CMSS Presents:

Sustainability and Member Engagement

October 31, 2022
CMSS Webinar: Sustainability and Member Engagement of Registries

Flora Lum, MD
Vice President, Quality and Data Science
American Academy of Ophthalmology
October 31, 2022
What is the IRIS Registry?

IRIS Registry (Intelligent Research in Sight) is the nation’s first comprehensive eye disease clinical database, started March 25, 2014

• Improve care delivery and patient outcomes
• Provides individual feedback on performance and comparison to benchmarks
• Helps practices meet Merit-based Incentive Payment System requirement (MIPS)
Current Stats (July 1, 2022)

Contracted
- **18,020** physicians from **4,147** practices

Contracted for EHR Integration
- **15,799** physicians from **3,002** practices

Number of patient visits
- **454.00** million, representing **75.40** million pts
Quality Improvement

• Does quality improve with Actionable Feedback and Targeted Education?

• There is demonstrated improvement on quality measures over 3 years using the IRIS Registry

## Quality Measures – EHR Dashboard

<table>
<thead>
<tr>
<th>FAVORITE</th>
<th>ID</th>
<th>MEASURE</th>
<th>ACHIEVED PERFORMANCE</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>QPP 12</td>
<td>Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation</td>
<td>76.26 %</td>
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<tr>
<td></td>
<td>QPP 19</td>
<td>Diabetic Retinopathy: Communication with the Physician Managing</td>
<td>96.48 %</td>
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<td></td>
<td>QPP 110</td>
<td>Preventive Care and Screening: Influenza Immunization</td>
<td>81.91 %</td>
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<tr>
<td></td>
<td>QPP 111</td>
<td>Pneumococcal Vaccination Status for Older Adults</td>
<td>90.01 %</td>
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<tr>
<td></td>
<td>QPP 117</td>
<td>Diabetes: Eye Exam</td>
<td>96.79 %</td>
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<tr>
<td></td>
<td>QPP 128</td>
<td>Preventive Care and Screening: Body Mass Index (BMI) Screening &amp;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>QPP 130</td>
<td>Documentation of Current Medications in the Medical Record</td>
<td>87.73 %</td>
</tr>
<tr>
<td></td>
<td>QPP 191</td>
<td>Cataracts: 20/40 or Better Visual Acuity within 90 Days Following C</td>
<td>81.59 %</td>
</tr>
</tbody>
</table>
Quality Measures – EHR Dashboard

Practice: Web Demo Test Data
Measure: QPP141 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care
Population: Denominator

<table>
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<tr>
<th>FIRST NAME</th>
<th>MIDDLE NAME</th>
<th>LAST NAME</th>
<th>MRN</th>
<th>GENDER</th>
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<td>Mouse</td>
<td>MOUSEM1</td>
<td>M</td>
<td>11/18/1928</td>
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</table>
How to Use IRIS Registry/EHR Integration to Boost Practice Performance

Why integrate your electronic health record (EHR) system with the IRIS Registry? First, it enables you to compare your performance against that of your peers and identify areas where you can improve patient care. It also provides the least burdensome way to participate in the Merit-Based Incentive Payment System (MIPS), and as a qualified clinical data registry (QCDR), it can offer subspecialty-specific MIPS quality measures that aren’t available anywhere else. Furthermore, use of the IRIS Registry is free for U.S. Academy members and their staff.

To help you make the most of IRIS Registry/EHR integration, this article highlights some proven strategies.

4 Practices Share Their Tips
The Academy spoke to 5 IRIS Registry users at 4 U.S. practices about their use of the IRIS Registry. All of them emphasized its convenience and utility for performance monitoring and quality improvement.

Karen Potts, in Oregon, that has 4 providers at 2 sites. Karen Potts stated that using the IRIS Registry to track performance rates had become second nature at her practice, thanks in no small part to its ease of use. Ms. Potts is the office manager at Kozioz-Thoms Eye Associates, a practice in Arlington Heights, Illinois, that has 6 providers.

Michele Huskins added that she runs reports on the group as a whole as well as reports for individual providers. She can print these and hand them to the clinicians, or send them electronically. She works at Rocky Mountain Eye Center, a 19-provider practice in Pueblo, Colorado.

Ufuk Fusun Cardakil, MD, described the IRIS Registry as a tremendous resource that helps her solo practice navigate MIPS. She runs EyeDoc Associates in Altoona, Pennsylvania.

Tip 1: Regularly Review Your IRIS Registry Dashboard
Look at the data monthly. All 5 interviewees urge you to regularly review the data following these numbers, looking monthly, as soon as the data are refreshed, comparing her performance to the IRIS Registry benchmarks. She sets a goal of reaching 95%-100% on the quality measures.

IRIS Registry benchmarks differ from MIPS benchmarks. The benchmarks on the IRIS Registry are derived from the current performance of all practices that have integrated their EHR system with it. These differ from the benchmarks that the Centers for Medicare & Medicaid Services (CMS) uses to evaluate performance on MIPS quality measures. For 2018, those CMS benchmarks are based on performance rates of all clinicians who used those measures in 2016.

Break down your practice’s performance on a measure. Clinicians can use the dashboard to see how they performed as individuals, how the practice performed as a group, and how the individual- and practice-level performance compares to the average across all physicians in the IRIS Registry.
Targeted Education

**Improving Outcomes in Cataract Surgery: Targeting Best Corrected Visual Acuity**

Leela V Raju MD
Comprehensive Ophthalmology, Refractive Management, Cataract/Anterior Segment

Launch Learning Plan

This learning plan, based on IRIS Registry measure IRIS59: Regaining Vision After Cataract Surgery, offers pearls for managing posterior capsule ruptures, preventing posterior segment complications of phacoemulsification, and managing intraoperative floppy iris syndrome (IFIS) and small pupils.

**Assessing Risk of Glaucoma Progression**

American Academy of Ophthalmology, Michelle R Butler MD, Helen L Kommann, MD
Glaucoma

Launch Learning Plan

This learning plan, based on IRIS Registry measure IRIS44: Visual Field Progression in Glaucoma, reviews tools to assess the risk of glaucoma progression and the factors to consider when deciding stepwise treatment.

**Anti-VEGF Therapy in Patients with Neovascular AMD**

American Academy of Ophthalmology, Ghazala A Datoo O'Keefe, MD
Retina/Vitreous

Launch Learning Plan

This learning plan, based on IRIS Registry measure IRIS45: Exudative Age-Related Macular Degeneration: Loss of Visual Acuity, reviews the impact of anti-VEGF injections in patients with wet age-related macular degeneration (AMD), including genetic predictive biomarkers of anti-VEGF treatment responses.
“The IRIS Registry will represent a seminal change in how the medical specialty of ophthalmology will improve performance and outcomes, while shortening the timeline for the dissemination of important clinical knowledge, research and results of drug and device surveillance.”

David W. Parke II, MD

Former Academy CEO
59 IRIS Registry Articles through Sept 2022
174 IRIS Registry Presentations/Posters through Sept 2022

ASRS | American Society of Retina Specialists
---|---
Canadian Ophthalmological Society | Société canadienne d’ophtalmologie
ASCRS | American Society for Retinal Disease
American Diabetes Association | The Retina Society
ARVO | The Association for Research in Vision and Ophthalmology
World Glaucoma Association | The Macula Society
AMERICAN | UVEITIS SOCIETY
Verana Research Network

An IRIS® Registry initiative to advance data-driven clinical research and care.

IRIS® Registry (Intelligent Research in Sight) is an initiative and registered trademark of the American Academy of Ophthalmology®
IRIS Registry Main MIPS Reporting Tool for Ophthalmologists, 2017-2021

• Higher average score for ophthalmologists than average MIPS participant
• $1.20 billion in avoided penalties or $118,962/ophthalmologist over 5 years
• Majority of ophthalmologists earned an exceptional performance bonus
• 0.10% - 1.87% of Medicare Fee Schedule (based on 2017-2021 reporting years)
• Translates to $402 - $7,191 bonus per ophthalmologist/year
• $1,608 - $28,764 bonus per ophthalmologist for 2017-2021 reporting years
IRIS Registry Participants MIPS Penalty Avoidance 2017-2021

$1.2 Billion
$118,962/opthalmologist
Summary: Reasons for Clinicians to Participate

• Quality Improvement
  o Benchmarks
  o Feedback
  o Targeted Education

• Scientific Discovery
  o Big Data Analyses
  o Clinical Trials

• Quality Payment Program
Sustainability and Member Engagement: The Why, What and How

A Society Perspective
Vishakha K. Kumar, MD, MBA
Director, Research and Quality
Society of Critical Care Medicine
@vishkkumar

Relevant to this presentation

Disclosures: Co-Principal Investigator for VIRUS Registry
Received funding: The Gordon & Betty Moore Foundation, Janssen R&D LLC, ASPE/FDA
Overview

• WHY: Need for Registry / Data Effort
• WHAT: Member Engagement
• HOW: Sustaining such an Effort
About SCCM

• The Society of Critical Care Medicine (SCCM) is the largest nonprofit medical organization dedicated to promoting excellence and consistency in the practice of critical care.

• With more than 17,000 members in 100+ countries, SCCM offers a variety of activities that ensure excellence in patient care, education, research, and advocacy.

• SCCM's mission is to secure the highest-quality care for all critically ill and injured patients.

• SCCM envisions a future where multiprofessional teams use knowledge, technology, and compassion to provide timely, effective, safe, efficient, and equitable patient-centered care.
Why the Need for Registry/Data Effort

• Focus was building the research infrastructure to support investigator initiated research studies.
• Early programmatic successes, however significant resources required with data collection for research studies.
• Specifically during the pandemic we learnt a few lessons along the way that helped us strategize to better support investigator/ members, with sustained and continued engagement.
Discovery VIRUS:COVID-19 Registry

VIRUS COVID-19 Registry
A COVID-19 REGISTRY OF CURRENT ICU AND HOSPITAL CARE PATTERNS

- The Viral Infection and Respiratory Illness Universal Study (VIRUS): An International Registry of Coronavirus 2019-Related Critical Illness
- Walkey, Allan J.; Kumar, Vishakha K.; Harhay, Michael O.; Bolesta, Scott; Bansal, Vikas; Gajic, Ognjen; Kashyap, Rahul; for the Society of Critical Care Medicine Discovery, Critical Care Research Network
- doi: 10.1097/CCE.0000000000000113

Timeline of Society of Critical Care Medicine (SCCM) Discovery Viral Infection and Respiratory Illness Universal Study (VIRUS) Coronavirus Disease 2019 (COVID-19) database design and development. CRF = case report form, FAQ = frequently asked question, IRB = institutional review board, REDCap = Research Electronic Data Capture, SOP = standard operating procedure.
**WHAT** did the Registry do for Members
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• Engaged a group of Core Investigators to drive adult and pediatric scientific content from the registry
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• Developed a scientific community of >3000 member and non-member volunteers globally
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• Created local data automation leaders
**WHAT** did the Registry do for Members

- Engaged a group of Core Investigators to drive adult and pediatric scientific content from the registry
- Developed a scientific community of >3000 Volunteers globally
- Created local data automation leaders
- **Collaborators**

![Collaborators Diagram]

- SCCM
- Academic/ Hospitals: Mayo, BU, Emory, PRISMA,
- Other Registries – AHA etc.
- PointClick Care
- EHRs
- American College of Radiology
**WHAT** did the Registry do for Members

- Engaged a group of Core Investigators to drive adult and pediatric scientific content from the registry
- Developed a scientific community of >3000 Volunteers globally
- Created local data automation leaders
- Collaborators
- Publications and Ancillary Projects
Guiding Principles for the Conduct of Observational Critical Care Research for Coronavirus Disease 2019 Pandemics and Beyond: The Society of Critical Care Medicine Discovery Viral Infection and Respiratory Illness Universal Study Registry

Allan J Walkey 1, R Christopher Sheldrick 2, Rahul Kashyap 3, Vishakha K Kumar 4, Karen Boman 4, Scott Bolesta 5, Fernando G Zampieri 6, Vikas Bansal 3, Michael O Harhay 7, Ognjen Gajic 8

Affiliations + expand

PMID: 32932348   DOI: 10.1097/CCM.0000000000004572

![Image](83x0 to 529x792)

**Figure 2.** Pathways for rapid and rigorous generation and dissemination of knowledge in a pandemic setting.
How Covid Overwhelmed One L.A. Hospital in California’s Worst-Hit County

https://nyti.ms/3jtagPC
WHAT did the Registry do for Members

Publications:
• Created member facing tools – VIRUS Dashboard, Critical Care Data Explorer (C2D2E), educational content through COVID-19 RRC
• Created an online platform for investigators to submit research ideas based on Registry Data
  ➢ More than 130 proposal ideas submitted, out of which 68 ancillary studies approved
  ➢ Created data sharing infrastructure (legal, policy, co-author and collaborative authorships guidance and data access and analytics)
• Ancillary Projects:
  ➢ STOP VIRUS: Quality Improvement Project that assessed the effectiveness of virtual coaching in a pragmatic implementation trial
  ➢ A Multicenter Qualitative Study on Facilitators and Barriers to the Implementation of New Critical Care Practices during COVID-19
Metabolic Syndrome and Acute Respiratory Distress Syndrome in Hospitalized Patients With COVID-19

Joshua L. Denson, MD, MS1; Aaron S. Gillett, BSc; Yuanhao Zu, MPH2; Margo Brown, BS1; Thidinan Phan, BS1; Yilin Yoshida, PhD1,2; Franch Massons-Jarvis, MD, PhD1,2; Ivo S. Douglas, MD3; Matthew Moore, BS1; Kevin Tao, BS1; Andrew Wetherbee, BS1; Rachel Stevens, BS1; John Lefante, PhD2; Jeffrey G. Shaffer, PhD2; Donna Lee Armanagac, PhD, APN3; Katherine A. Bleden, MD3; Margit Kaufman, MD3; Smith F. Heaver, MS, RN4; Valerie C. Danesh, PhD, RN1; Sreekankth R. Cherukuri, MD, MPH1,2; Catherine A. St. Hill, DVM, PhD5; Karen Boman, BS1,4; Neha Deo, BS1,4; Vikas Bansal, MBBS, MPH2,5; Vishakha K. Kumar, MD, MBA1,2; Allan J. Wallen, MD, MSc1,2; Rahul Kashyap, MBBS, MBA1,2; for the Society of Critical Care Medicine COVID-19 Registry Investigators

Author Affiliations | Article Information
PMCID: 14920214

Lessons From a Rapid Project Manager: Pandemic Methodology for a Global CC Database

PMCID: 31769096

Early combination therapy with immunoglobulin and steroids is associated with shorter ICU length of stay in Multisystem Inflammatory Syndrome in Children (MIS-C) associated with COVID-19: A retrospective cohort analysis from 28 U.S. Hospitals

Aaron A. Harthan, Meghan Nadiger, Jeremy S. McGarvey, Keith Hanson, Varsha P. Charpure, Erica C. Bjornstad, Kathleen Chiotas, Aaron S. Miller, Ronald A. Reikoff, Ognjen Gajic... See all authors

First published: 06 June 2022 | https://doi.org/10.1002/phar.2709
HOW to Sustain & Build further on this Effort

**Challenges:**

- Volunteer driven
- Resources heavy at many institutions – manual or local data entry
- Limitation on institutional data sharing
- COVID-19 burnout
- Keeping registries up to date
HOW to Sustain & Build further on this Effort

*Strategy to Sustain:*

- Leverage collaborations
HOW to Sustain & Build further on this Effort

Strategy to Sustain:

• Leverage collaborations
• Provide a mentorship platform
HOW to Sustain & Build further on this Effort

**Strategy to Sustain:**
- Leverage collaborations
- Provide a mentorship platform
- Expand institutional infrastructure

**Discovery Data Science Campaign**

**Mission**
The mission is to improve the care of critically ill patients by leveraging the use of large-scale data (big data) for research capabilities with the ultimate goal of application in a clinical environment through standardized data models and shared resources.

**Vision**
The vision is to leverage the opportunities afforded by the rapidly evolving field of data science to enhance knowledge, advance research, and improve outcomes for critically ill patients.
HOW to Sustain & Build further on this Effort

**Strategy to Sustain:**

- Leverage collaborations
- Provide a mentorship platform
- Expand institutional infrastructure
- Leverage investigator/sites involved for other studies

**Aggregating and Analyzing COVID-19 Treatments from EHRs & Registries Globally using the EDGE Tool**
HOW to Sustain & Build further on this Effort

Strategy to Sustain:

• Leverage collaborations
• Provide a mentorship platform
• Expand institutional infrastructure
• Leverage investigator/sites involved for other studies
• Going beyond COVID and leveraging infrastructure for new initiatives

Development of clinical practice embedded adaptive platform, for randomized clinical trials to develop safe and effective drug treatments for hospitalized patients
Summary

• For continuous engagement and sustainability of registries driving the WHY, WHAT, and HOW is driven by the organizational and programmatic strategies.

• For deploying such strategies important to have the value proposition to those involved at all levels, clear guidance around key performance metrics, and open to broader collaborations.
Thank you

Vishakha K. Kumar, MD, MBA
@vishkkumar

vkumar@sccm.org
Coordinated Registry Networks: a research/development agenda to increase value and sustainability

Gregory Pappas MD PhD
FDA/CBER/OBE  Associate Director
Disclosure

This presentation represented the views of the presenter and not policy of FDA or FDA Centers.
Overview

- Where we started with RWE: Policy context
- Development of CRN

*I’m going to whiz through these two, more as a recap of what you heard. The slides with links are here as a reference.*

- Research and development agenda for CNR: determination of value of RWE and a to build national infrastructure for RWE
Registries and CRNs: Intersections of FDA, MDEpiNet and NEST

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

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

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

2010 MDEpiNet Launch
International Registry Consortia (e.g. ICOR)

2011

2012

2013

2014

2015

2016

2017

2018

2019

2020

MDEpiNet Methodology Center at Harvard
MDEpiNet Science and Infrastructure Center at Cornell

ICVR

NEST Data Collaborators Network

CRN Collaborative Learning Communities

CRN Community of Practice

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

ICVR

NEST Data Collaborators Network

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

ICVR

NEST Data Collaborators Network

CRN Collaborative Learning Communities

CRN Community of Practice

Tools for assessing the Usability of Registries for Regulatory Decision Making, March 2018
Federal Partners supporting CRN development

- ONC, NLM, NIH, AHRQ working closely with a CRN
- ASPE through the PCORTF has funding CRN
21st Century Cures Act

- **Cures Act** was signed into law on December 13, 2016
- Authority and funding for RWE
- Administration is tasked with developing a program to “evaluate the use of RWE to support approval of new indications for approved drugs or to satisfy post-approval study requirements”

  Section 3022. 21st Century Cures Act, 21 USC §355g.
Pre-post market balance final guidance part of a broader effort to make regulatory decision making “better, faster, and cheaper”

Pre-post market balance requires the robust post market data sources that CRN can provide.
Coordinated Registry Networks (CRNs) have emerged as a key resource

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.)

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

A decade of development; over 300 publications.
CRN business model: “Collect once; use many times.”:

- Quality assurance/improvement
- Benchmarking of hospital and interventionist performance.
- Support training
- Research and development
- FDA for post approval studies, label changes and expansions, compliance studies, signal detection
- CMS national coverage decisions
CRN business model: “Collect once; use many times.”:

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- Benchmarking of hospital and interventionist performance.
- Support training
- Research and development
- FDA for post approval studies, label changes and expansions, compliance studies, signal detection
- CMS national coverage decisions

*Sustainable resources.*
CRN Methods: Data sources and linkage

Cohort of patients and exposures to products

Outcomes
CRN Methods: Data sources and linkage

Based on a rich literature lead by MDEpiNet
Creation of a data network = CRN

Add PRO from apps, add EHR, add data from wearables, add data out of medical devices, add mortality statistics.
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.

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)

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

30 publications / 6 validation studies in high impact journals

Total Procedures Captured (as of 1/1/2022)

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<td>Open AAA Repair</td>
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<tr>
<td>Vascular Medicine Consult</td>
<td>376</td>
</tr>
<tr>
<td>Venous Stent</td>
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880 clinical sites
3000 providers
> 200 types of devices
Current CRNs: a community of practice

**National:**
- Robotic-Assisted Surgical Devices (RASD)
- Abdominal Core Health
- Women’s Health Technologies (WHT)
  - Urogynecology Devices CRN
- Vascular Implant Surveillance and Interventional Outcomes Network (VISION)
- Orthopedic Devices
- Study of Prostate Ablation Related Energy Devices (SPARED)
- National Breast Implant Registry (NBIR)
- Devices used for Acute Ischemic Stroke Intervention (DAISI)
- Temporomandibular Joint (TMJ)
- Venous Access: National Guideline & Registry Development (VANGUARD)
- Cardiac Devices
- End Stage Renal Disease (ESRD)
- American Society for Hematology Data Hub

**International:**
- International Cooperative of Colorectal Cancer (IC3)
- International Consortium of Orthopedic Registries (ICOR)
- International Consortium of Vascular Registries (ICVR)
Framework of Maturity of CRNs and Registries

7 Key Domains and 5 Levels of Maturity

**Product Identification:**
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

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

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Example: Optimized Data Collection Efficiency

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

* in press – “Advancing the Real-World Evidence for Medical Devices through Coordinated Registry Networks” BMJ SIT
The case for Biologics: specialty registries collect data on multiple products (regulated by different FDA Centers)

- Biologics in the pipeline
  - Gene editing
  - Biologic valves
  - Biologic vascular devices
  - Zenotransplants
- Some of the mature CRN (example cardiology, vascular surgery) will be collecting data on biologic products as those products become available.
- Vaccine safety increasingly rely on registries, including international
- Dr. Marks is supportive of work with the Data Hub of at the American Society for Hematology Research Collaborative
A new CRN

- **American Society for Hematology Research Collaborative** is building a Data Hub that current is collecting data on patients with Sickle Cell Disease and Multiple Myeloma

- A combination of a platform trial and post market registry of the 30 academic medical centers that have hematology departments and a CRN.
My reading of 21st Century Cure is that the FDA evaluation of RWE should determine if it is “better, faster, cheaper”,

- Isn’t this why we are interested in RWE?
- Needs measurement
Three case studies document the value created by the CRN; this is the basis for a broader framework to guide future work.


Pouline et al. “Determining Value of the use of US Abdominal Hernia Registries to support evaluation of Safety and Efficacy of Surgical Mesh and Related Technology.” under review
Value created by CRN has been documented*

Over $100 million saving to three companies on 23 decisions, years of time saves, and more robust findings

* “Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions” CDRH 90 examples
Time frame from study design to regulatory submission

- Study Design
- IRB Review / IDE Approval
- Clinical Data Generation
  - Study Enrollment / Accrual
  - Follow-up
  - Analysis
- Marketing Application Submission

1. First subject enrolled
2. Last subject enrolled
3. Follow-up Complete Database locked.
"Better" documented through case studies

- Post approval studies tend to use a small sample
  - Registries can provide study of large population and explore **heterogeneity of effect**; race, ethnicity, age, sex, operator, context/site

- Registry also can begin to understand the full complexity of a patient with multiple conditions and treatments, something RCT avoid.

- In the past many post approval studies were never completed; feasibility of studies and lower burden is another criteria for "better"
A decade of exploration on RWE at FDA has led to some conclusions and a convergence between medical product centers around registries and CRN.

- **CDRH has documented 90 decisions** supported by RWE
  - 70% of them use Coordinated Registry networks. The others are “one-off” solutions
  - Registries have been used for post approval, label changes, compliance studies, and signal detection
- **CBER using and exploring use of registries**
  - Vaccine registries
  - Linkage of CMS claims data
  - ASH RC RWE Initiative
- **OCE have benefited by platform trials – e.g., iSPY**
- **CDER using and exploring use of registries**
  - Concato and Corrigan-Curay “Real-World Evidence — Where Are We Now?” NEJM 2022 describes two approvals using registries.
  - Guidance for the use of registries has been produced.
  - CDER CBER RWE Subcommittee
Research agenda: to support CRN development across medical product areas

- **Determination of value of RWE**
- **Build infrastructure for CRN**
Determination of value of RWE efforts will benefit from a framework to guide future work: need to expand to other products and other stakeholders.

<table>
<thead>
<tr>
<th>Medical product industry</th>
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<tbody>
<tr>
<td>Patients</td>
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<tr>
<td>Clinicians and their professional societies</td>
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<tr>
<td>Regulatory Agencies</td>
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<tr>
<td>Public Health</td>
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Value determination started with product manufactures, to encourage them to consider using RWE/CRN, but can be extended to other stakeholders.
### Start of a framework: MDEpiNEt work in progress

#### Value propositions for stakeholders

<table>
<thead>
<tr>
<th>Support regulatory decision making</th>
<th>Research for improved product development –</th>
<th>Quality assurance/improvement –</th>
<th>Training</th>
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<tbody>
<tr>
<td>• Improved determination of safety and efficacy – FDA, industry, clinicians, public health</td>
<td>• patients, clinicians, industry</td>
<td>• clinicians and their associations, medical systems, and patients</td>
<td>• clinicians and their associations</td>
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<td>• Support evidence of reimbursement – CMS, industry</td>
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<td>• Support evidence of value for cost – CMS, industry</td>
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<tr>
<td>• Support negotiation of price based on contribution of public/federal to products – CMS, industry, patients, health care providers</td>
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Operationalize the value proposition in three buckets: key performance indicators (metrics and case studies)
Key performance indicators in three buckets: metrics and case studies to operationalize the value proposition

-CHEAPER
Saving on cost of producing evidence
-ROI, percent savings

-Saving on time needed to produce evidence
-Faster to market, faster access by clinicians and patients
-More rapid signal detect within small groups, and rare events

-MORE ROBUST AND USEFUL EVIDENCE (CASE STUDIES)
-Post market safety is enhanced (history of post market commitment is weak)
-Label expansion adds to understanding of safety and efficacy
-Greater understanding of heterogeneity of effect
Key performance indicators in three buckets: metrics and case studies to operationalize the value proposition

- Saving on cost of producing evidence
- ROI, percent savings

- FASTER
  Saving on time needed to produce evidence
  - Faster to market, faster access by clinicians and patients
  - More rapid signal detection

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Key performance indicators in three buckets: metrics and case studies to operationalize the value proposition

- Saving on cost of producing evidence
- ROI, percent savings

- Saving on time needed to produce evidence
- Faster to market, faster access by clinicians and patients
- More rapid signal detect within small groups, and rare events

- BETTER: MORE ROBUST AND USEFUL EVIDENCE (CASE STUDIES)
- Post market safety is enhanced (history of post market study commitment is weak)
- Existing post market system consensus (FAERS, VAERS, MAUDE are weak)
- Label expansion adds to understanding of safety and efficacy
- Greater understanding of heterogeneity of effect

A manuscript to develop a framework is underway.

As public health doctor, this is the most important to me. Safety first!
To increase the use and value of the CRN, they need to mature.

We need a research and development agenda to help them mature.

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Building national infrastructure that support all CRN.
National agenda that builds infrastructure supporting all CRN.

Knowledge management

Improve curation methods

- Data we are collecting in practice is not “semantic interoperability”; messy data is difficult to aggregate
  - “Recommendations for achieving interoperable and shareable medical data in the USA” Szarfman et. al

Linkages

- Mortality data linkage project, ASPE/PCORFT supported project
- Linkage methods
- Linkage to patient app, EHR, and other additional data

Provision of a national All Payer Claims Database (APCD) for linkage

- An APCD for over 65 exists (Medicare) and is very useful
- Legislation support and some funding via ASPE and AHRQ programs

Big data epidemiology and biostatistics

- Methods
The financial sustainability of the registries depends on decreasing the burden on clinicians.

Improve curation methods: Decrease the need for manual curation to lower cost and time of RWE

- Up stream application of harmonization of standards to address semantic interoperability, “messy data.”
  ✓ e.g., SHIELD
- Semi-automated curation tools
  ✓ e.g., eSource
- **Re-design of clinical workflow** to make data collection seamless part of care
- **Natural language processing**

*Drill down on one of the agenda items. If you are interested, we can share a deep dive each area in the broader agenda.*
Anyone can aggregate data, but the Specialty Societies are the right strategic choice; creating a “learning health care systems.”

**CRN are the logical focus for building the Learning Health Care Systems**

- Evidence-based practice
- Clinical decision support (CDS)
- Improve efficiency of larger systems
- Contribute towards broader scientific/medical questions
- Automated REMS
- Its not just about the FDA; its about improving health care
Thank you.

gregory.pappas@fda.hhs.gov