CMSS WEBINAR SERIES:
Registry Science and Research

*CMSS Presents:*

# *Defining and Creating the Registries of the Future*

September 22, 2022

# **Registry and Research Initiative:**
# Defining and Creating Registries of the Future

CMSS Registry Webinar Series

While clinical trials focus on efficacy—the extent to which medical interventions achieve health improvements under ideal circumstances—registries **provide strong evidence** for the extent to which **medical interventions** achieve health **improvements in real practice** settings.

An organized system that uses **observational study methods** to collect uniform data (clinical. and other) to **evaluate specified outcomes** for. a population defined by a particular disease, condition, or exposure, and that serves one or.

What is a registry in medical terms?
A disease registry is **a special database that contains information about people diagnosed with a specific type of disease**. Most disease registries are either hospital based or population based.

Types of Registries

- Improvement of patient care.
- Professional education.
- Administrative information.
- Clinical research.

A clinical registry is a **computer database** that collects information about your health and the care you receive as a patient. The data in the registry comes from the information your healthcare provider collects while providing your care and is added to information on other patients who are similar to you. It is then used to help improve the quality of your care as well as the care of other patients, now and in the future. This article provides answers to the most common questions patients have about clinical registries.

Database: a collection of information (i.e., data) arranged for ease of search and retrieval of information. Registry: a collection of information or databases whose organizers receive information from multiple sources, maintain the information over time, and control access to the information.

Registries focused on specific diseases or conditions collect information voluntarily from people with those conditions. Clinical trials registries **collect basic health information from people who agree to be contacted about participating in future clinical trials or studies**.

Mortality
Hospitalizations
Health
New Generations


Why Do We Exist?

**Is our Purpose Changing?**

**Data is Everywhere!**

Systematic Health IT is Alive

**Where Should we Invest?**


Innovative clinical registries
Leveraging federal data standards
Patient-generated data
Multi-stakeholder governance
Data quality
Evolving strategies for sustainability


It’s Time to Reasses

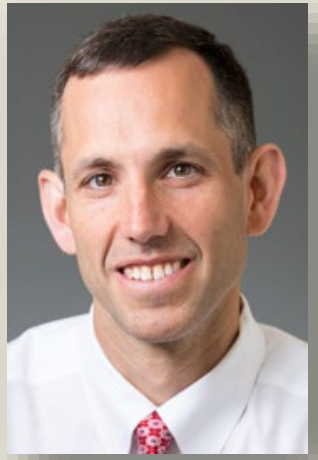
Co-Moderator

Kathleen Hewitt, DNP, MSN, RN

Co-Moderator

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE

Bill Wood, MD, MPH



Philip P. Goodney, MD, MS

Art Sedrakyan, MD, PhD

# Coordinated Registry Networks (CRNs): Foundational Building Blocks

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Associate Director
Office of Clinical Evidence and Analysis
FDA/CDRH

MDEpiNet

U.S. FOOD & DRUG ADMINISTRATION

# It Takes a Village!

**Need:** **Curated, fit for purpose, interoperable, real-world, longitudinal data, available for decision making, regulatory science and public health**

**Journey:** ***From one-off studies to strategically aligned RWD and registry-embedded studies***

## Key Milestones


**Public Private Partnerships: Intersections with FDA Strategic Initiatives and CRNs**

| CCR | CRN Name | Clinical Area (current phase) |
|---|---|---|
| 1. | Women's Health Technology Coordinated Registry Network (WHT-CRN) | Women's Health Women's Health (uterine fibroids, pelvic organ prolapses, stress urinary incontinence, sterilization) |
| 2. | Vascular Implants Surveillance and Outcomes Network (VISION-CRN) | Vascular |
| 3. | Cardiac Devices Coordinated Registry Network (CD-CRN) | Cardiac |
| 4. | Orthopedic Devices Coordinated Registry Network (Ortho-CRN) | Orthopedic |
| 5. | Devices Intended for Acute Ischemic Stroke Intervention (DAISI-CRN) | Acute ischemic stroke |
| 6. | Venous Access National Guideline & Registry Development Coordinated Registry Network (VANGUARD-CRN) | Venous access |
| 7. | Robotic Surgery Coordinated Registry Network (Robotic-CRN) | Robotic surgery |
| 8. | Study of Prostate Ablation Evidence Development (SPARED-CRN) | Prostate ablation |
| 9. | Temporo-mandibular Joint Coordinated Registry Network (TMJ-CRN) | Temporomandibular joint |
| 10. | National Breast Implants Registry (NBIR) | Breast implants |
| 11. | Obesity CRN | Obesity devices |
| 12. | End Stage Kidney Disease Coordinated Registry Network (ESKD-CRN) | End stage Kidney disease |
| 13. | Abdominal Core | Abdominal Core |

## CRN Maturity Framework**

*FHIR® enabled/FHIR® enhanced*

***UDI*:** Precise identification of medical devices and their attributes

***Data collection efficiency*:** Structured data capture, mobile apps and automation with interoperability solutions

***Data Quality*:** Coverage, completeness of enrollment & records at both baseline and follow-up, and periodic audits

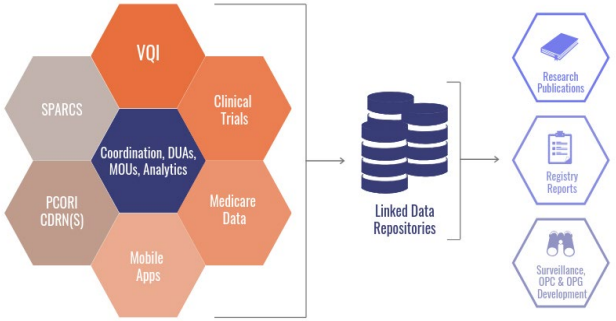
**Engaging patients and incorporation of patient generated data:** Engage, evaluate preferences and measure general and disease specific PROs

***Governance and Sustainability*:** Engage major stakeholders: societies, payers, various states. Obtain major & diverse funding

***Healthcare Quality Improvement*:** Device technologies require continuous evaluation: Feedback, benchmarking and outlier assessments

***Total Product Life Cycle*:** Infrastructure for conducting research and surveillance at different stages of device evaluation. Important role for data linkages

## Example: Mature CRN (VQI/VISION)




Linkage Breadth:
88 % of all EVAR patients
93 % of all AAA patients

*Recommendations for a National Medical Device Evaluation System Strategically Coordinated Registry Networks to Bridge Clinical Care and Research (accessed at: https://www.fda.gov/media/93140/download)

** Sedrakyan A, Marinac-Dabic, D., Campbell, B., Aryal, S., et al. Advancing the Real-World Evidence for Medical Devices through Coordinated Registry Networks BMJ Surgery, Interventions, & Health Technologies 2022; In Press.

# Registries and CRNs: Intersections of FDA, MDEpiNet and NEST

MDEpiNet Launch

International Registry Consortia (e.g. ICOR)

THE VISION FOR NATIONAL SYSTEM LAUNCHED
FDA 4- day Public Meeting
Day 1. Launch of FDA strategy
Day 2. MDEpiNet Annual Mtg.
Days 3-4. Registries

ICVR

**Reports:**
- Planning Board
- MDEpiNet Registry Task Force
- IMDRF

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
About Projects News & Events MDICx Series 2016
MDIC NEST Coordinating Center

NEST Data Collaborators Network

2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020

Develop and test drive novel methods and scientific infrastructure for device evidence generation synthesis and appraisal nationally and internationally

MDEpiNet Methodology Center at Harvard

MDEpNet Science and Infrastructure Center at Cornell



CRN
Community of Practice

CRN Collaborative Learning Communities

IMDRF

International Medical Device Regulators Forum

Title: Principles of International System of Registries Linked to Other Data Sources and Tools

Authoring Group: IMDRF Patient Registries Working Group

Date: 30 September 2016

IMDRF

Methodological Principles in the Use of International Medical Device Registry Data

Authoring Group: IMDRF Patient Registries Working Group

16 March 2017

IMDRF

Tools for assessing the Usability of Registries for Regulatory Decision Making , March 2018

# CRNs - Key Concepts

- Embedded in routine practice (better, faster , cheaper)
- Strategically coordinated/harmonized within the ecosystem
  - Clinical core data sets (including PRO where possible)
  - Informatics solutions (including UDI, SDC)
  - Sustainability (value propositions, ROI, maturity models)
- Network
  - Term was ” Coined” for registries - but applies beyond
- Include national and international/global opportunities

# Coordinated Registry Networks (CRNs)

CRNs are the real-world data sources encompassing strategically partnered electronic health information systems serving one or more clinical area (e.g. orthopedic, vascular, abdominal hernia etc.)

The CRNs build on the national/regional registry(ies), strategically harmonize data elements and link data to comparable data across the systems ( e.g. EHR, administrative claims, patient generated data etc.)

Complementary clinical conditions areas can be harmonized via family of CRNs ( e.g. WHT-CRN harmonizes registries in fibroid, SUI, POP)

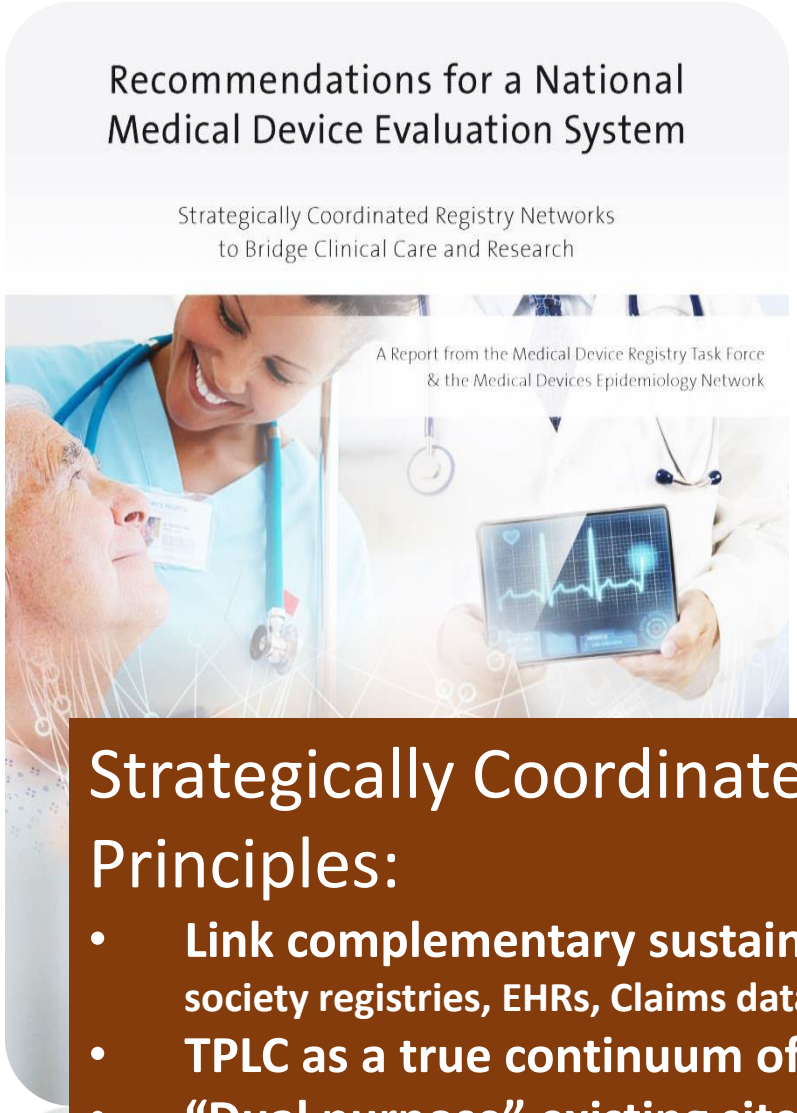
CRNs from diverse clinical areas are further strategically aligned though CRN Learning Community, established and coordinated by the MDEpiNet via grant from FDA

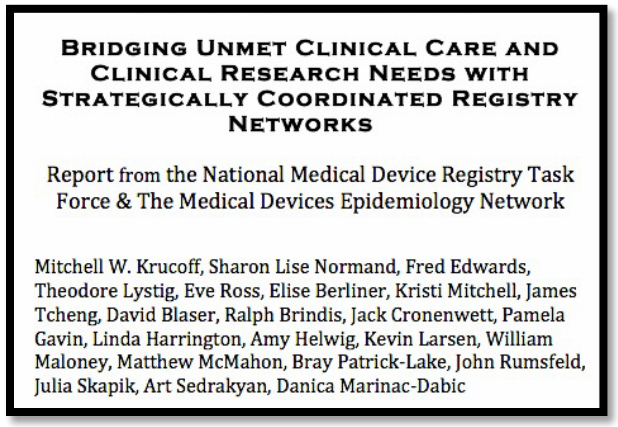
Office of the Assistant Secretary for Planning and Evaluation (ASPE). Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies. https://aspe.hhs.gov/developing-strategically-coordinated-registry-network-crn-womens-health-technology.

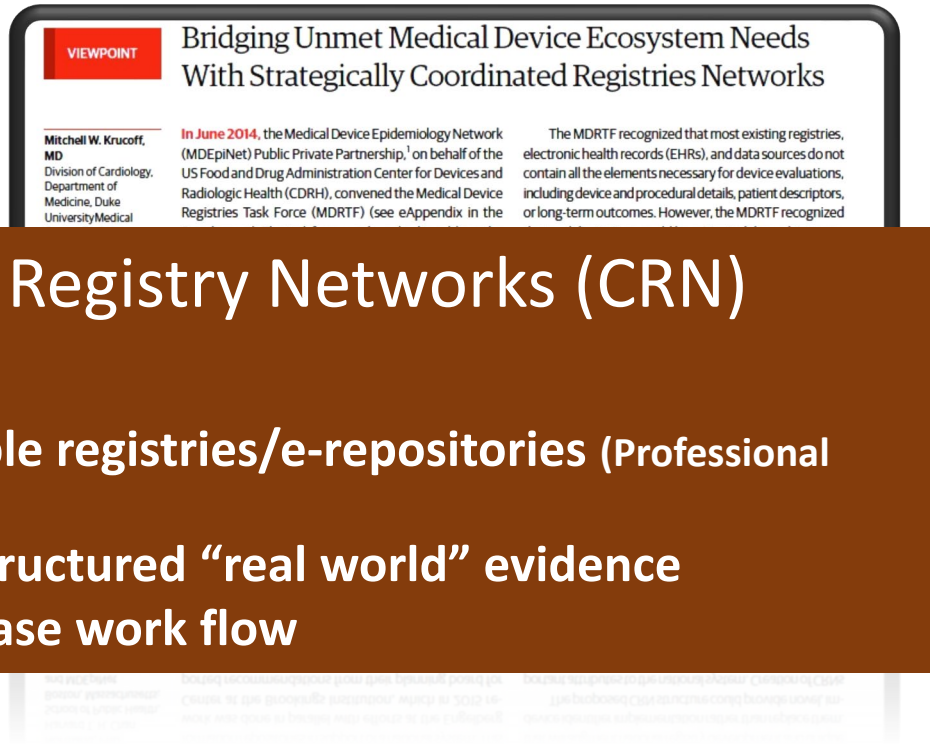
Office of the Assistant Secretary for Planning and Evaluation (ASPE). Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Community of Practice. https://aspe.hhs.gov/bridging-pcor-infrastructure-and-technology-innovation-through-coordinated-registry-networks-crn-community-practice

.

# Birth of the CRN Concepts




## Strategically Coordinated Registry Networks (CRN) Principles:

- **Link complementary sustainable registries/e-repositories (Professional society registries, EHRs, Claims data)**
- **TPLC as a true continuum of structured "real world" evidence**
- **"Dual purpose" existing site-base work flow**

# CRNs Build on International Models and Standards

"Organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system").

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160930-principles-system-registries.pdf

# Partnership between the FDA and Office of the Assistant Secretary for Planning and Evaluation (ASPE)

Office of the Assistant Secretary for Planning and Evaluation (ASPE). Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies. https://aspe.hhs.gov/developing-strategically-coordinated-registry-network-crn-womens-health-technology.

Office of the Assistant Secretary for Planning and Evaluation (ASPE). Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Community of Practice. https://aspe.hhs.gov/bridging-pcor-infrastructure-and-technology-innovation-through-coordinated-registry-networks-crn-community-practice


https://www.mdepinet.net/coordinated-registry-networks

# Framework of Maturity of CRNs and Registries
# 7 Key Domains and 5 Levels of Maturity

***UDI*:**
Precise identification of medical devices and their attributes

***Data Collection Efficiency*:**
Structured data capture, mobile apps and automation with interoperability solutions

***Data Quality*:**
Coverage, completeness of enrollment & records at both baseline and follow-up, and periodic audits

***Total Product Life Cycle*:**
Infrastructure for conducting research and surveillance at different stages of device evaluation. Important role for data linkages

***Governance and Sustainability*:**
Engage major stakeholders: societies, payers, various states. Obtain major & diverse funding

***Healthcare Quality Improvement*:**
Device technologies require continuous evaluation: Feedback, benchmarking and outlier assessments

***Engaging patients and incorporation of patient generated data:***
Engage, evaluate preferences and measure general and disease specific PROs

**Level 1. Early Learner**
**Level 2. Making progress**
**Level 3. Defined path to success**
**Level 4. Well managed**
**Level 5. Optimized**

Example: Optimized Data Collection Efficiency

Technologies are in place (e.g. structured data extraction from EHRs/ mobile apps for all core minimum data elements, and there is a full adoption and integration of data and terminology standards (assumes complete interoperability)

* Paper accepted for publication in BMJ-SIT, expected April, 2022

# Example: Data Collection Efficiency Domain

- Extent to which the registry is embedded in the healthcare quality improvement system so that data collection occurs as part of care delivery

Level 1. Early Learner

Heavy burden with ad hoc data elements on a project basis but without an agreement on clinically relevant minimum core data elements

Level 2. Making progress

Level 3. Defined Path to Success

Level 4. Well-Managed

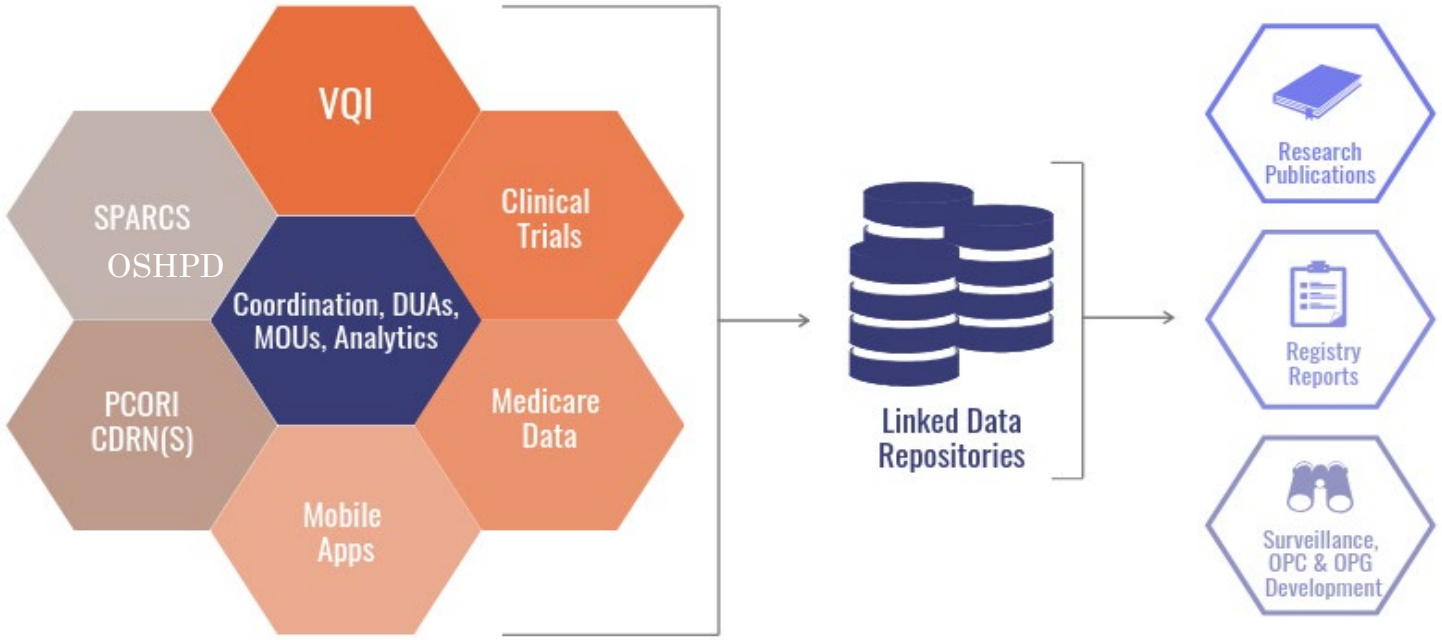
Level 5. Optimized

Technologies are in place (e.g. structured data extraction from EHRs/ mobile apps for all core minimum data elements, and there is a full adoption and integration of data and terminology standards (assumes complete interoperability)

# Example of a Mature CRN

**CRNs typically include data from national registry, claims data, EHRs, PGHD.**

**In the case of VISION, the CRN also includes the (NY- SPARCS and CA- OSHPD ), PCORNet, and clinical trial data tailored for multiple uses.**




| Total Procedures Captured (as of 1/1/2022) | 905,355 |
|---|---|
| Peripheral Vascular Intervention | 305,540 |
| Carotid Endarterectomy | 168,754 |
| Infra-Inguinal Bypass | 71,889 |
| Endovascular AAA Repair | 69,508 |
| Hemodialysis Access | 68,362 |
| Carotid Artery Stent | 67,413 |
| Varicose Vein | 50,909 |
| Supra-Inguinal Bypass | 23,214 |
| Thoracic and Complex EVAR | 23,450 |
| Lower Extremity Amputations | 23,300 |
| IVC Filter | 16,715 |
| Open AAA Repair | 15,861 |
| Vascular Medicine Consult | 376 |
| Venous Stent | 64 |

30 publications /
6 validation studies in high impact journals

Linkage Breadth:
88 % of all EVAR patients
93 % of all AAA patients

Linkages: 2002 – 2019
Up to 15 years of follow up – Mean 3-4 years
415,616 patients captured in current linkage efforts
14, 000 patients captured in current validation efforts

Amputation laterality (Yale, Dartmouth, ~ 4,000 patients, ongoing)
Stroke after carotid revascularization (multisite, ~10,000 patients, initial stages)
Thoracic reinterventions after TEVAR (planning stages)

880 clinical sites
3000 providers
> 200 types of devices

# US CRN Learning Community

| CCR | CRN Name | Clinical Area (current phase) |
|---|---|---|
| 1. | Women's Health Technology Coordinated Registry Network (WHT-CRN) | Women's Health Women's Health (uterine fibroids, pelvic organ prolapses, stress urinary incontinence, sterilization) |
| 2. | Vascular Implants Surveillance and Outcomes Network (VISION-CRN) | Vascular |
| 3. | Cardiac Devices Coordinated Registry Network (CD-CRN) | Cardiac |
| 4. | Orthopedic Devices Coordinated Registry Network (Ortho-CRN) | Orthopedic |
| 5. | Devices Intended for Acute Ischemic Stroke Intervention (DAISI-CRN) | Acute ischemic stroke |
| 6. | Venous Access National Guideline & Registry Development Coordinated Registry Network (VANGUARD-CRN) | Venous access |
| 7. | Robotic Surgery Coordinated Registry Network (Robotic-CRN) | Robotic surgery |
| 8. | Study of Prostate Ablation Evidence Development (SPARED-CRN) | Prostate ablation |
| 9. | Temporo-mandibular Joint Coordinated Registry Network (TMJ-CRN) | Temporomandibular joint |
| 10. | National Breast Implants Registry (NBIR) | Breast implants |
| 11. | Obesity CRN | Obesity devices |
| 12. | End Stage Kidney Disease Coordinated Registry Network (ESKD-CRN) | End stage Kidney disease |
| 13. | Abdominal Core | Abdominal Core |

- **Crosspollination areas**: clinical, data science, epidemiology/statistics, digital tools, blockchain, imaging, international
- **16 tools shared and applied** : (a) harmonization efforts in CRN architecture and data exchange ( logic model for clinical work flow), (2) methods ( validation, data linkages, outcomes studies, ROI, ML/AI ), (3) mobile apps ( patient and provider-based) and others

# Registries Without Borders:
# International Consortium of Vascular Registries (ICVR)

- Launched in November 2014
- Supported by the MDEpiNet Analytic Center at Weill Cornell Medicine and High Performance Integrated Virtual Environment (HIVE) – under grant from FDA
- Represents a collaboration of 28 reginal and national registries:
  - FDA and Vascular Device Manufacturers are at the table
- Embraced the CRN concept
- Rich portfolio of harmonization, validation and outcomes studies
- Collaborative study under way for labeling change in rAAA space

# CRNs: *Pragmatic Advantages & Efficiencies*

- Registries and Beyond !
- Existing systems participating in CRNs:
  - **Minimize re-engineering (cost, time to implement)**
  - **Leverage established clinical work flow**
  - **Established governance & sustainability**
- Strategic data sharing across participating CRN systems:
  - **Flexibility in design:  accommodate emerging e-systems**
  - **Customizable across device, stakeholder and other diversity**
  - **Builds architectural consistency (use/re-use of structured data sets & data sharing solutions across device areas)**

# CRNs are Already Producing the Regulatory Grade Evidence


- Used for postmarket surveillance, mandated post-approval studies, labeling expansions
- ROI Studies documented up to 550%  Return on Investment


a. Pappas G, Berlin J, Avila-Tang E, et al. Determining value of Coordinated Registry Networks (CRNs): a case of transcatheter valve therapies **BMJ Surgery, Interventions, & Health Technologies** 2019;1:e000003. doi: 10.1136/bmjsit-2019-000003
b. Cronenwett JL, Avila-Tang E, Beck AW, Bertges D, Eldrup-Jorgensen J, Resnic FS, Radoja N, Sedrakyan A, Schick A, Smale J, Bloss RA, Phillips P, Hasenbank M, Wang S, Marinac-Dabic D, Pappas G. Use of data from the Vascular Quality Initiative registry to support regulatory decisions yielded a high return on investment. **BMJ Surg Interv Health Technol**. 2020 Oct 30;2(1):e000039. doi: 10.1136/bmjsit-2020-000039. PMID: 35051256; PMCID: PMC8749325.

# Registries and CRNs to Advance Evaluation of Technologies

**Art Sedrakyan, MD, PhD**
Professor, Weill Cornell Medicine,
New York Presbyterian Hospital
Director of Institute For Technologies and Interventional care
Director, MDEpiNet Coordinating & Science Infrastructure Center
Co-Chair, IDEAL Collaboration
Co-Editor-In-Chief, BMJ Surgery Innovations & Technologies

# CRNs leverage all RWD to Enrich the Registry

"Organized system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonable generalizable scale (e.g., international, national, regional, and health system) with a primary aim to improve the quality of patient care." - International Medical Device Regulatory Forum

1. Device data: the registry contains sufficient information to uniquely identify the device. Ideally, the unique device identifier would be included, but when unavailable, the registry would include a combination of identifiers (catalogue number, manufacturer, description)
2. Quality improvement system: is part of a healthcare delivery improvement system or evolving into one as device technologies are diffused into practice and need continuing evaluation (including outlier identification).
3. Beneficial change: has established mechanisms to bring about beneficial change in healthcare delivery through stakeholder participation, ownership, and intergration into the relevant healthcare systems.
4. Efficiency: the registry is embedded in the healthcare delivery system so that data collection occurs as part of care delivery (i.e., not overly burdensome, not highly complicated, not overly costly) and integrated with workflow of clinical teams.
5. Actionable data: the registry provides actionable information in a relevant and timely manner to decision makers.
6. Transparency: the governance structure, data access, and analytical processes of the registry are transparent.
7. Linkability: information in the registry can be linked with other data sources for enhancement, including adequate follow-up achievement.
8. Total device lifecycle: the registry can serve as infrastructure for seamless integration of evidence throughout the device lifecycle.

- CRN is a data and partnership network to achieve the regulatory, clinical and scientific vision of generating RWE for evaluation of technologies and address limitations of any single registry

# Our Current Data Contributing to CRNs

Clinical Data
(Various clinical cohorts, IPD meta-analysis)

Public and Private Payer Data (state longitudinal discharge datasets, Private insurers)


Medicare Data (100% Medicare data on hospitalizations, Part B and carrier data for many clinical cohorts)

Patient Reported / Generated Data
(Developing mobile apps and collecting PROs)

Registries (conducting data linkages with registries and claims data e.g. Medicare)

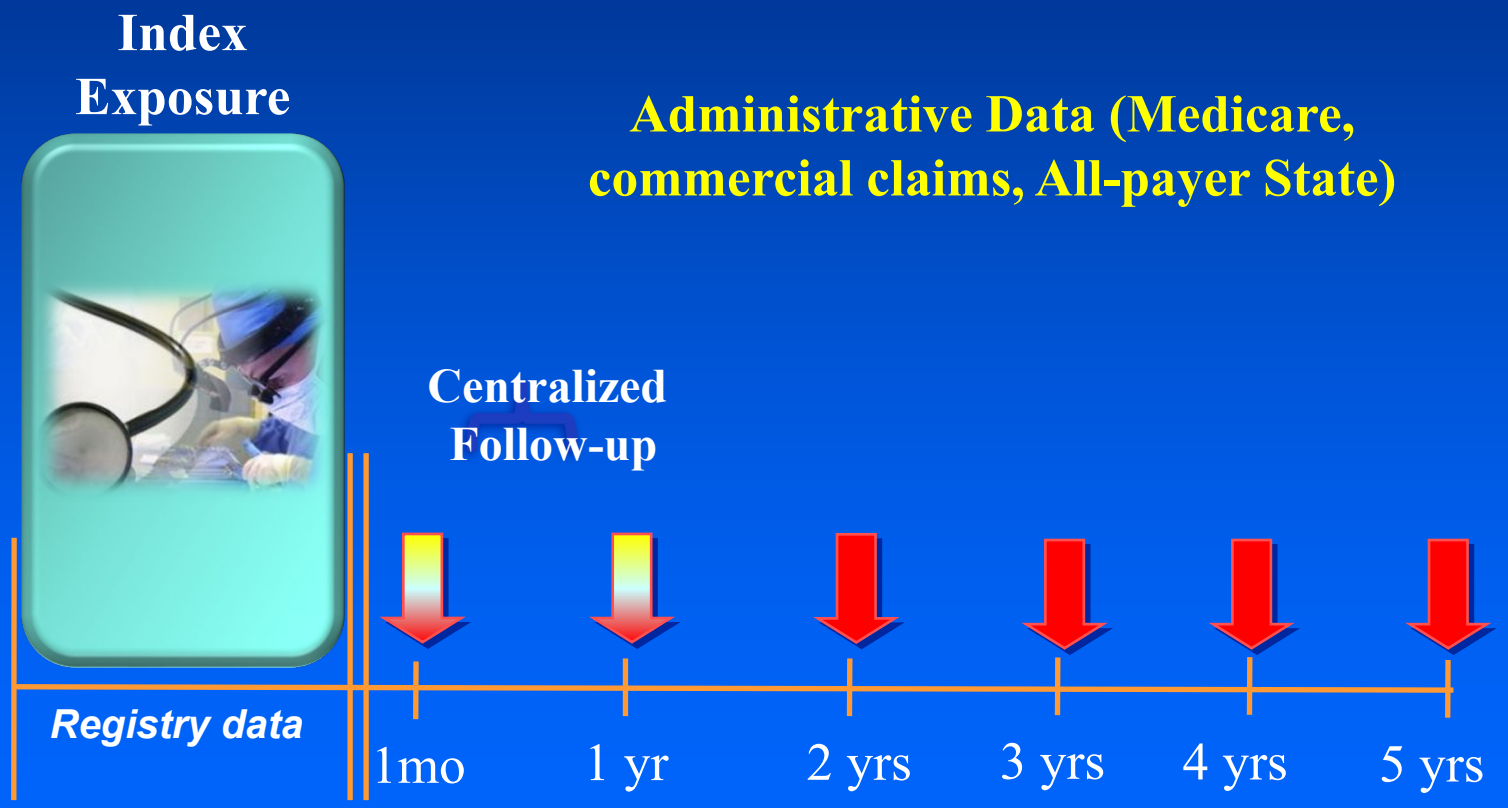
Social Determinants (Various state and national data linkages)

EHRs (Collaboration with PCORI CDRNs and Informatics groups)

# Key Areas of Focus to Get Good ROI

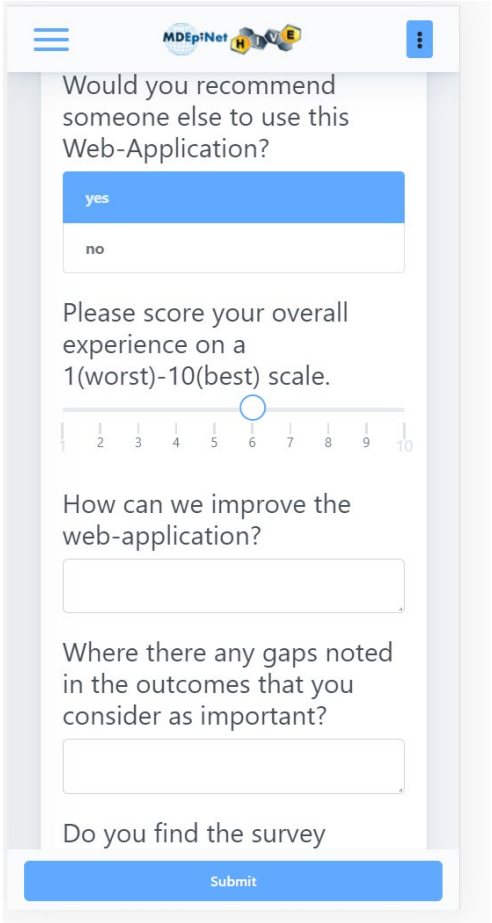
- Data linkages
- Mobile apps
- Clinician practice help
- Analytics

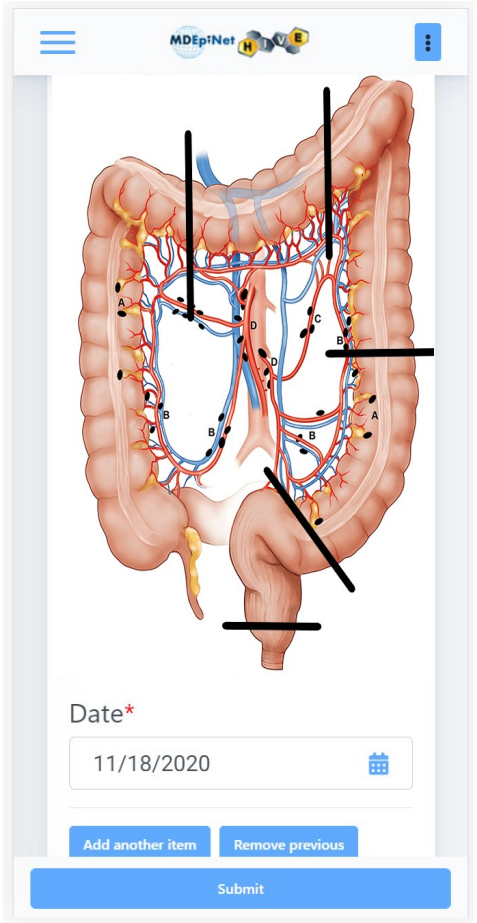
# Data Linkages: VISION Vascular CRN



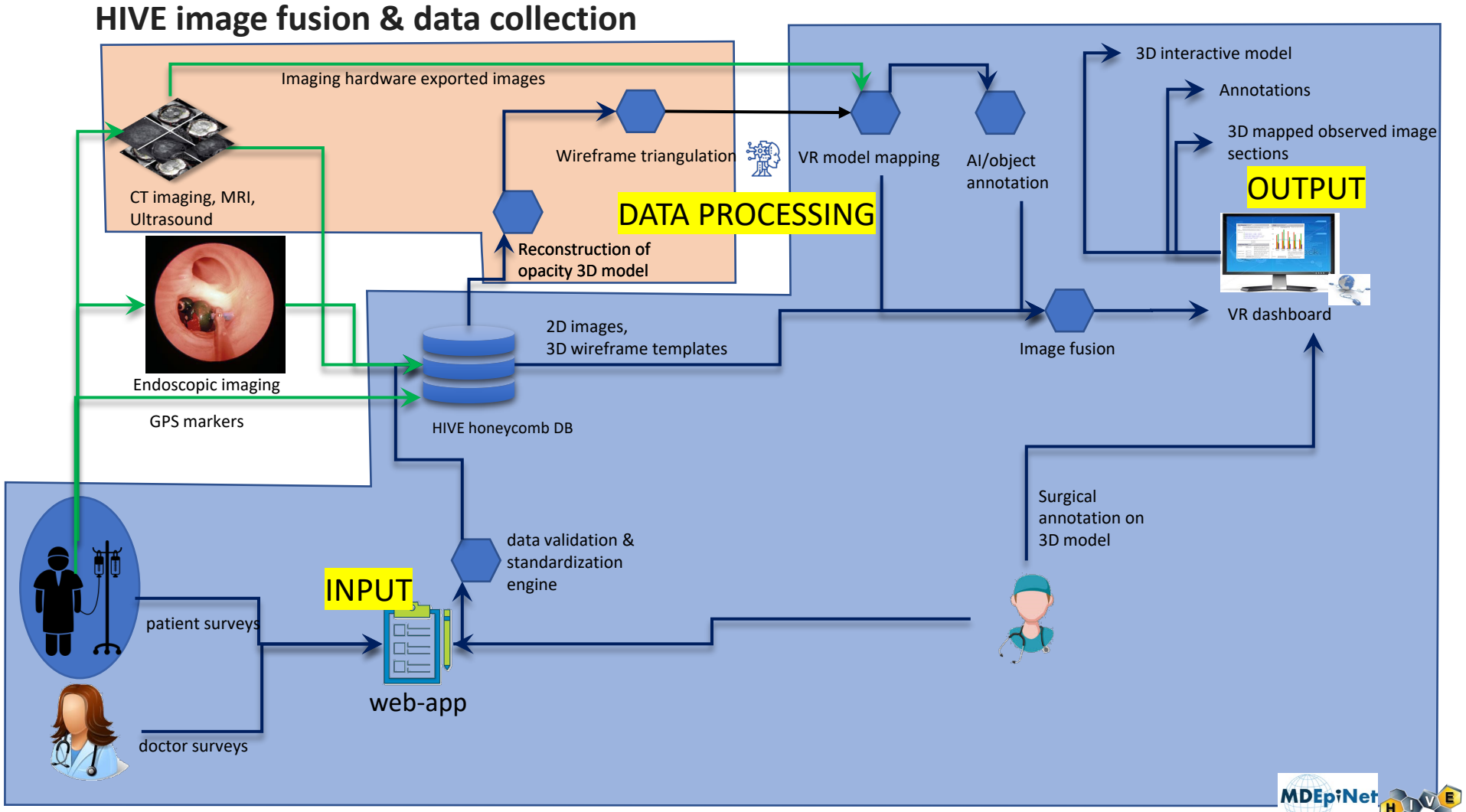
# Mobile apps: Colorectal CRN

**Patients are the key partners and work collaboratively with Doctors**



# Registry Data Systems: Value for Clinicians



# Analytics

## Example OPCs and OPGs Developed by MDEpiNet

- The freedom from Target Lesion Revascularization (TLR) OPGs at one year in the popliteal artery were 81.3% (PTA), 81.3% (stenting), 80.2% (atherectomy), and 81.1% (any treatments)
- Revision rates after hip and Knee Surgery at two years were 2.1% and 1.7% respectively. Disease specific and general PRO measure based estimates also calculated

Journal of Vascular Surgery | SVS Society for Vascular Surgery

FULL LENGTH ARTICLE | ARTICLES IN PRESS

Registry Assessment of Peripheral Interventional Devices Objective Performance Goals for Superficial Femoral and Popliteal Artery Peripheral Vascular Interventions

Daniel J. Bertges, MD • Roseann White, MA • Yu-Ching Cheng, PhD • ... Pablo Morales, MD • Mitchell W. Krucoff, MD • Jack L. Cronenwett, MD • Show all authors

Published: October 17, 2020 • DOI: https://doi.org/10.1016/j.jvs.2020.09.030

**Abstract**

Background

The Superficial Femoral Artery-Popliteal EvidencE Development (SPEED) Study Group developed contemporary objective performance goals (OPG) for peripheral vascular interventions (PVI) for superficial femoral (SFA)-popliteal artery disease utilizing the Registry Assessment of Peripheral Interventional Devices (RAPID).

**Developing Objective Performance Criteria (OPC) for Outcomes after Hip and Knee Replacement**

NEST Coordinating Center



Technology of Interest

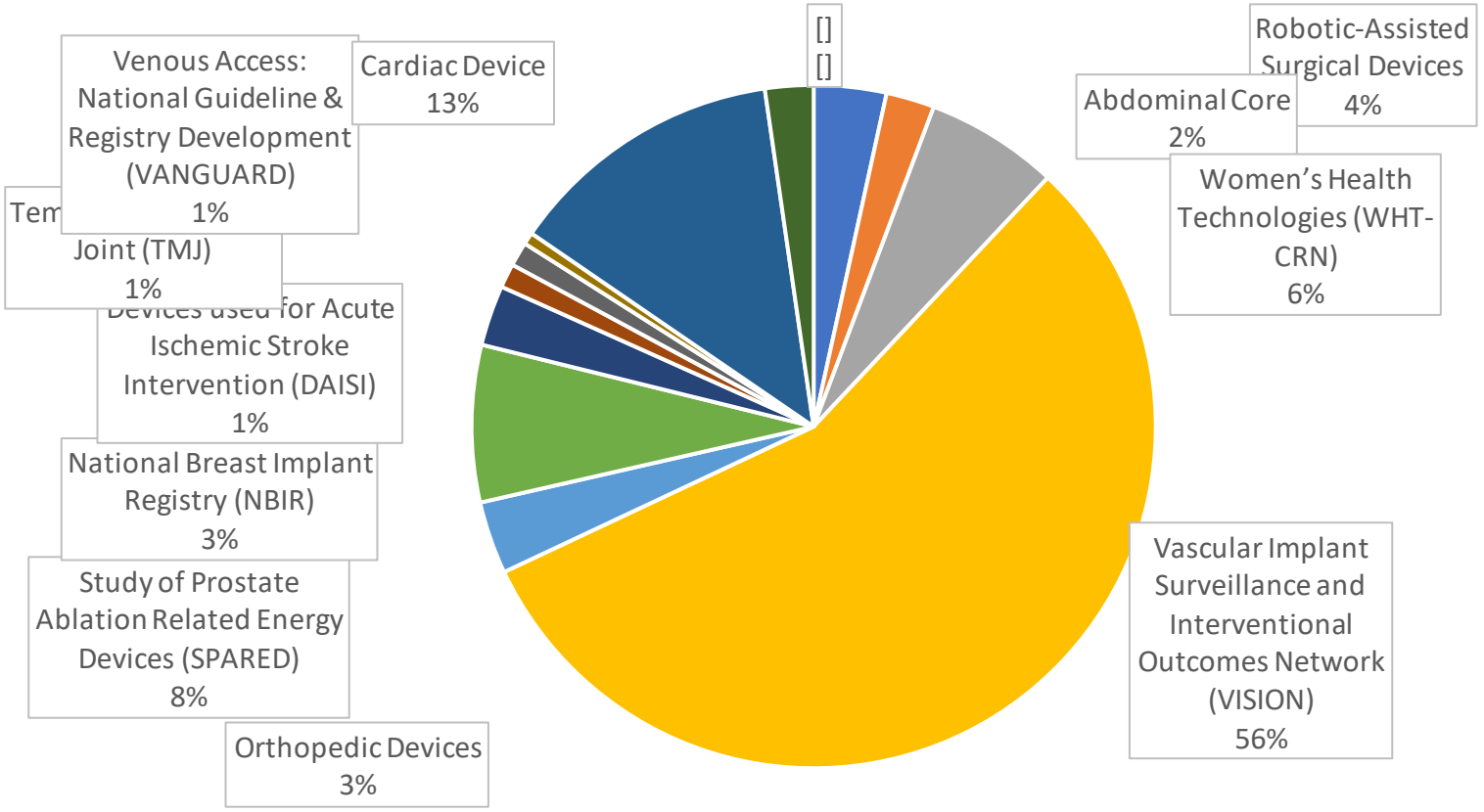
Knee and Hip Implants

**OVERVIEW**

The objective of this Test-Case is to develop objective performance criteria (OPC) or goals (OPG) for major outcomes following (Class II or III) implantable device use in primary hip and knee replacements.

Hip and knee joint replacements are the most common procedures in the US, and there has been a continuous increase in the use of these two procedures over time. The major outcome measures following hip and knee replacements are revisions, and quality of life (QoL) changes. However, specific objective measures for outcomes after treatment have not been developed by the healthcare community. An OPC is a target performance that was derived from historical data from clinical studies and/or registries which may be used for comparison of safety or effectiveness endpoints for medical devices

# Manuscripts by MDEpiNet CRN Learning Community by Clinical Area
# ( A total of 175 2017-2022)



# Please Send Your Best (And Good) Studies!


https://sit.bmj.com/pages/authors/

## Registry report

Registry reports should document specific registry findings that have the potential to improve modern healthcare; examples include results of outlier physician or technology/device analysis, specific quality of care improvement achievements, successful and sustainable implementation of unique device identification, and data linkages leading to long-term outcome assessments. Please review the International Medical Device Regulatory Forum's essential registry principles document for more information.

More specific studies using registry infrastructure (e.g., IDEAL stage 1-4 studies) should be submitted as research articles.

All registry reports should include the following:

**The article title should be short and informative**. Titles should not declare the results of the study.

**Unstructured abstract/executive summary** should be no longer than 350 words and include a crisp summary of the report, including methods and specific registry findings.

Manuscripts should be divided into the following sections:

- **Background**
- **Purpose of the Registry**
- **Aims of the Report**
- **General Methods (Data Collection Process, Data Validation)**
- **Main Findings with Discussion**

We recommend that your main findings section be no longer than eight paragraphs; we also recommend that you use at least several subheadings. This section should include discussion of results, possible explanations of each finding, implications for clinicians and policymakers, and future research plans.

- **Funding Statement,** preferably worded as follows:
"This work was supported by [name of funder] grant number [xxx]. You must ensure that the full, correct details of your funder(s) and any relevant grant numbers are included. This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.
- **Competing Interests Statement**
See the BMJ Author Hub for details on what to include as competing interests.
- **Articles should list each author's contribution individually at the end**.
This section may also include contributors who do not qualify as authors. Please visit the ICMJE website for more information on authorship.
- **Data Sharing Statement**, such as:
"Technical appendix, statistical code, and dataset available from the Dryad repository, DOI: [include DOI for dataset here]."

Supplementary and raw data can be placed online alongside the article. We may request that you separate out some material into supplementary data files to make the main manuscript clearer for readers.

Following the lead of *The BMJ* and its patient partnership strategy, *BMJ Surgery, Interventions, & Health Technologies* is encouraging active patient involvement in setting the research agenda. As such, we require authors to add a Patient and Public Involvement (PPI) statement in the Methods section. Please see our FAQs regarding PPI statements.

**Word Count**: up to 4,500 words
**Abstract**: up to 350 words
**Tables/Figures**: up to 8 tables or figures
**References**: up to 75
**Authors**: up to 20 (no more than 8 from a single institution)
**APC**: $2,800

# Thank You!

Email: ars2013@med.cornell.edu

**http://mdepinet.net/**

ASH
RESEARCH
COLLABORATIVE™
DATA HUB

# The ASH Research Collaborative Data Hub

**William Wood, MD, MPH**
Chair, ASH RC Data Hub Oversight Group

ASH RESEARCH COLLABORATIVE™ DATA HUB

# The Data Hub:

*Capturing Real-World Data to Generate Real-World Evidence for Hematology*

People Living with Hematologic Conditions

OMOP FIHR

## Real-World Data

- Electronic health records
- Electronic case report forms/NLP for clinical information maintained outside structured EHR fields
- Patient-reported outcomes
- Patient-generated health data
- Claims data
- Other population data

## Multi-Stakeholder

- Patients and community members
- Clinicians
- Clinical care sites
- Researchers
- Quality improvement specialists
- Federal entities

## Research

- Contemporaneous control groups
- Post market surveillance
- Academic research
- Cohort identification

## Enhance Clinical Care

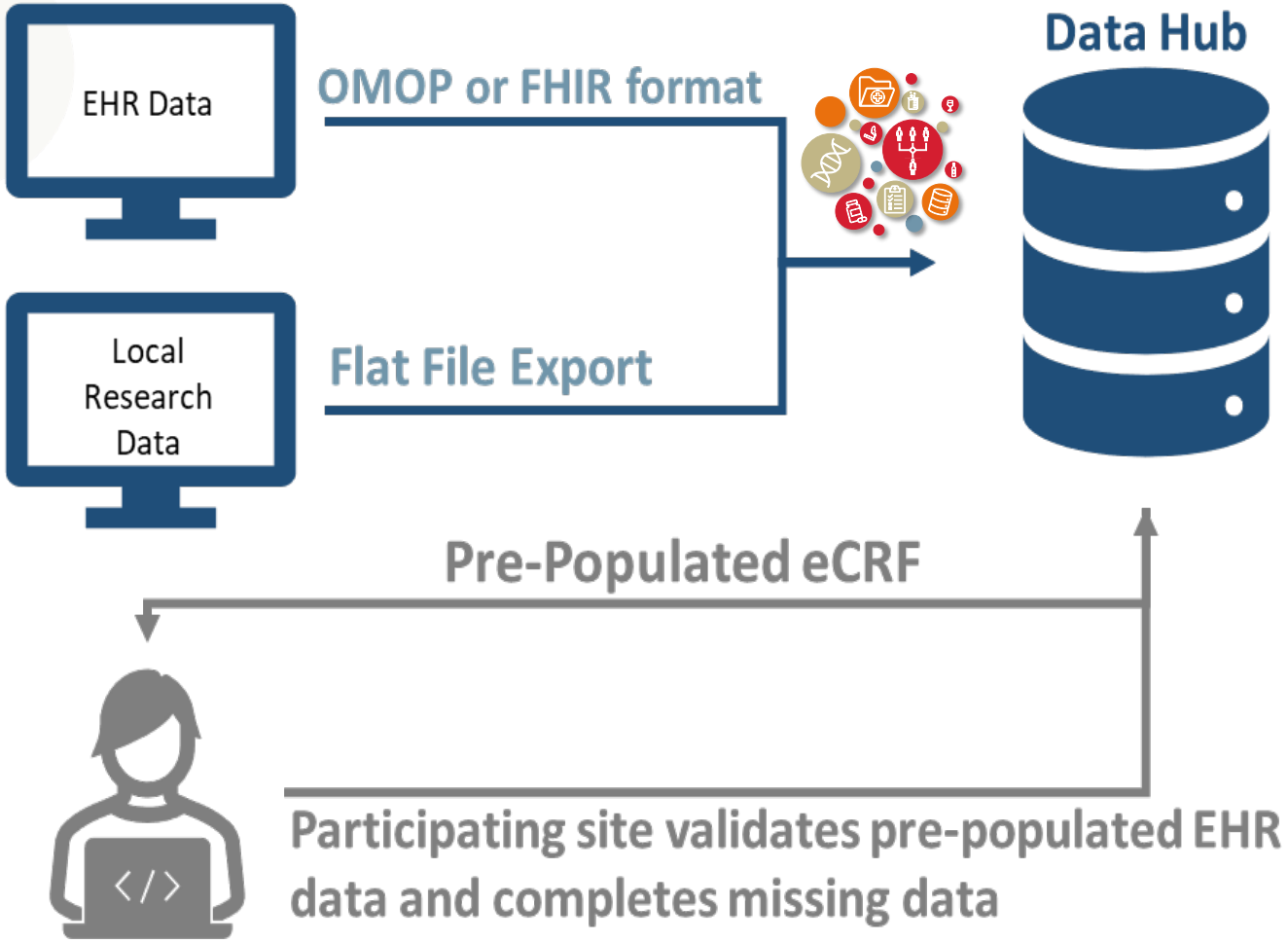
- Access site-specific outcomes
- Exchange best practices

ASH RESEARCH COLLABORATIVE™ DATA HUB

# Data Submission and Validation

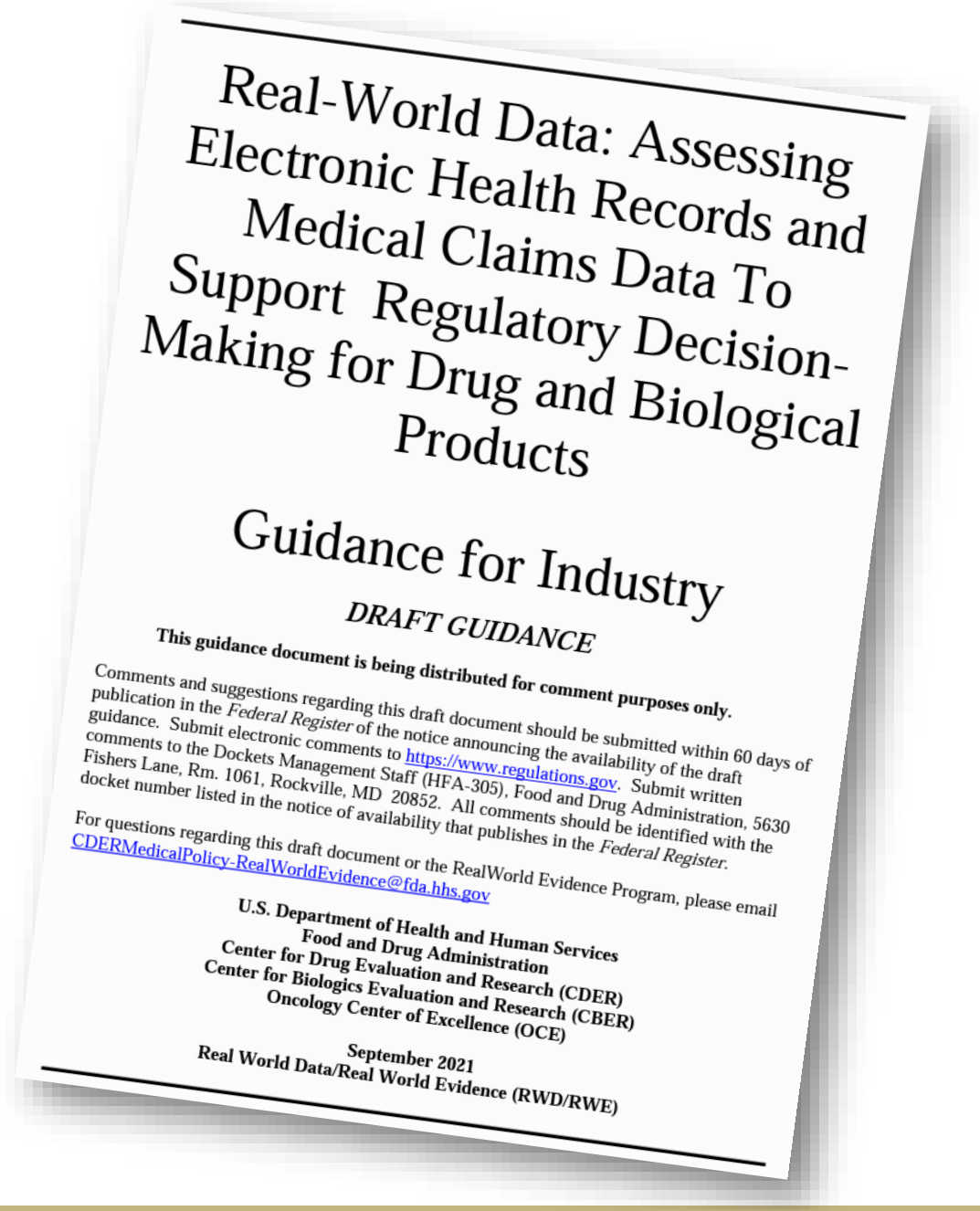
**Phase 2**

**Phase 1**



# Data Quality

- ✓ Accuracy
- ✓ Completeness
- ✓ Conformance
- ✓ Plausibility
- ✓ Reproducibility
- ✓ Provenance



Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry

*DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

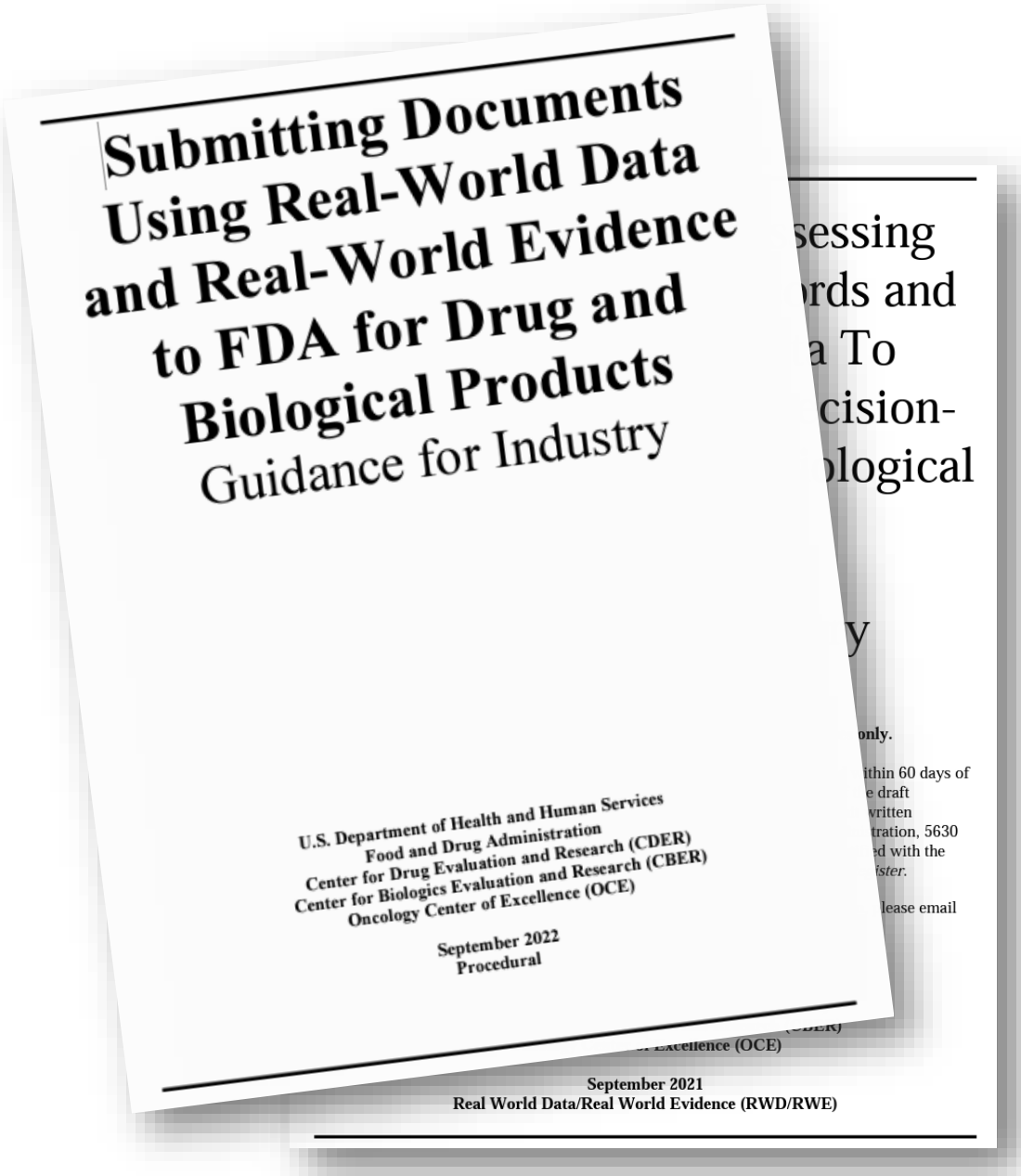
For questions regarding this draft document or the RealWorld Evidence Program, please email CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**
**Oncology Center of Excellence (OCE)**

**September 2021**
**Real World Data/Real World Evidence (RWD/RWE)**

# Data Hub Fit for Use for FDA Regulated Research

- RCTs clinical outcomes
- External control arms
- Observational studies to support an efficacy supplement
- Fulfill post-marketing requirement/commitment



# ePhenotyping

**Rule-Based**

Value Set

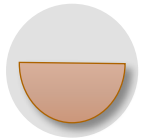
Business Logic

**Model-Based**

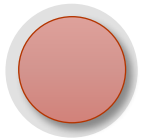
Machine Learning / AI

## Validating ePhenotyping

Explicit



Reproducible



Valid

Dashboard
Data Quality Report
Cohort Finder
Data Submissions
Data Export
User Management

RESOURCES
SCD Program

Date Range | Age Range | Birth Sex | Genotype | Saved Filters | Clear All | Save Filter

Start: May 2019 | End: Feb 2021

PARTICIPANT CHARACTERISTICS | ACUTE CARE EVENTS | PHARMACOTHERAPY | CEREBROVASCULAR | RENAL

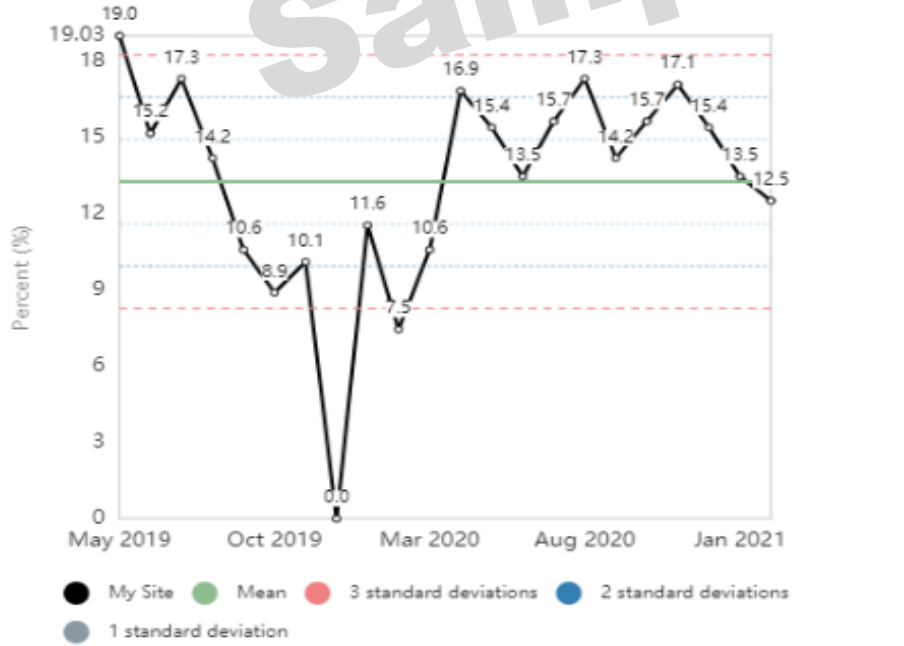
# Pharmacotherapy



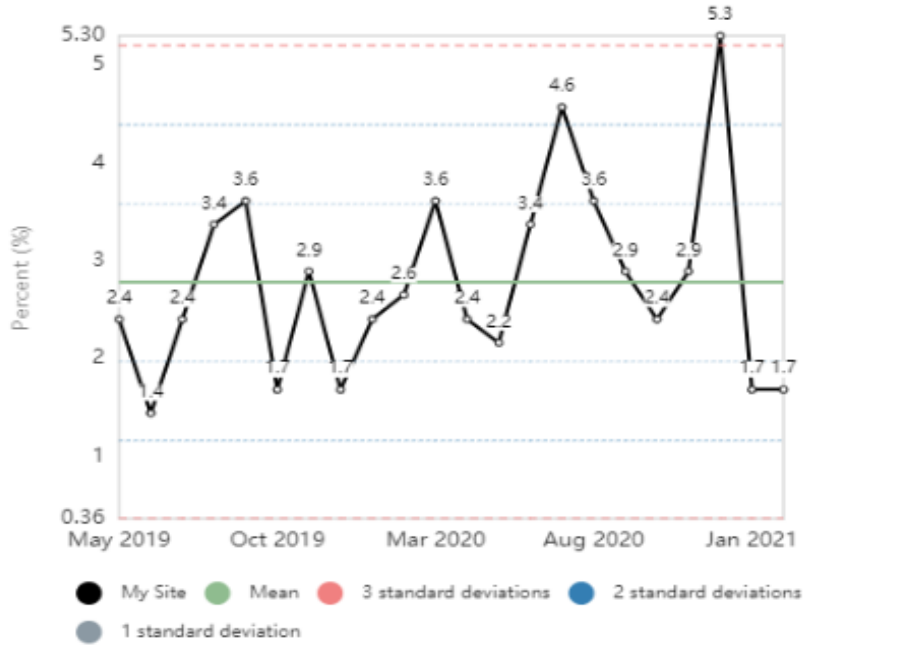
Last refreshed on
July 07, 2022

Participant drill down

## Disease-Modifying Therapy Prescription Rate




## No Disease-Modifying Therapy Prescription Rate



Dashboard

Data Quality Report

Cohort Finder

Data Submissions

Data Export

User Management

RESOURCES

SCD Program

DQ LEVEL 1 SUBMISSION REPORT | DQ LEVEL 2 CONSISTENCY REPORT

## Summary Metrics

The counts represent all SCD data in the Data Hub as of your most recent data submission. The percentages represent the changes in the counts since your previous data submission.

Previous submission: May 04, 2022
Most recent submission: July 07, 2022

| 39.33% | 418 Participants | 560% | 1,980 Encounters | 60% | 8 Providers |
|---|---|---|---|---|---|



| Metric | Current Value | % Change |
|---|---|---|
| Average Participants per Provider | 52.25 | -12.92% |
| Maximum Participants per Provider | 339 | 160.77% |
| Minimum Participants per Provider | 5 | -82.14% |
| Office Encounters | 132 | 100% |

| Metric | Current Value | % Change |
|---|---|---|
| Inpatient Admissions | 249 | 315% |
| Other Encounters | 4 | 100% |
| Laboratory Test Orders | 192 | 60% |
| Imaging Study Orders | 60 | 0% |

COHORT 1

COHORT 2

Save Cohort

Clear all

Saved Cohort

Cohort Source

Active MM Diagnosis Date

On or after

3-16-2020

Age at Active MM Diagnosis

Birth Sex

Active MM Type

Active MM Isotype

Other Plasma Cell Disorders

## COHORT CRITERIA

Cohort 1: **52**

INCLUDES:

**Diagnosis Of Active Multiple Myeloma**
**Age at Active Multiple Myeloma Diagnosis:** Between 40 - 60
**Birth Sex:** Male
**Active Multiple Myeloma Type:** Heavy Chain Myeloma, Light Chain Myeloma

EXCLUDES:

**Chromosomal Abnormalitiess include all of the following:**
TP53, 1q gain
**ISS Stage:** I

Cohort 2: **392**

## METRICS

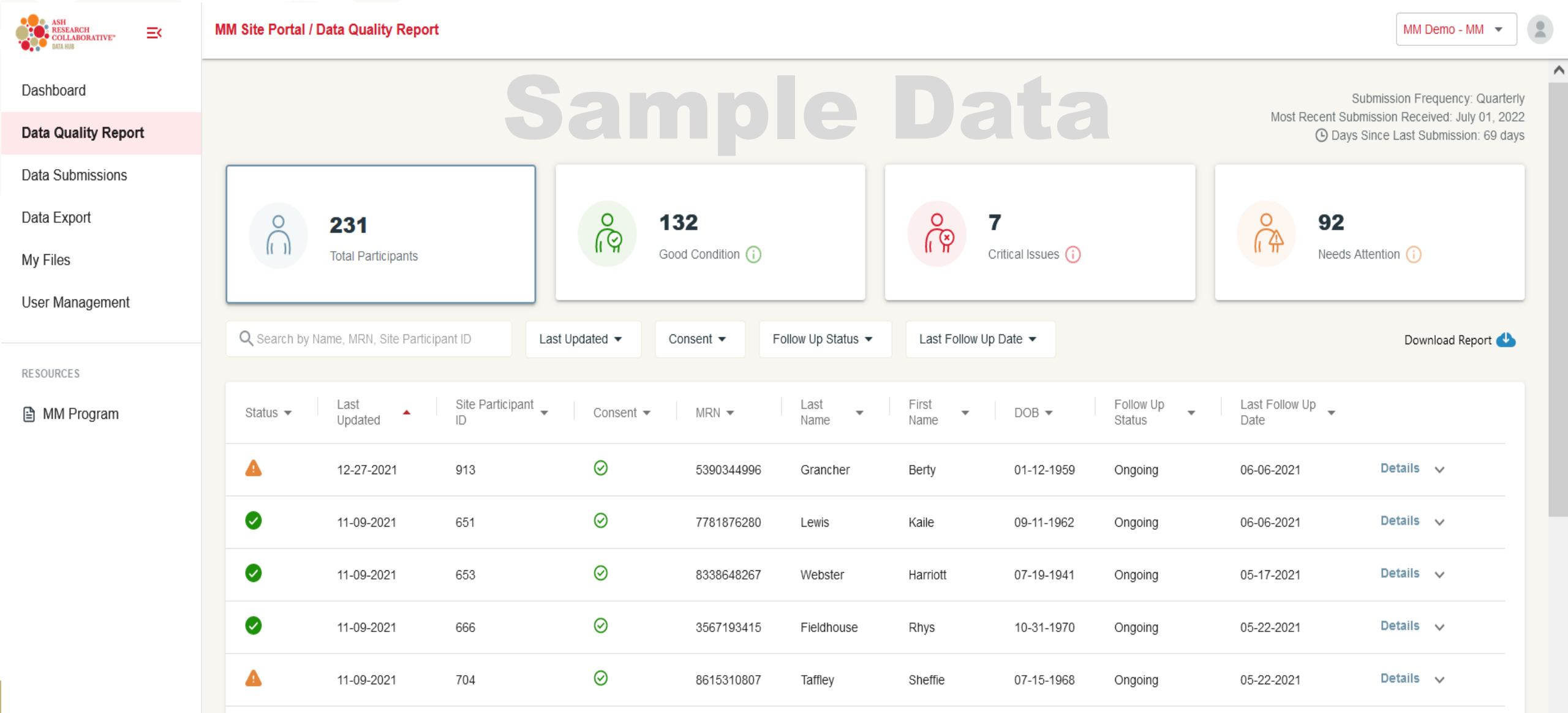
- Age at First Active MM Diagnosis
- Birth Sex
- Active MM Type & Isotype
- Chromosomal Abnormalities
- Therapy Classes & Agents
- Stem Cell Transplants
- Overall Survival
- Time to Treatment Failure
- Participant Accrual

GRAPH VIEW | TABLE VIEW

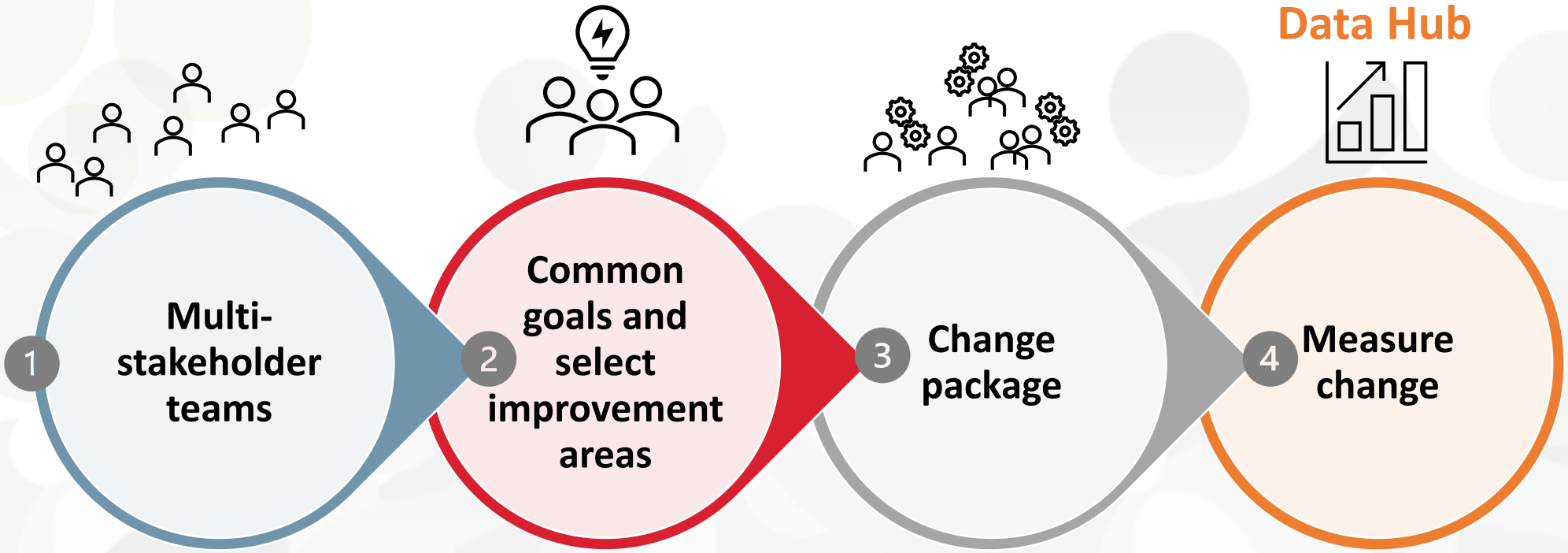
### Age at First Active MM Diagnosis

The distribution of age (years) at first diagnosis of active multiple myeloma for participants in the cohort.

# Data Quality Report



# Data Hub-powered SCD Learning Community



# Federal Collaborations

- HHS Office of Minority Health
- NHLBI
- FDA

# Real-World Evidence Initiative

ASH RESEARCH COLLABORATIVE™ DATA HUB

Innovative Genomics Institute

*Engage stakeholders*

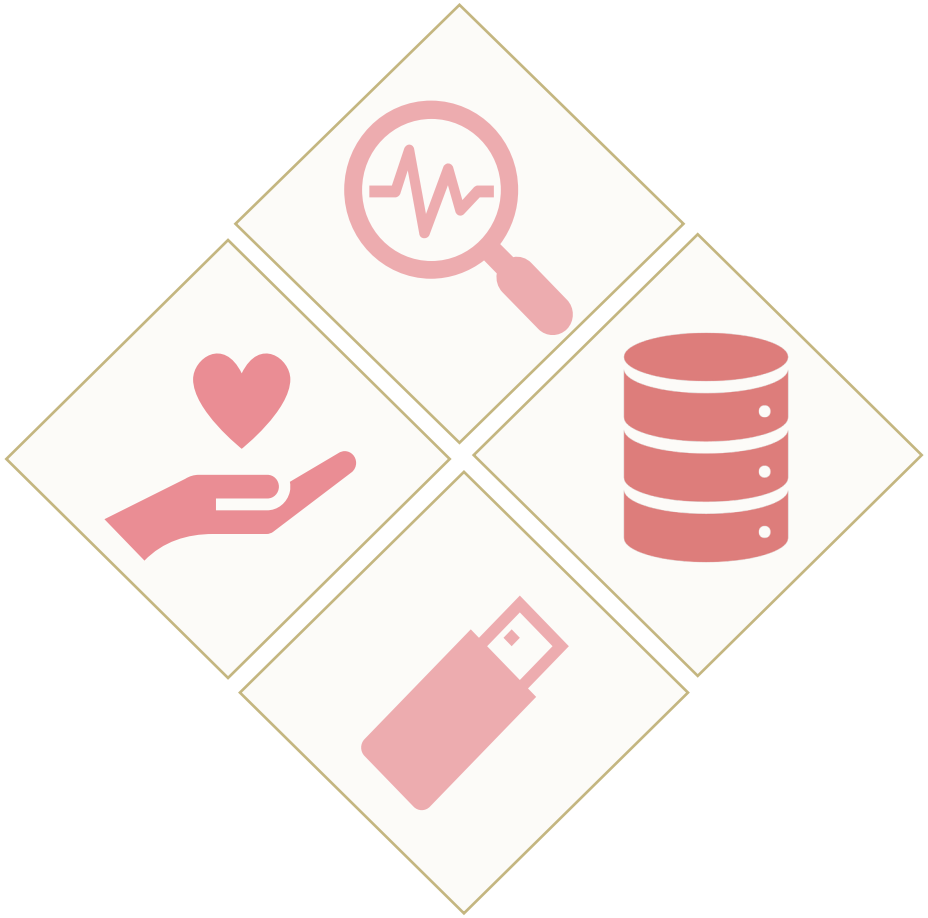
*Support the development of the ASH RC's Data Hub*

*Explore methods for "Accelerating Innovations for Sickle Cell Disease with Real-World Evidence"*

# Results and Recommendations

**Four Topic Areas:**

1. Data Fit for Use
2. Data Access and Use
3. Data Sources, Including Patient Experience Data
4. Sustainability



# Public Comment Open Now!

Comments due **no later than October 15, 2022** and can be [submitted here](#).


[Draft recommendations](#)

ASH RESEARCH COLLABORATIVE™
DATA HUB

# Thank You!

info@ashrc.org

@ash_collab

@ashcollab

@ASHResearchCollaborative

# *The Vascular Quality Initiative – Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION): Building Infrastructure For Success*

Philip Goodney, MD and Kayla Moore, MS

On behalf of the VQI VISION Steering Committee

SVS | VQI

In collaboration with NCDR®

# Disclosures

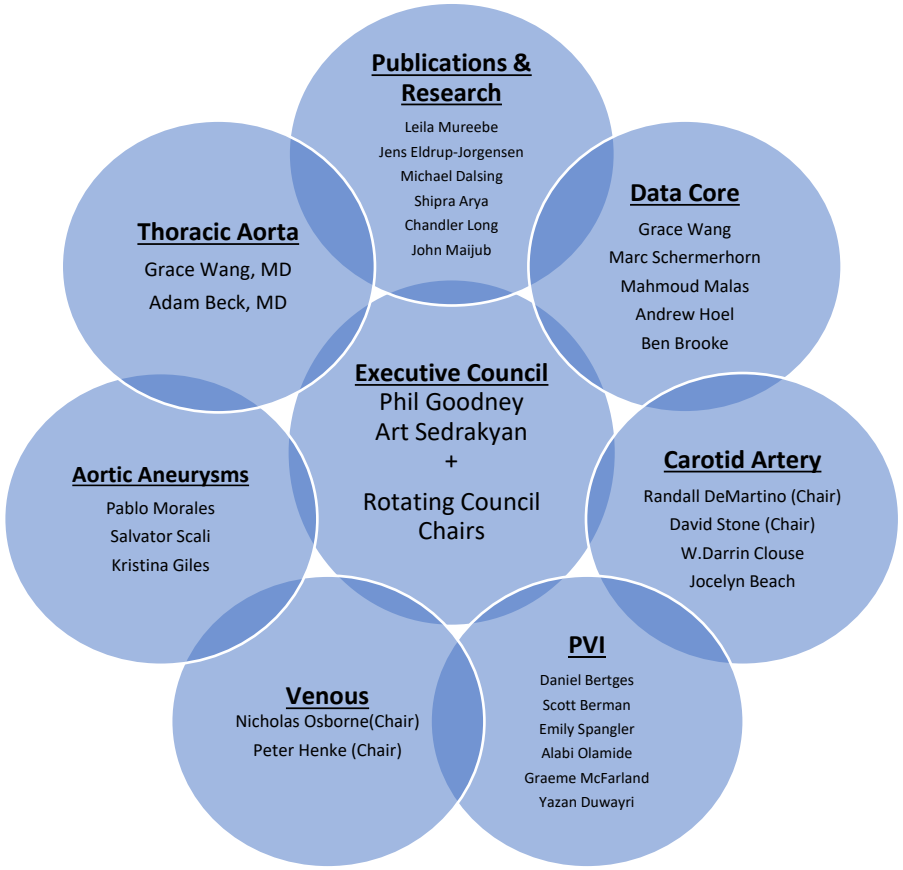
- FDA U01FD005478 (Sedrakyan = PI)
- NIA U01AG046830 (Skinner = PI)
- PCORI ME-1503-28261 (O'Malley = PI)
- NEST-CC Pilot Award (Sedrakyan = PI)
- AHA SFRN (Creager / Goodney = Project PI)
- SVS-PSO / Society for Vascular Surgery
- AHRQ R21 HS021581 (Goodney = PI)

MDEpiNet

SVS | VQI
In collaboration with NCDR®

KAISER PERMANENTE®

# VISION Steering Committee


FDA U.S. FOOD & DRUG ADMINISTRATION

# Goals

- **Outline the VQI-VISION coordinated registry network**
- **Share Key Findings from VQI-VISION, and VISION Infrastructure**
- **Describe what is next for VQI-VISION**

MDEpiNet

SVS | VQI

In collaboration with NCDR®

KAISER PERMANENTE®

# Goals

- **Review data shared at FDA panel in November outlining the role of device type in long-term EVAR outcomes.**
- Summarize FDA's guidance for next steps
- Outline the  Long term EVAR Assessment and Follow up (LEAF) System, our multi-stakeholder plan to meet FDA's goals for long-term post-EVAR surveillance

MDEpiNet

SVS | VQI
In collaboration with NCDR®

KAISER PERMANENTE®

# Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION)

PRACTICE MANAGEMENT



## The Vascular Implant Surveillance and Interventional Outcomes (VISION) Coordinated Registry Network: An effort to advance evidence evaluation for vascular devices

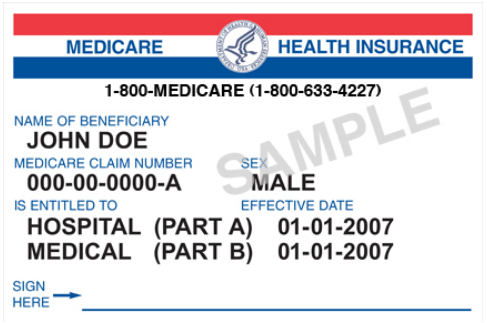
Greg Tsougranis, BS,[a,b,c] Jens Eldrup-Jorgensen, MD,[d] Daniel Bertges, MD,[e] Marc Schermerhorn, MD,[f] Pablo Morales, MD,[g] Scott Williams, MS, RAC,[h] Roberta Bloss, MS,[i] Jessica Simons, MD, MPH,[j] Sarah E. Deery, MD, MPH,[k] Salvatore Scali, MD,[l] Graham Roche-Nagle, MD, MBA, ME,[m] Leila Mureebe, MD, MPH, MMC,[n] Matthew Mell, MD,[o] Mahmoud Malas, MD, MHS,[p] Brian Pullin, MS,[g] David H. Stone, MD, MS,[a,b] Misti Malone, PhD,[g] Adam W. Beck, MD,[q] Grace Wang, MD, MS,[r] Danica Marinac-Dabic, MD, PhD,[g] Art Sedrakyan, MD, PhD,[s] *and* Philip P. Goodney, MD, MS,[a,b] *Lebanon and Hanover, NH; White River Junction and Burlington, Vt; Portland, Me; Boston, Mass; Rockville, Md; Bloomington, Ind; Flagstaff, Ariz; Gainesville, Fla; Toronto, Ontario, Canada; Durham, NC; Davis, San Diego, Calif; Birmingham, Ala; Philadelphia, Pa; New York, NY*

**Journal of Vascular Surgery, December 2020 Dec;72(6):2153-2160**

# How this works….

**Start With VQI Data**

**Mr. Jones (name, SS#)**
**Clinical Factors (comorbidities)**
**Implant Data (Graft XYZ)**
**Surgical Details (how it was placed)**
**Surgeon Details**
**Hospital Information**
**Short term complications**




**Data Linkages to Medicare Claims**
**The Dartmouth Institute**

**Measure Long-Term Events:**

- **Survival**
- **Effectiveness of the Procedure**
- **Long-Term Device Failures/Revisions**
- **Cost**

•. 2021 Jul 1;274(1):179-185.

## Accurately Measure Long-Term Post-Surgical Outcomes:

- Survival
- Reintervention
- Need for further procedures

generalizable, real-world effectiveness research

VISION

ssessment

SVS | VQI

In collaboration with NCDR®

ORIGINAL ARTICLE

## Long-term Reintervention After Endovasc… Aneurysm Repair

*Jesse A. Columbo, MD, MS,*†‡§✉ Pablo Martinez-Camblor, PhD, Bjoern D. Suckow, MD, MS,* Andrew W. Hoel, MD,¶ David H. St… Marc L. Schermerhorn, MD,** Art Sedrakyan, MD, PhD,†† and Philip … the Society for Vascular Surgery's Vascular Qu…*

Interve…

Outcomes…

(VQI Vis…

## A comparison of reintervention rates after endovascular aneurysm repair between the Vascular Quality Initiative registry, Medicare claims, and chart review

Jesse A. Columbo, MD,[a,b,c,d,e] Ravinder Kang, MD, MS,[a,b,c,d,e] Andrew W. Hoel, MD,[f] Jeanwan Kang, MD,[a,d] Kathleen A. Leinweber, BA,[d] Karissa S. Tauber, BA,[d] Regis Hila, BA,[d] Niveditta Ramkumar, MPH,[e] Art Sedrakyan, MD, PhD,[g] *and* Philip P. Goodney, MD, MS,[a,c,d,e] *Lebanon and Hanover, NH; White River Junction, Vt; Chicago, Ill; and New York, NY*

Check for up…

Circulation

RESEARCH LETTER

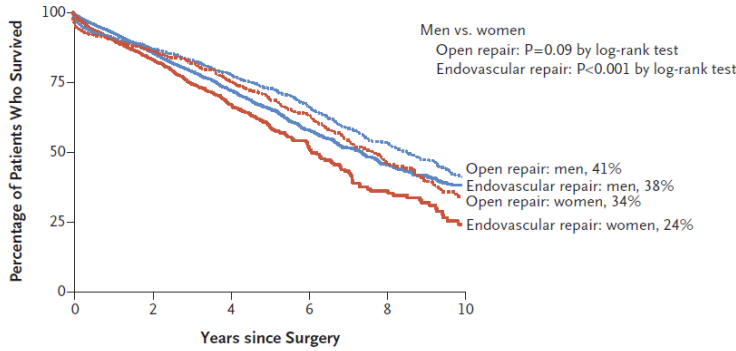
## Characterization of Endovascular Abdominal Aortic Aneurysm Repair Surveillance in the Vascular Quality Initiative

Each year in the United States, >30 000 patients undergo endovascular abdominal aortic aneurysm repair (EVAR).[1] Guidelines from the Society for Vascular Surgery and American College of Cardiology Foundation/American

Zachary J. Wanken, MD
Spencer W. Trooboff, MD, MBA

al of Vas…

The NEW ENGLAND JOURNAL of MEDICINE




| No. at Risk | | | |
|---|---|---|---|
| Open repair | | | |
| Men | 1847 | 364 | 108 |
| Women | 813 | 142 | 40 |
| Endovascular repair | | | |
| Men | 9454 | 441 | 84 |
| Women | 2325 | 111 | 20 |

**Figure 1. Survival among Men and Women Undergoing Elective Endovascular or Open Surgical Repair of Abdominal Aortic Aneurysm.**

The study involved 14,439 patients who underwent elective repair (endovascular or open) of abdominal aortic aneurysm within the Vascular Quality Initiative.[3,4]

Search...

(603) 298-5509 Members Login

SVS | VQI

In collaboration with NCDR®

| 495 | 928 | 936,887 |
|---|---|---|
| PUBLICATIONS | PARTICIPATING CENTERS | PROCEDURES CAPTURED |

About | Quality Improvement | Regional Groups | Industry Partners | Data Analysis | Members Only | Resources | Contact Us/Join Us

Home / Data Analysis / SVS VQI VISION

## Data Analysis

- Data Analysis
- SVS VQI Publications
- RAC Approved Project Search
- SVS VQI VISION
- SVS PSO Data Analysis Guidelines for Use
- Industry Project Charters and Process
- CREST-2 Randomized Control Trial

# SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

### Overview

The SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is a partnership between the SVS VQI and MDEpiNet that directly supports the mission of the SVS VQI to improve the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information. VISION links SVS VQI registry data to Medicare claims to generate novel registry-claims linked datasets. The datasets combine the clinical detail from the SVS VQI with long-term outcome variables derived from Medicare claims. VISION data is used to generate center-specific feedback reports called, Survival, Reintervention and Surveillance (SRS) and to analyze device performance and long-term outcomes of vascular surgical techniques. Use of the data is governed by a Data Use Agreement (DUA) between Weill Cornell Medical College and the Center for Medicaid and Medicare Services (CMS).

### Dataset Description

Medicare-Match data are available for EVAR, OAAA, PVI, TEVAR, CAS, INFRA and SUPRA datasets. For each dataset, the following SVS VQI-Medicare derived outcomes are available:

1. Death
2. Procedure-specific adverse outcome (stroke, aortic rupture, amputation)
3. Reintervention (repeated vascular procedures)

## Data Analysis Updates

National RAC Submissions Link

**Latest RAC Approved Project List**

RAC Approved Project List - Updated December 2021

## NEW SVS PSO Instructional Videos for Requesting VQI Data

Requesting VQI Data - Part 1

DCORE0032-Hospi....rdp

Each year dominal aortic aneurysm repair (EVAR).[1] Guidelines from the Society for Vascular Surgery and American College of Cardiology Foundation/American

Spencer W. Trooboff, MD, MBA

within the Vascular Quality Initiative.[3,4]

Search... (603) 298-5509 Members Login

SVS | VQI
In collaboration with NCDR®

495 PUBLICATIONS
928 PARTICIPATING CENTERS
936,887 PROCEDURES CAPTURED

About Contact Us/Join Us

**vqi.org/data-analysis/vision**

Home / Data Analysis / SV

## Data Analysis

- Data Analysis
- SVS VQI Publications
- RAC Approved Project Search
- SVS VQI VISION
- SVS PSO Data Analysis Guidelines for Use
- Industry Project Charters and Process
- CREST-2 Randomized Control Trial

## SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

### Overview

The SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is a partnership between the SVS VQI and MDEpiNet that directly supports the mission of the SVS VQI to improve the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information. VISION links SVS VQI registry data to Medicare claims to generate novel registry-claims linked datasets. The datasets combine the clinical detail from the SVS VQI with long-term outcome variables derived from Medicare claims. VISION data is used to generate center-specific feedback reports called, Survival, Reintervention and Surveillance (SRS) and to analyze device performance and long-term outcomes of vascular surgical techniques. Use of the data is governed by a Data Use Agreement (DUA) between Weill Cornell Medical College and the Center for Medicaid and Medicare Services (CMS).

### Dataset Description

Medicare-Match data are available for EVAR, OAAA, PVI, TEVAR, CAS, INFRA and SUPRA datasets. For each dataset, the following SVS VQI-Medicare derived outcomes are available:

1. Death
2. Procedure-specific adverse outcome (stroke, aortic rupture, amputation)
3. Reintervention (repeated vascular procedures)

## Data Analysis Updates

National RAC Submissions Link

**Latest RAC Approved Project List**

RAC Approved Project List - Updated December 2021

## NEW SVS PSO Instructional Videos for Requesting VQI Data

Requesting VQI Data - Part 1

DCORE0032-Hospi....rdp

Each year dominal aortic aneurysm repair (EVAR).[1] Guidelines from the Society for Vascular Surgery and American College of Cardiology Foundation/American

Spencer W. Trooboff, MD, MBA

within the Vascular Quality Initiative.[3,4]

# Key Issue

# Device-Specific Late Reintervention After EVAR

# Role of Real-World Evidence

# FDA Executive Summary

Circulatory System Devices Panel Meeting

November 3, 2021

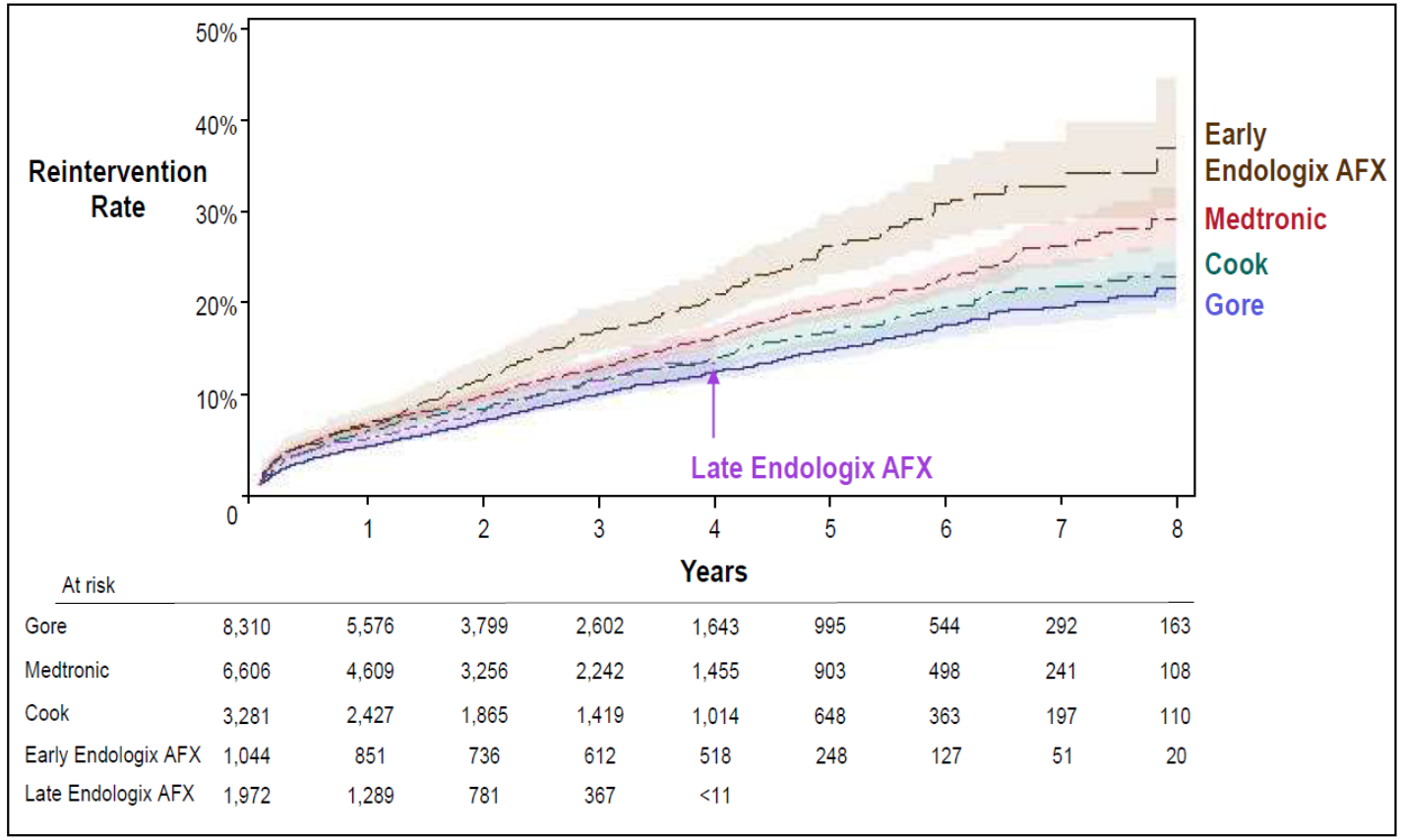
General Issues Panel

2 opposing forces

Real World Surveillance of AAA Endovascular Stent Grafts

# Reintervention, By Device Type (VQI/VISION) (In Press, BMJ)

**Figure 1.A:** Long-term rate of reintervention across the different device manufacturer types.



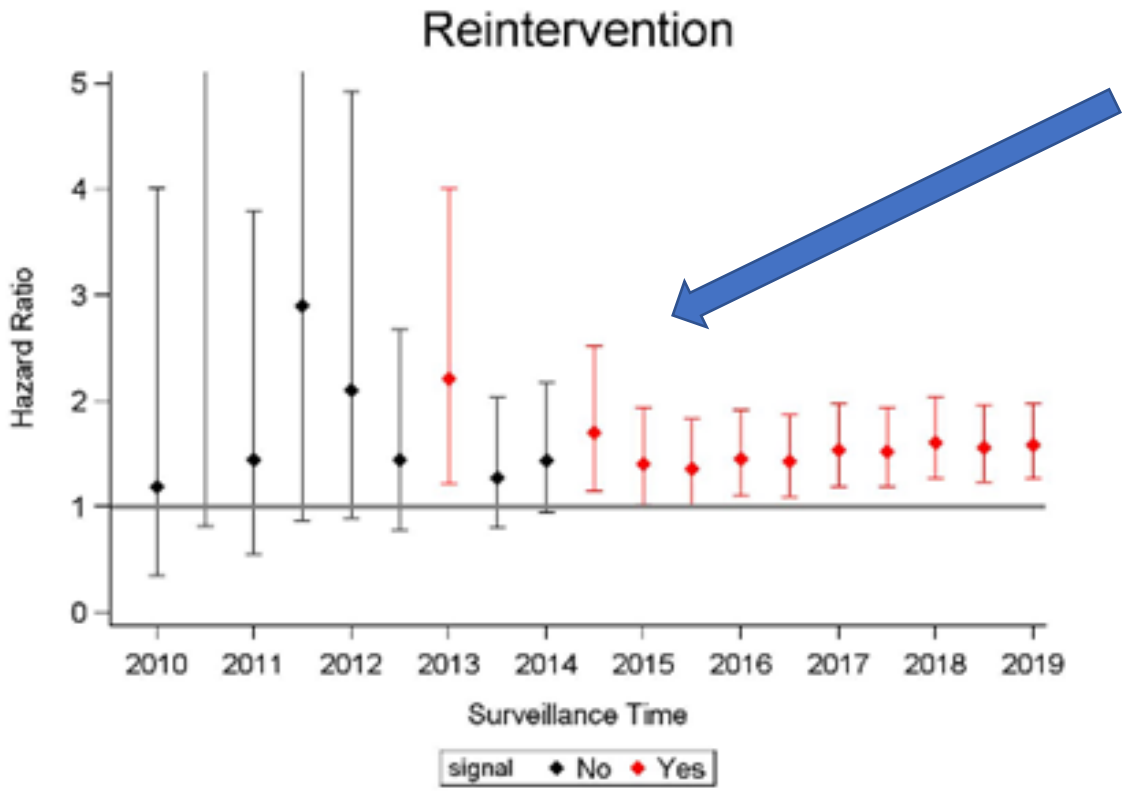

| At risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Gore | 8,310 | 5,576 | 3,799 | 2,602 | 1,643 | 995 | 544 | 292 | 163 |
| Medtronic | 6,606 | 4,609 | 3,256 | 2,242 | 1,455 | 903 | 498 | 241 | 108 |
| Cook | 3,281 | 2,427 | 1,865 | 1,419 | 1,014 | 648 | 363 | 197 | 110 |
| Early Endologix AFX | 1,044 | 851 | 736 | 612 | 518 | 248 | 127 | 51 | 20 |
| Late Endologix AFX | 1,972 | 1,289 | 781 | 367 | <11 | | | | |

MDEpiNet

SVS | VQI
In collaboration with NCDR®

KAISER PERMANENTE®

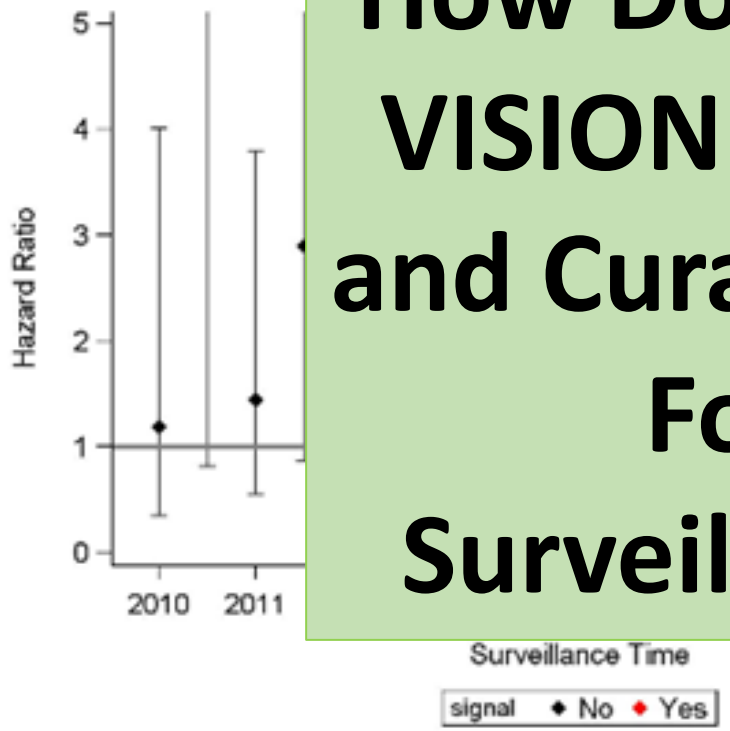
# Signals Detected In LEAF Could Prompt Clinical Review in VQI, Imaging Evaluation, and Further Data collection




**Signal Detection in LEAF**

**Secondary data elements (imaging, chart review)**

# Signals Detected In LEAF Could Prompt Clinical Review in VQI, Imaging Evaluation, and Further Data collection




## How Does VQI-VISION Create and Curate Date For Surveillance?

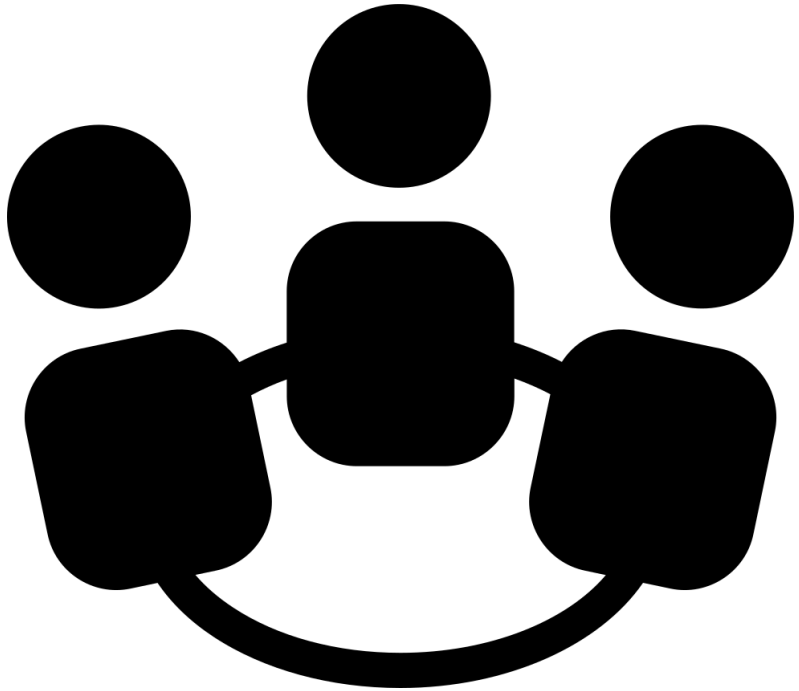
**Signal Detection in LEAF**

↓

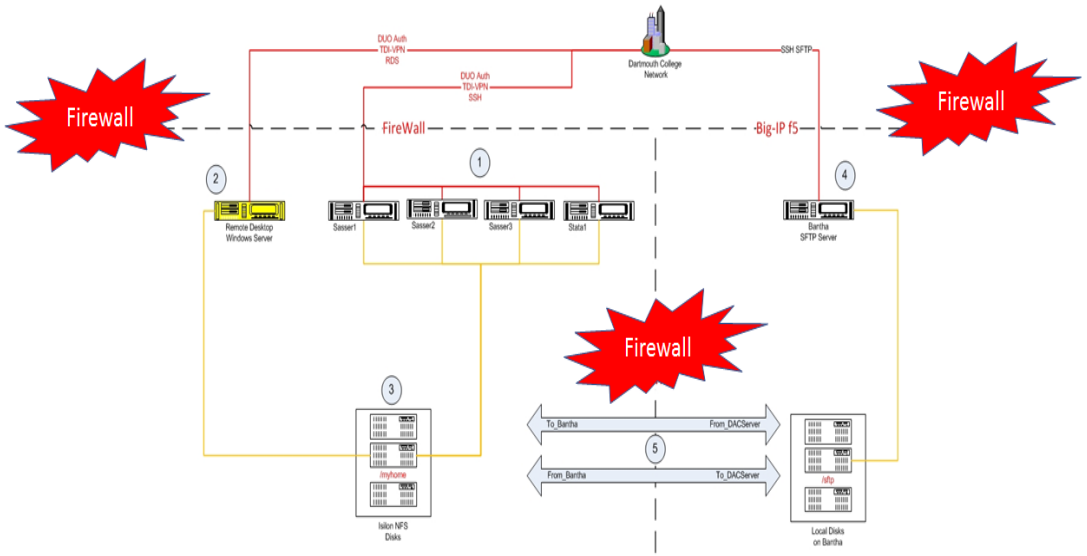
**Secondary data elements (imaging, chart review)**

# 2 opposing forces

Data as Community Resource



Data Security



# 2 opposing forces

## VISION as a Community Resource

- VISION is a community dedicated to generating RWE to improve the quality and effectiveness of vascular care
- All members provide data to the PSO and data is made available to the community for the purposes of improving vascular care
- VQI has a process in place for data usage in which members to submit proposals to a Research Advisory Council.
- Once approved by the RAC, investigators receive a blinded dataset which they can use to conduct their analyses.

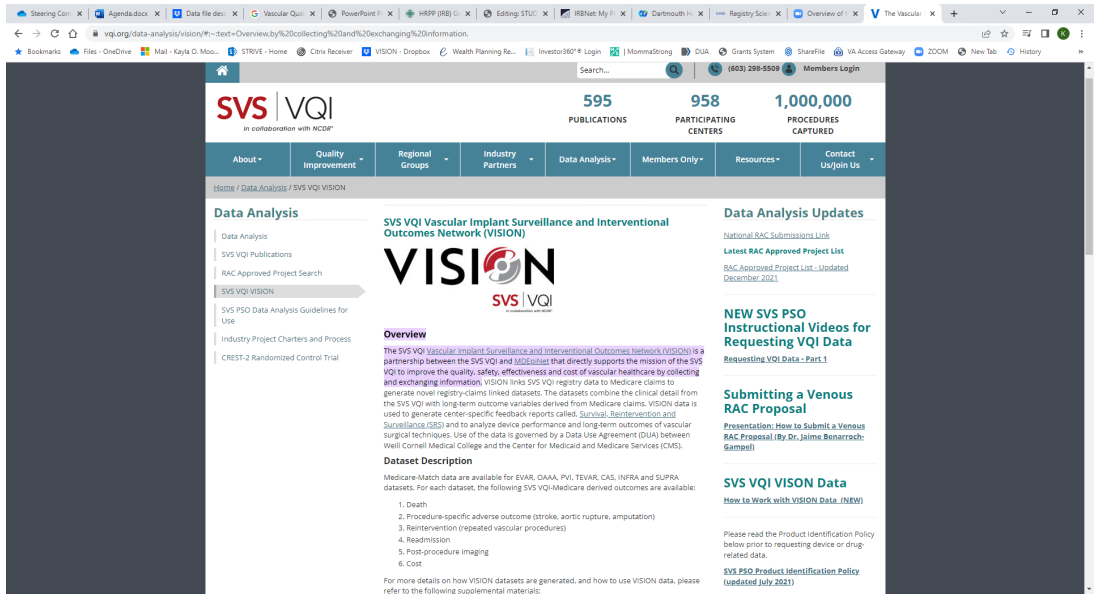
## Rules Governing use of CMS Data

- Data must remain on secure HIPAA/FISMA compliant server
- Access is restricted to individuals named on the DUA
- No individual level data can be removed from the server
- Only aggregate/de-identified data (tables, figures) can be removed from the server.
- Output is reviewed by IT security team prior to transfer to ensure  suppression requirements are applied (no cell sizes less than 11)
- In addition, CMS requires that each DUA be project-specific and tied to a single funding source

# Process for using VQI VISION data

1. Obtain VQI/RAC approval
2. VISION Priorities Committee conducts secondary screening to ensure:
   - ❑Clarity/feasibility of research question
   - ❑Clear need for Medicare data
   - ❑Falls within scope of DUA
3. VISION Analytic Team requests research memorandum
4. VISION Analytic Team works with investigators to refine analytic plan and conduct analyses
5. Aggregate tables and figures are shared for dissemination of findings

https://www.vqi.org/data-analysis/vision

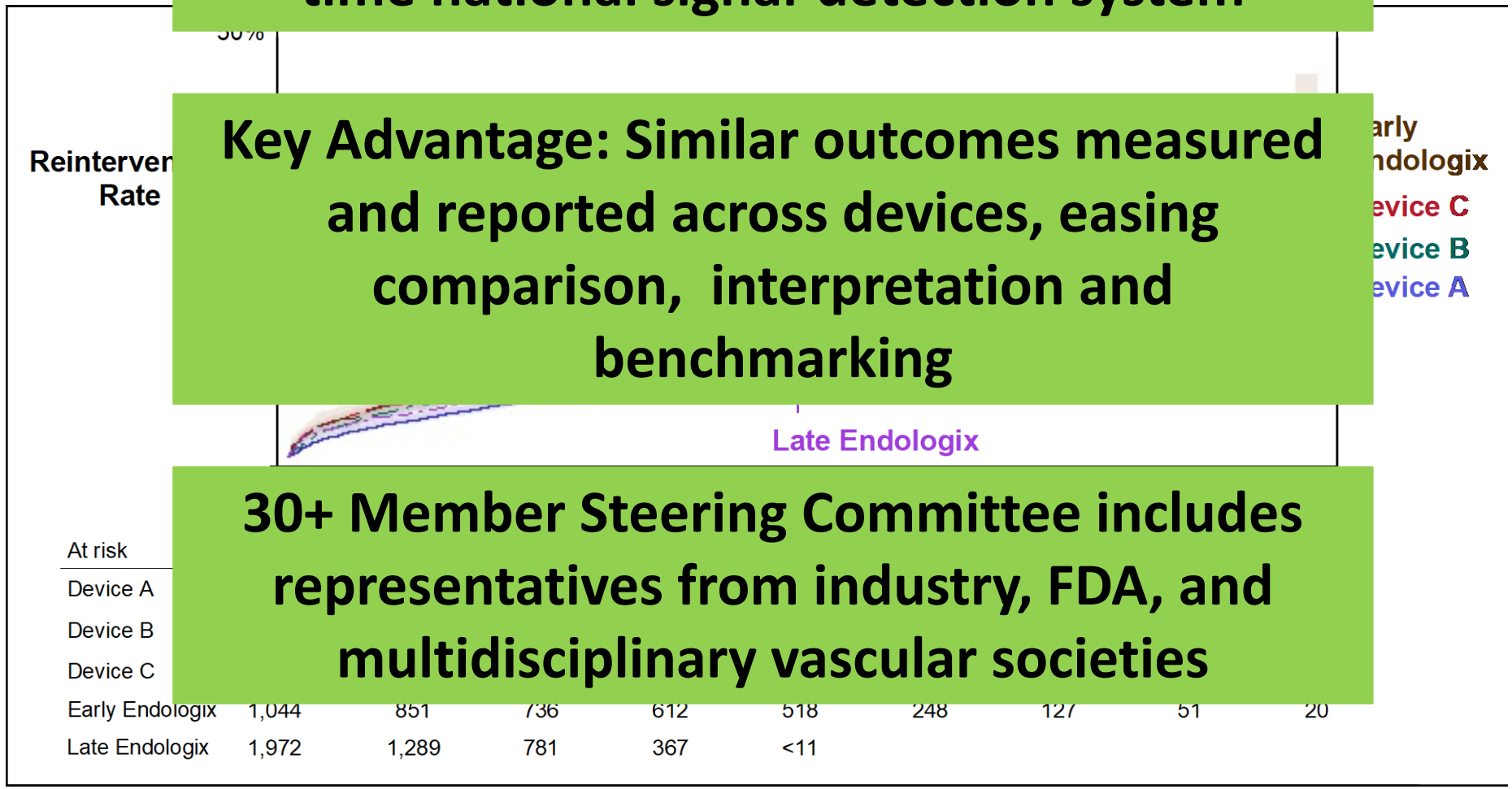


# What's Next: VQI-VISION and Kaiser Collaboratively Built LEAF for Long-Term EVAR Surveillance

**"Device Dashboards" can serve as a near real-time national signal-detection system**

**Key Advantage: Similar outcomes measured and reported across devices, easing comparison, interpretation and benchmarking**

**30+ Member Steering Committee includes representatives from industry, FDA, and multidisciplinary vascular societies**



# VQI/ VISION / Kaiser Permanente Scope, Timeline and Deliverables

**Phase 1**

- Analyses of 2003-2018 data (current CMS DUA)
- Deliverable: Device-Specific SRS Report (2018 data)
- Timeline: 4-8 weeks from start date

**DONE 11/2021**

**Phase 2**

- Analyses of 2003-2019 data (linkages and late-outcomes updated
- Deliverable: Device Specific SRS Report (2019 data)
- Timeline: 2-5 months from start date

**DONE 6/2022**

**Phase 3**

- <u>New VRDC DUA</u>- Analyses of most recent available data (2003 - present)
- Deliverable: Device-Specific SRS Report (up to present year)
- Timeline: 12 – 18 months from start date

**Phase 4**

- <u>Phase 4a: Vascular Research Collaborative (VRC) – Led Chart Review:</u>
  - VQI Centers to collect additional reporting via additional existing CRF
  - Deliverable: Additional CRF collected for device-specific analyses as prompted by Phases 1-3
  - Timeline 6-12 months from start date
- <u>Phase 4b: Vascular Research Collaborative (VRC) – Led Chart Review and Imaging Upload and Review:</u>
  - VQI Centers to collect additional images for Core Lab review for relevant questions
  - Deliverable: Additional imaging and clinical data collected and reviewed as prompted by Phases 1-3
  - Timeline 12-18 months from start date

# Preliminary Collaboration and Planning

| Preliminary Work | SVS VQI In collaboration with NCDR® | KAISER PERMANENTE® | Industry Teams |
|---|---|---|---|
| Defining outcomes | Existing data/discussions | Existing data/discussions | Conference calls, planning, review |
| Preliminary data harmonization | Existing data/discussions | Existing data/discussions | Conference calls, planning, review |
| Mock Report Generation | Modification of standardized existing process | Modification of standardized existing process | Conference calls, planning, review |
| Data gathering, Sharing, and Governance planning | Collaborative plans and discussions | Collaborative plans and discussions | Collaborative plans and discussions |

# Efficiency: LEAF Reports Are Built on Existing VQI Survival, Reintervention, and Surveillance Reports

SVS | VQI
VASCULAR QUALITY INITIATIVE

## Vascular Quality Initiative Endovascular Abdominal Aortic Aneurysm Repair (EVAR) Survival, Reintervention, and Surveillance Report

This report presents the following three outcomes related to the quality of care provided to Medicare patients treated with EVAR:

A: Your center's five-year freedom from reintervention rate compared to all other VQI centers.

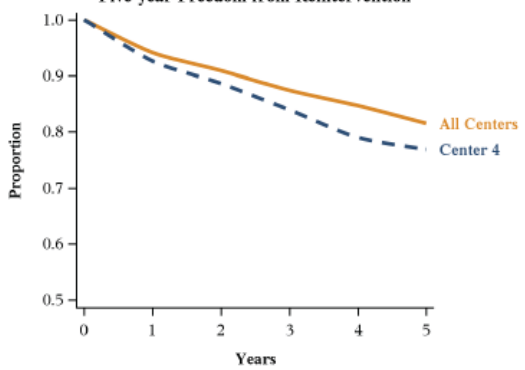
B: Your center's five-year survival rate compared to all other VQI centers.

C: Your center's five-year freedom from imaging surveillance failure rate compared to all other VQI centers.

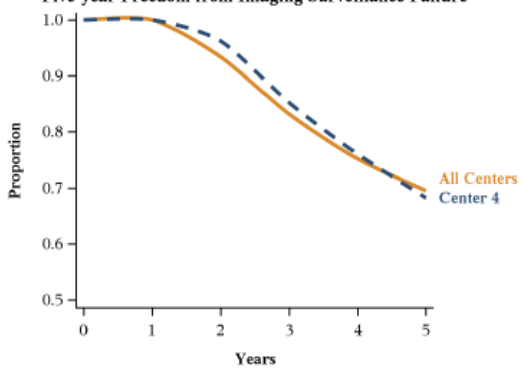
These data are derived from 2003-2016 VQI registry data matched to Medicare fee-for-service claims, and are made possible by the Vascular Implant and Interventional Outcomes Network (VISION), a partnership between the SVS PSO and MDEpiNet.

*Center data are not shown for centers with fewer than 11 events due to CMS suppression requirements.*

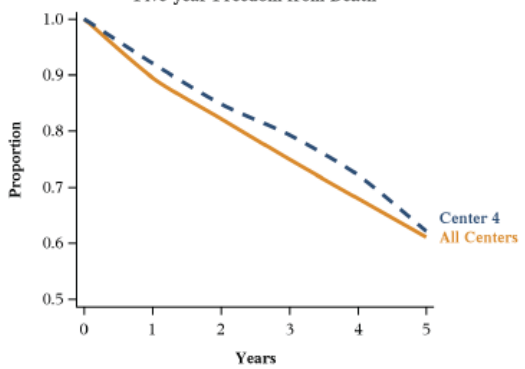
Five-year Freedom from Reintervention




Five-year Freedom from Imaging Surveillance Failure




Five-year Freedom from Death




***Selected Patient Characteristics***

| Characteristic | Center 4 | Overall |
|---|---|---|
| Median AAA Diameter | 5.7 | 5.5 |
| Median Age | 77.0 | 76.0 |
| % Male | 75.8 | 79.2 |
| % Urgent/Emergent | 9.0 | 12.5 |

'---' indicates fewer than 11 events; data suppressed per CMS requirements

**References:** Columbo et al, Ann Surg 2019; Hoel et al, JVS 2019, Columbo et al, JVS 2019, Wanken et al, JVS 2019

SVS | VQI
*In collaboration with NCDR®*

KAISER PERMANENTE®

# Summary

- **Outline the VQI-VISION coordinated registry network**
  - ***Seminal publication for device surveillance using linked datasets***
- **Share Key Findings from VQI-VISION, and VISION Infrastructure**
  - ***Linkage to registries are an important element***
- **Describe what is next for VQI-VISION**
  - ***Industry partnership and reporting for sustainability and impact***

MDEpiNet

SVS | VQI
In collaboration with NCDR®

KAISER PERMANENTE®