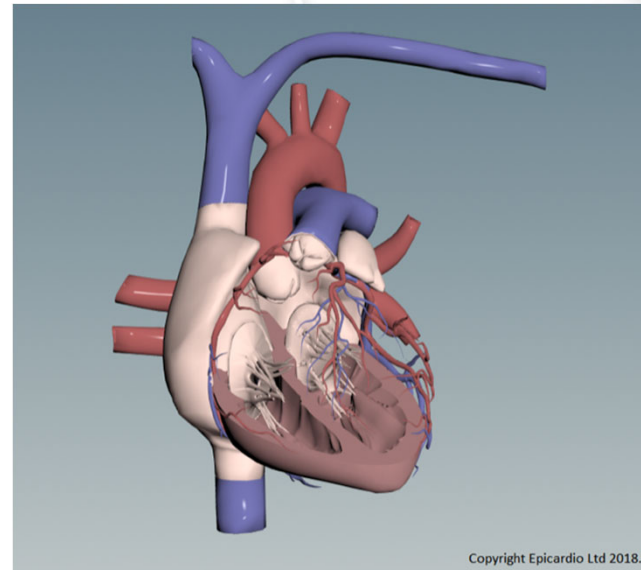
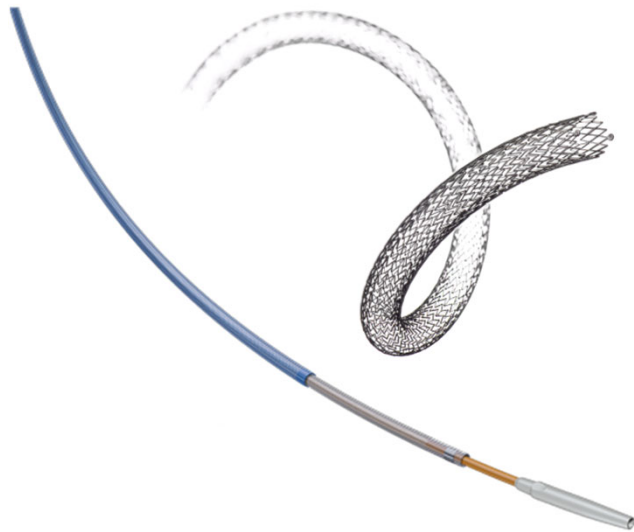




Vision for the Future

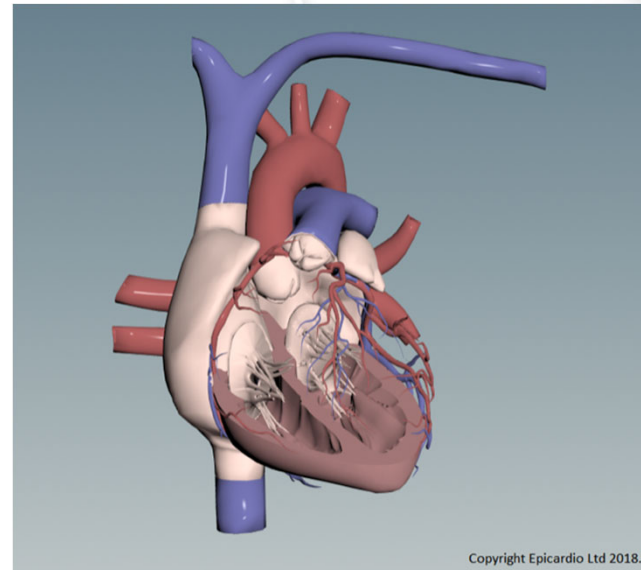
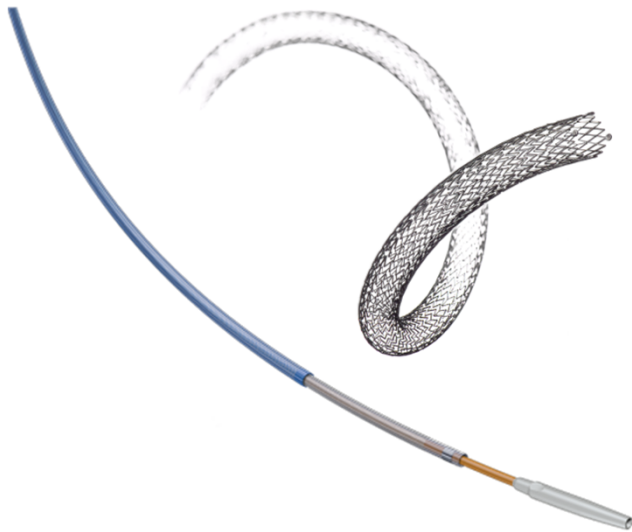


The Goal: Better, Faster, Cheaper Devices to Patients' Bedside



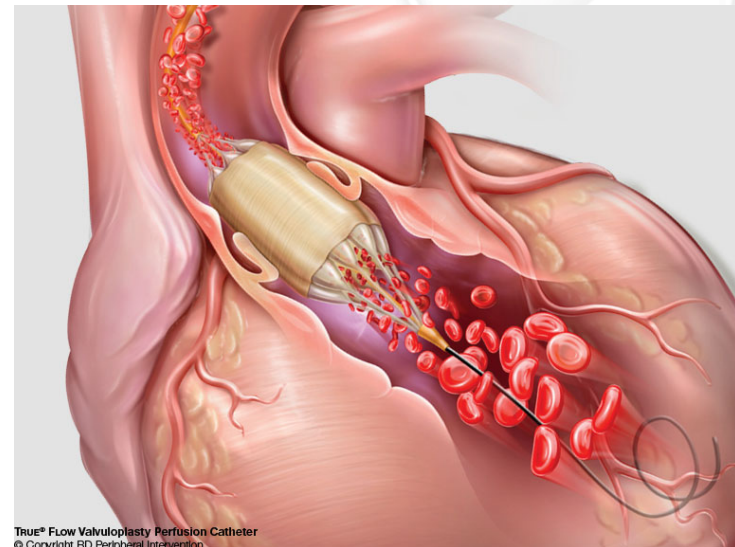
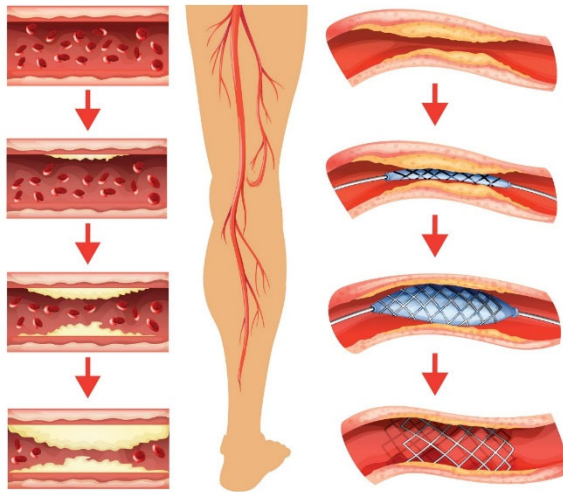
The Goal: Better, Faster, Cheaper Devices to Patients' Bedside

- FDA, clinician, and manufacturer partners benefit
- More partners = Greater diversity = Better data and results
- Medical device manufacturers can leverage real world data and clinical trial evidence in RAPID Phase III



Going Forward

- **Device manufacturers: Utilize** real world evidence in evaluating and releasing new devices and expanding indications.
- **Clinicians: Contribute** to the generation of real world evidence.
- **Regulatory bodies: Increase use** of real world evidence and patient level data for device approval.



Organizations that provided images in this presentation

- Boston Scientific Corporation
- Cardiovascular Systems, Inc.
- Cook Medical
- CRBard, Inc. / Becton Dickinson (BD)
- Duke Clinical Research Institute
- Epicardio
- Intact Vascular, Inc.
- Medtronic
- Society for Vascular Surgery



Contact Information and Web Sites

- Join us by emailing: MDEpiNet@dm.duke.edu / sarah.palmer@duke.edu
- Web sites:
 - MDEpiNet: <http://mdepinet.org>
 - RAPID Project: <http://mdepinet.org/rapid/>
 - NESTcc Demonstration Projects: <https://nestcc.org/demonstration-projects/>
 - FDA: <https://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm>



RAPID Publications and Guidance

Endovascular Today, Sept. 2018

- <https://evtoday.com/2018/09/speed-a-new-initiative-in-real-world-pad-evidence-evaluation/>

Journal of Vascular Surgery, Feb. 2018

- <https://www.ncbi.nlm.nih.gov/pubmed/29389426>

Circulation Journal (Japan), 2018

- https://www.jstage.jst.go.jp/article/circj/82/2/82_CJ-17-1156/article/-char/en

Endovascular Today, Oct. 2017

- <https://evtoday.com/2017/10/current-considerations-on-real-world-evidence-use-in-fda-regulatory-submissions/>

FDA Guidance, Aug. 2017

- <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf>

Endovascular Today, Aug. 2016

- <http://evtoday.com/2016/08/registry-assessment-of-peripheral-interventional-devices-rapid/>

