CMSS WEBINAR SERIES:
Registry Science and Research

CMSS Presents:

Sustainability and Member Engagement

October 31, 2022

AMERICAN ACADEMY OF OPHTHALMOLOGY®

Protecting Sight. Empowering Lives.®

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

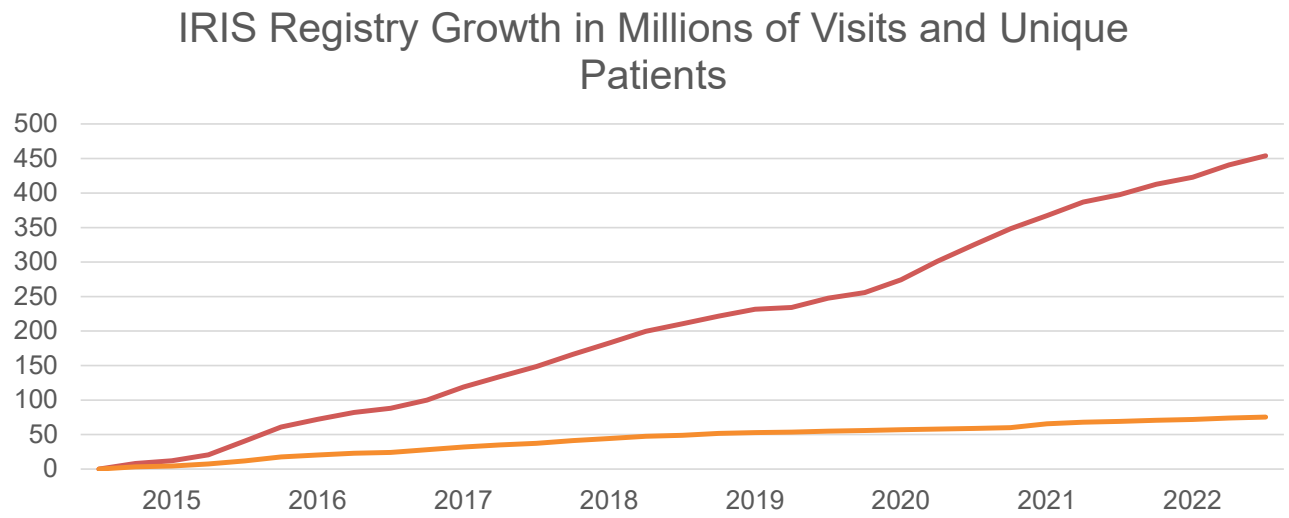
- **18,020** physicians from **4,147** practices

Contracted for EHR Integration

- **15,799** physicians from **3,002** practices

Number of patient visits

- **454.00** million, representing **75.40** million pts



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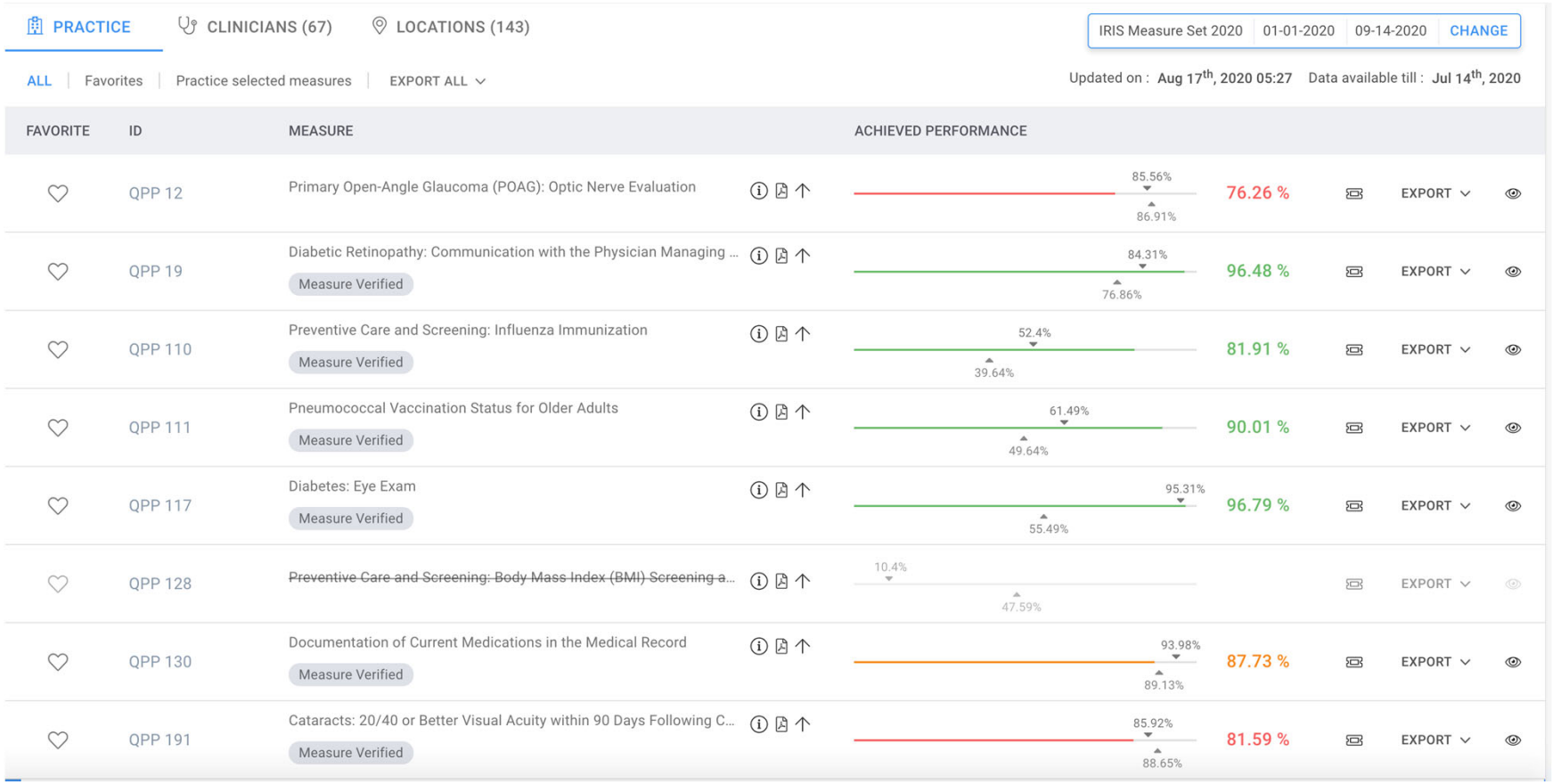
Quality Improvement

- Does quality improve with **Ac*tionable Feedback*** and ***Targeted Education*** ?
- There is demonstrated improvement on quality measures over 3 years using the IRIS Registry
- *Rich W et al. Performance Rates Measured in the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight).* Ophthalmology 2018

Quality Measures – EHR Dashboard



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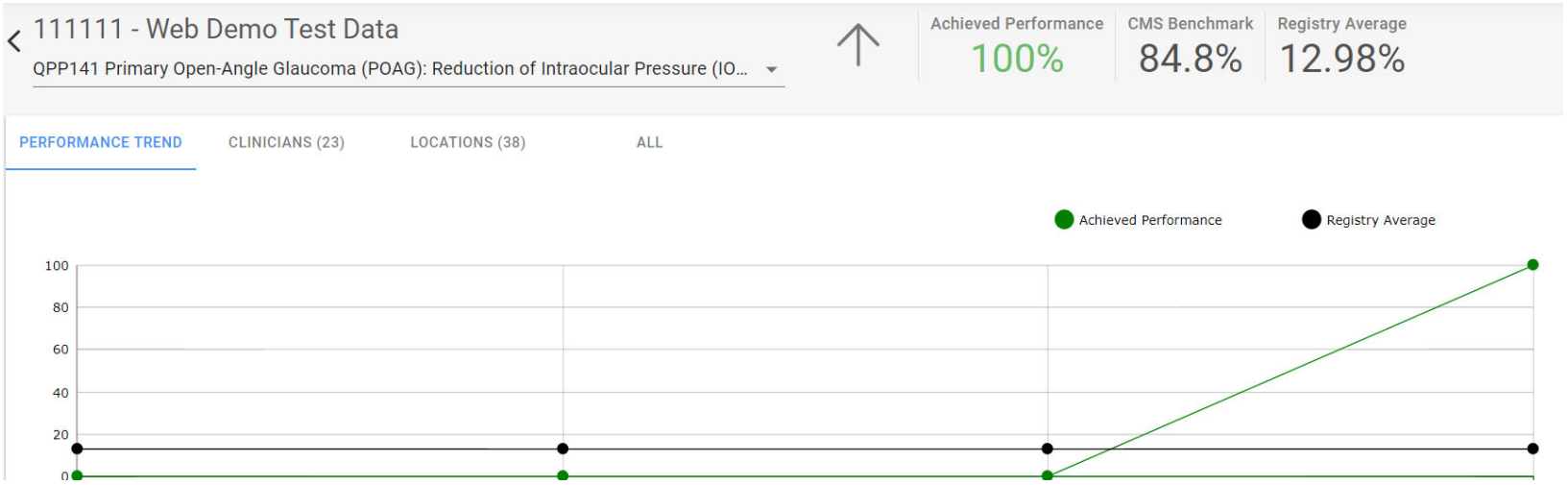
Quality Measures – EHR Dashboard



Practice: Web Demo Test Data

Practice :	111111-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

2019Q1-Denominator-1

EXPORT ALL

FIRST NAME	MIDDLE NAME	LAST NAME	MRN	GENDER	DOB
Mickey		Mouse	MOUSEM1	M	11/18/1928

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 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 Koziol-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 Cardakli, 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 Oregon, that has 4 providers at 2 sites.

follows 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.

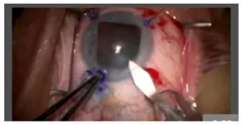
IRIS Registry benchmarks differ from MIPS benchmarks. The benchmarks on the IRIS Registry are derived from the current performance of all practices that have integrated their EHR system with it. These differ from the benchmarks that the Centers for Medicare & Medicaid Services (CMS) uses to evaluate 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

JAN 15, 2020

Improving Outcomes in Cataract Surgery: Targeting Best Corrected Visual Acuity



Leela V Raju MD

Comprehensive Ophthalmology, Refractive Mgmt/Intervention, Cataract/Anterior Segment

CME 2 Self-Assessment *AMA PRA Category 1 Credits™*

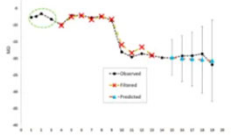
Launch Learning Plan

Add to My Bookmarks | Comments | Views 4965

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.

JAN 15, 2020

Assessing Risk of Glaucoma Progression



American Academy of Ophthalmology, Michelle R Butler MD, Helen L Kornmann, MD

Glaucoma

CME 3 Self-Assessment *AMA PRA Category 1 Credits™*

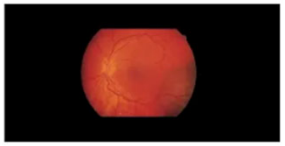
Launch Learning Plan

Add to My Bookmarks | Comments | Views 3434

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.

JAN 15, 2020

Anti-VEGF Therapy in Patients with Neovascular AMD



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

Retina/Vitreous

CME 2.5 Self-Assessment *AMA PRA Category 1 Credits™*

Launch Learning Plan

Add to My Bookmarks | Comments 1 | Views 4444

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.

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“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

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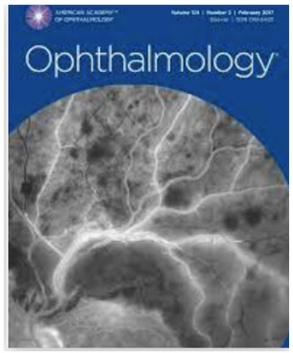
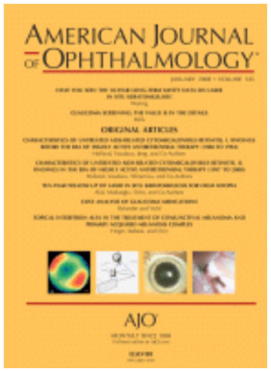
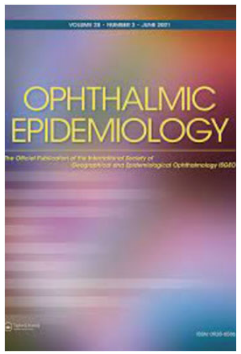
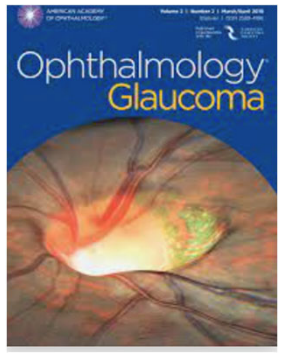
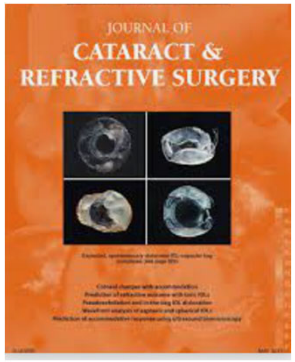
59 IRIS Registry Articles through Sept 2022

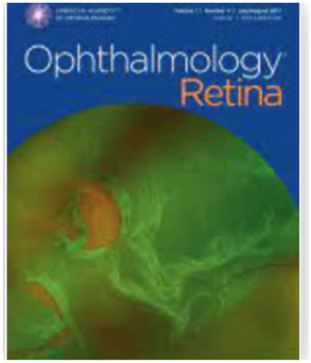












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174 IRIS Registry Presentations/Posters through Sept 2022

ASRS American Society of Retina Specialists

Canadian Ophthalmological Society | Société canadienne d'ophtalmologie
EYE PHYSICIANS AND SURGEONS OF CANADA | MÉDECINS ET CHIRURGIENS OPHTALMOLOGISTES DU CANADA

ARVO The Association for Research in Vision and Ophthalmology

World Glaucoma Association
The Global Glaucoma Network

The Macula Society
Established in 1977

ASCRS

American Diabetes Association

The Retina Society

American Society of Ophthalmic Plastic & Reconstructive Surgery
OCULOFACIAL PLASTIC SURGERY

aapos American Association for Pediatric Ophthalmology and Strabismus

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AMERICAN GLAUCOMA SOCIETY
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Verana Research Network

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

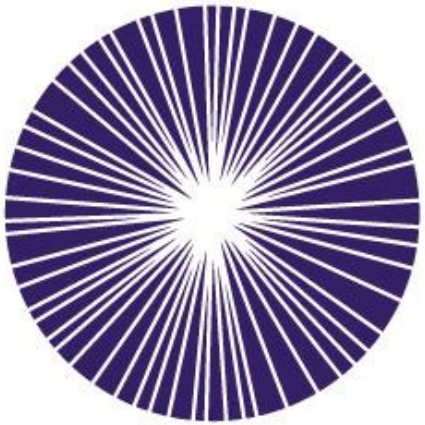
IRIS Registry Main MIPS Reporting Tool for Ophthalmologists, 2017-2021

- 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

Summary: Reasons for Clinicians to Participate

- Quality Improvement
  - Benchmarks
  - Feedback
  - Targeted Education
- Scientific Discovery
  - Big Data Analyses
  - Clinical Trials
- Quality Payment Program



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CMSS Registry Science and Research Initiative

Sustainability and Member Engagement: The Why, What and How

A Society Perspective

Society of Critical Care Medicine
The Intensive Care Professionals

Right Care Right Now

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

Society of Critical Care Medicine
The Intensive Care Professionals

Right Care Right Now

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 then 17,000 member 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.

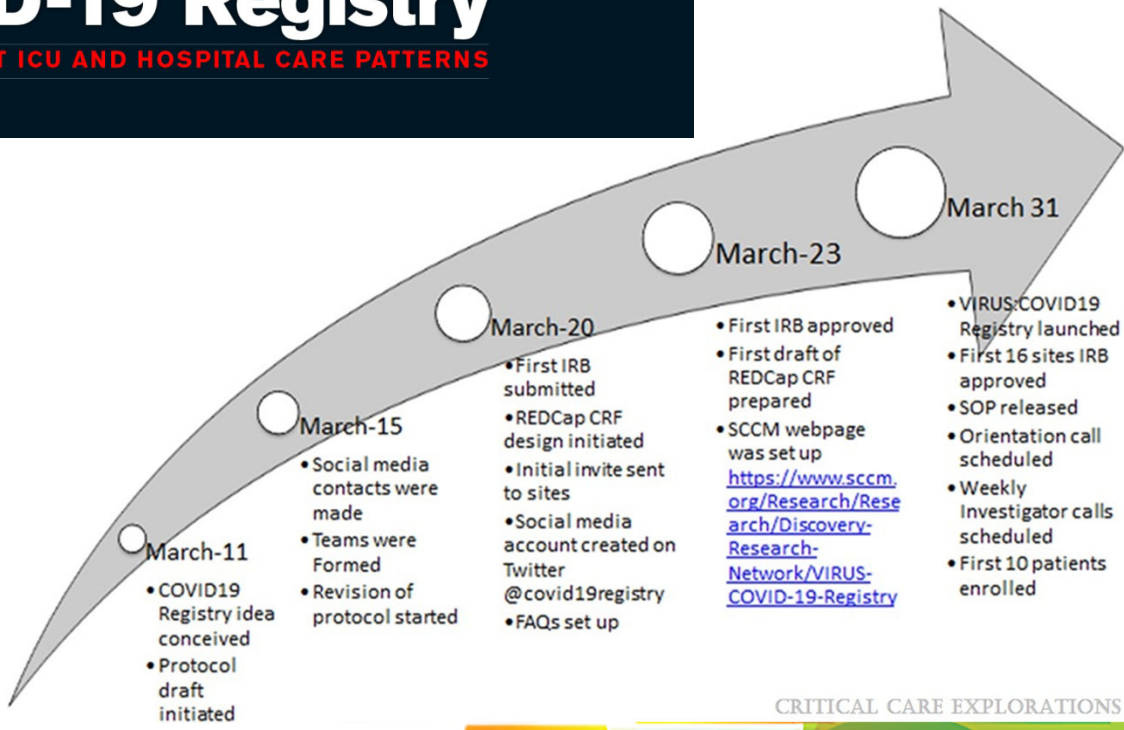
Why the Need for Registry/Data Effort

- Discovery, SCCM's Critical Care Research Network, initiated in 2017.
- 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.

@covid19registry

Discovery VIRUS:COVID-19 Registry

- **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
- Critical Care Explorations2(4):e0113, April 2020.
- doi: 10.1097/CCE.0000000000000113



CRITICAL CARE EXPLORATIONS

Society of Critical Care Medicine
The Intensive Care Professionals

Right Care Right Now

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

Society of Critical Care Medicine
The Intensive Care Professionals

Right Care Right Now

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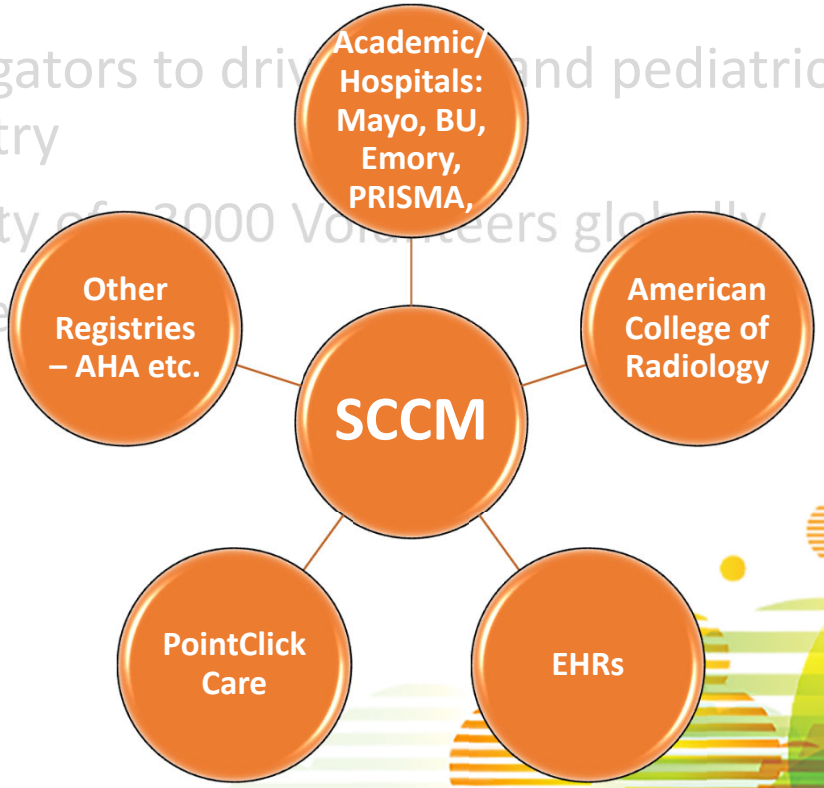
WHAT did the Registry do for Members

- Engaged a group of Core Investigators to driv[illegible]nd pediatric scientific content from the registry
- Developed a scientific community of [illegible]000 Volunteers globally
- Created local data automation le[illegible]
- Collaborators



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
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- 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

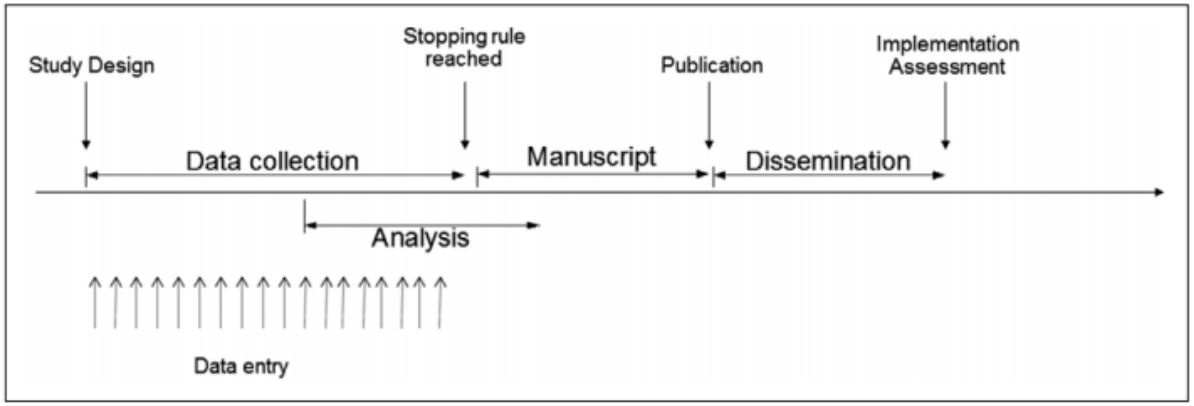

Figure 2. Pathways for rapid and rigorous generation and dissemination of knowledge in a pandemic setting.

TABLE 1. Pandemic Registry Common Data Standards for Critically Ill Patients

Data Goals	Electronic Data Capture
Demographic patient profile	Age, gender, race, ethnicity, geographic localization, presentation to healthcare facility, coronavirus disease 2019 testing.
Clinical patient profile and processes of care	Signs and symptom, comorbidities, Acute Physiologic Assessment and Chronic Health Evaluation-II score, admission diagnosis, prehome medication, daily laboratories, daily vital signs, daily radiological and cardiology evaluation including electrocardiogram, echocardiogram, daily hospital medication/therapy, ventilator-associated pneumonia bundle compliance.
ICU and hospital-related outcomes	ICU length of stay, hospital length of stay, need of ICU admission/support, need for invasive or noninvasive mechanical ventilation, other oxygenation methods, renal replacement therapy need and duration, ICU or hospital discharge status and disposition, ICU and hospital mortality.

Early Publications

List › Crit Care Explor › v.2(4); 2020 Apr › PMC7188422

Critical Care Explorations

Society of Critical Care Medic

Crit Care Explor. 2020 Apr; 2(4): e0113.
Published online 2020 Apr 29. doi: 10.1097/CCE.0000000000000113

The Viral Infection and Respiratory Illness Universal S
International Registry of (

Allan J. Walkey, MD, MSc,[1] Vishakha
Vikas Bansal, MBBS, MPH,[5] Ognjen G
Critical Care Medicine Discovery, Critic

**Guiding Principle
Critical Care Res
2019 Pandemics
Critical Care Mec
Respiratory Illnes**

Allan J. Walkey, MD, MSc[1]; R.
Vishakha K. Kumar, MD, MBA
Vikas Bansal, MBBS, MPH[7]; M

Critical Care Medicine

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Outline

Images

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LATE BREAKER ARTICLES

Outcomes of Patients With Coronavirus Disease 2019 Receiving Organ Support Therapies: The International Viral Infection and Respiratory Illness Universal Study Registry

Domecq, Juan Pablo MD[1]; Lal, Amos MBBS[2]; Sheldrick, Christopher R. PhD[3]; Kumar, Vishakha K. MD, MBA[4]; Boman, Karen[4]; Bolesta, Scott PharmD[5]; Bansal, Vikas MBBS, MPH[2]; Harhay, Michael O. PhD[6]; Garcia, Michael A. MD[7]; Kaufman, Margit MD[8]; Danesh, Valerie PhD, RN[9,10]; Cheruku, Sreekanth MD, PhD[11]; Banner-Goodspeed, Valerie M. MPH[12]; Anderson, Harry L. III MD[13]; Milligan, Patrick S. MD[14]; Denson, Joshua L. MD, MSc[15]; St. Hill, Catherine A. DVM, PharmD[16]; Dodd, Kenneth W. MD[17,18]; Martin, Greg S. MD, MSc[19]; Gajic, Ognjen MD[2]; Walkey, Allan J. MD, MSc[7]; Kashyap, Rahul MBBS, MBA[20]

Author Information

Society of Critical Care Medicine
The Intensive Care Professionals

Right Care Right Now

#CCC50 Society of Critical Care Medicine Critical Care Congress

Outcomes of Patients With Coronavirus Disease 2019 Receiving Organ Support Therapies: The International Viral Infection and Respiratory Illness Universal Study Registry

Domecq, Juan Pablo MD[1]; Lal, Amos MBBS[2]; Sheldrick, Christopher R. PhD[3]; Kumar, Vishakha K. MD, MBA[4]; Boman, Karen[4]; Bolesta, Scott PharmD[5]; Bansal, Vikas MBBS, MPH[2]; Harhay, Michael O. PhD[6]; Garcia, Michael A. MD[7]; Kaufman, Margit MD[8]; Danesh, Valerie PhD, RN[9,10]; Cheruku, Sreekanth MD, PhD[11]; Banner-Goodspeed, Valerie M. MPH[12]; Anderson, Harry L. III MD[13]; Milligan, Patrick S. MD[14]; Denson, Joshua L. MD, MSc[15]; St. Hill, Catherine A. DVM, PharmD[16]; Dodd, Kenneth W. MD[17,18]; Martin, Greg S. MD, MSc[19]; Gajic, Ognjen MD[2]; Walkey, Allan J. MD, MSc[7]; Kashyap, Rahul MBBS, MBA[20]

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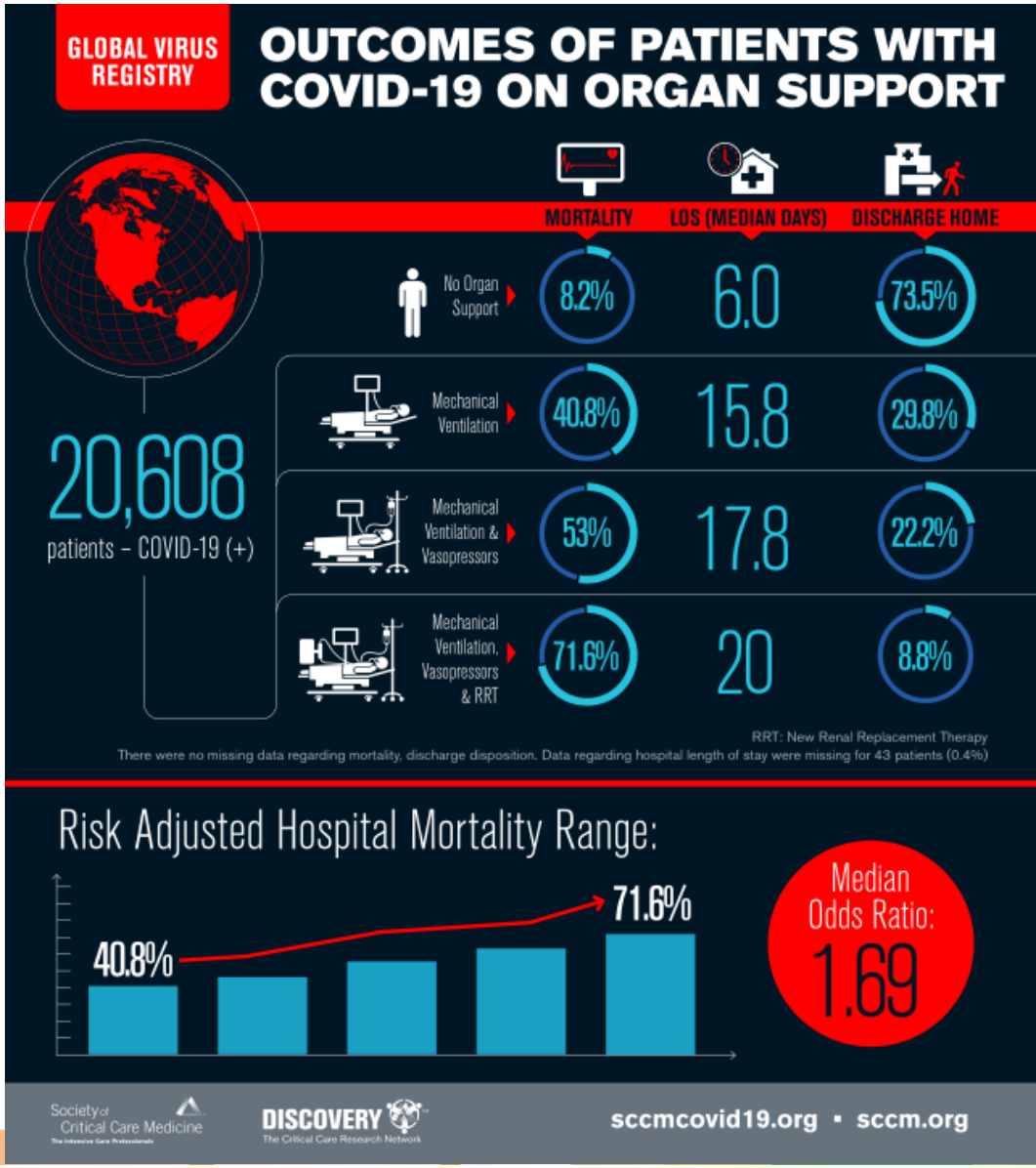
*NYTimes: How Covid Overwhelmed One L.A. Hospital in California's Worst-Hit County

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

Hospital Variation in Managem
Respiratory Distress Syndrome
Johnson SW, Garcia MA, Sisson EKQ, Sh
Lal A, Domecq JP, Melamed RR, Christie
Crit Care Explor. 2022 Feb 18;10(2):e063
eCollection 2022 Feb.
PMID: 35211681

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OBJECTIVES: To describe hospital variati
respiratory distress syndrome (ARDS) d
observational **study**. SETTING: The Socie
Infecti ...

Cutaneous manifestations of h
VIRUS COVID-19 registry.
Deo N, Tekin A, Bansal V, Koritala T, Mul
Gharpure VP, Bogojevic M, Qamar S, Sin
Kashyap R, Domecq JP, Alavi A; From Th
Infection and Respiratory Illness Univers
Group.
Int J Dermatol. 2022 Feb 19. doi: 10.111
PMID: 35182396

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Original Investigation | Critical Care Medicine

December 22, 2021

Metabolic Syndrome and Acute Respiratory Distress Syndrome in Hospitalized Patients With COVID-19

Joshua L. Denson, MD, MS[1]; Aaron S. Gillet, BS; Yuanhao Zu, MPH[2]; Margo Brown, BS[1]; Thaidan Pham, BS[1]; Yilin Yoshida, PhD[3,4]; Franck Mauvais-Jarvis, MD, PhD[3,4]; Ivor S. Douglas, MD[5,6]; Mathew Moore, BS[1]; Kevin Tea, BS[1]; Andrew Wetherbie, BS[1]; Rachael Stevens, BS[1]; John Lefante, PhD[2]; Jeffrey G. Shaffer, PhD[2]; Donna Lee Armaignac, PhD, APRN[7]; Katherine A. Belden, MD[8]; Margit Kaufman, MD[9]; Smith F. Heavner, MS, RN[10]; Valerie C. Danesh, PhD, RN[11]; Sreekanth R. Cheruku, MD, MPH[12]; Catherine A. St. Hill, DVM, PharmD[13]; Karen Boman, BS[14]; Neha Deo, BS[15]; Vikas Bansal, MBBS, MPH[15]; Vishakha K. Kumar, MD, MBA[14]; Allan J. Walkey, MD, MSc[16]; Rahul Kashyap, MBBS, MBA[15]; for the Society of Critical Care Medicine Discovery Viral Infection and Respiratory Illness Universal Study (VIRUS): COVID-19 Registry Investigator Group

≫ Author Affiliations | Article Information

JAMA Netw Open. 2021;4(12):e2140568. doi:10.1001/jamanetworkopen.2021.40568

Outline

Images

V, Boman K, Kumar VK, Walkey
icine Discovery Viral Infection,
ry Investigator Group.
tation.2021.12.011. Epub 2021

PMID: 34920014

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RATIONALE: The impact of palliative care consultatic
previously been evaluated in a multi-center **study**. C
palliative care consultation on the incidence of cardi
performed and com ...

Lessons From a Rapid Project Managem
Pandemic: Methodology for a Global CC
Database.
Turek JR, Bansal V, Tekin A, Singh S, Deo N, Sharma
Kumar V, Kashyap R.
JMIR Res Protoc. 2022 Mar 15;11(3):e27921. doi: 10
PMID: 34762062

The Pediatric Infectious Disease Journal
An official publication of the European Society for Paediatric Infectious Diseases

Articles & Issues | Online First | Collections | For Authors | Journal Info

COVID REPORTS

Gastrointestinal Manifestations in Hospitalized Children With Acute SARS-CoV-2 Infection and Multisystem Inflammatory Condition: An Analysis of the VIRUS COVID-19 Registry

ventilated COVID-19 patients receiving interleukin-6 receptor antagonists and corticosteroid therapy: a preliminary report from a multinational registry.
Amer M, Kamel AM, Bawazeer M, Maghrabi K, Butt A, Dahhan T, Kseibi E, Khurshid SM, Abujazar M, Alghunaim R, Rabee M, Abualkhair M, Al-Janoubi A, AlFirm AT, Gajic O, Walkey

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Original Investigation | Caring for the Critically Ill Patient | ONLINE FIRST | FREE

October 3, 2022

Association of Early Steroid Administration With Outcomes of Children Hospitalized for COVID-19 Without Multisystem Inflammatory Syndrome in Children

Sandeep Tripathi, MD, MS[1]; Meghana Nadiger, MD[1]; Jeremy S. McGarvey, MS[2]; et al

https://jamanetwork.com/journals/jamapediatrics/newonline/2022/10

PHARMACOTHERAPY | accp

ORIGINAL RESEARCH ARTICLE | Free Access

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, Meghana Nadiger, Jeremy S. McGarvey, Keith Hanson, Varsha P. Gharpure, Erica C. Bjornstad, Kathleen Chiotos, 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

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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

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

Title: Methodological Principles in the Use of International Medical Device Registry Data

Authoring Group: IMDRF Patient Registries Working Group

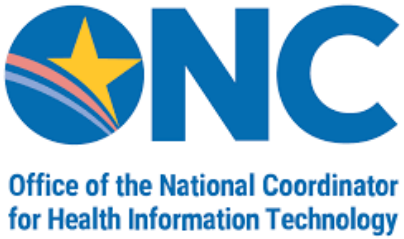
Date: 16 March 2017

IMDRF

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



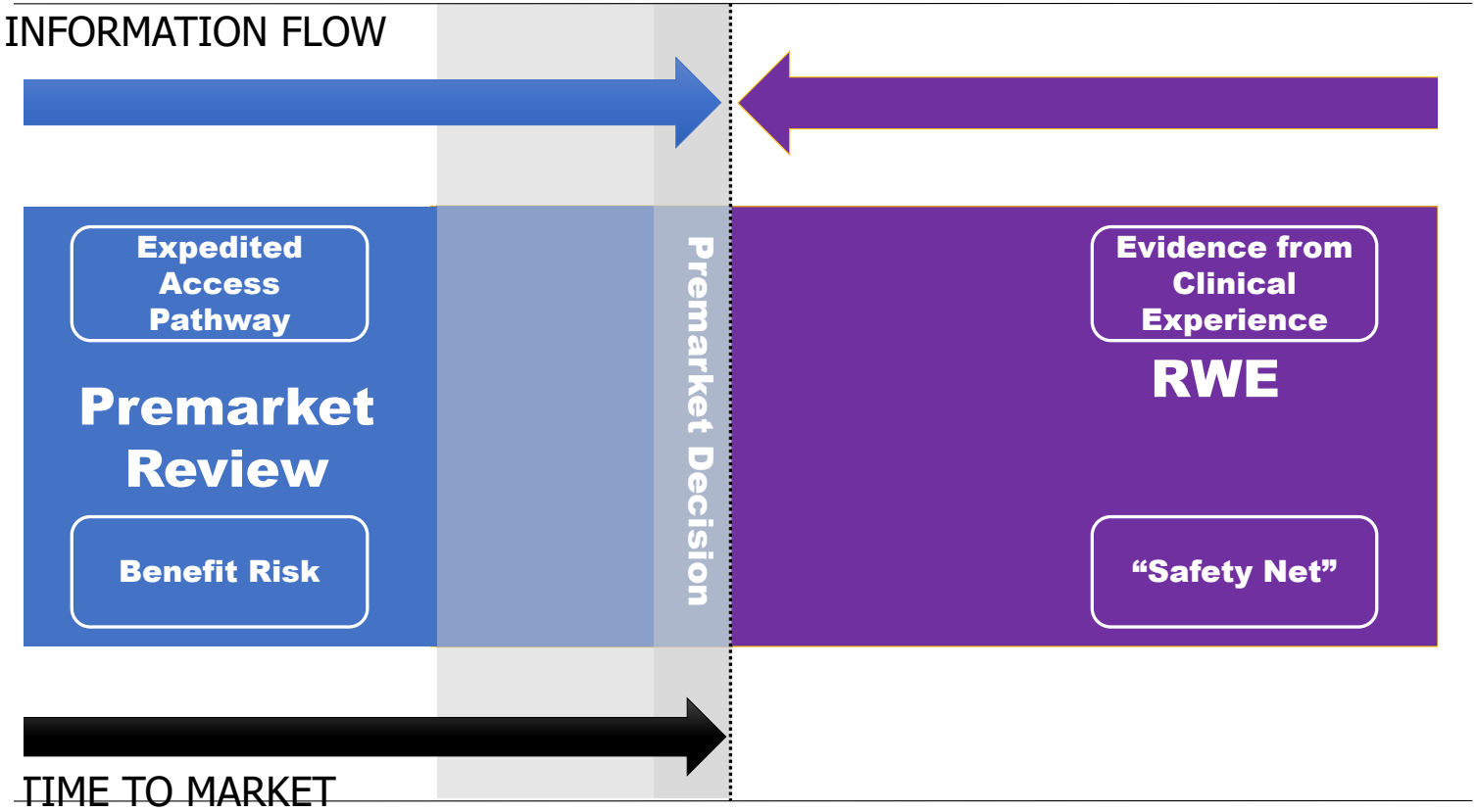
Policy context

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, fasters, 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.

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

.

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

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- CMS national coverage decisions

Sustainable resources.

CRN Methods: Data sources and linkage

SVS | VQI

In collaboration with NCDR®

Cohort of patients and exposures to products

Outcomes

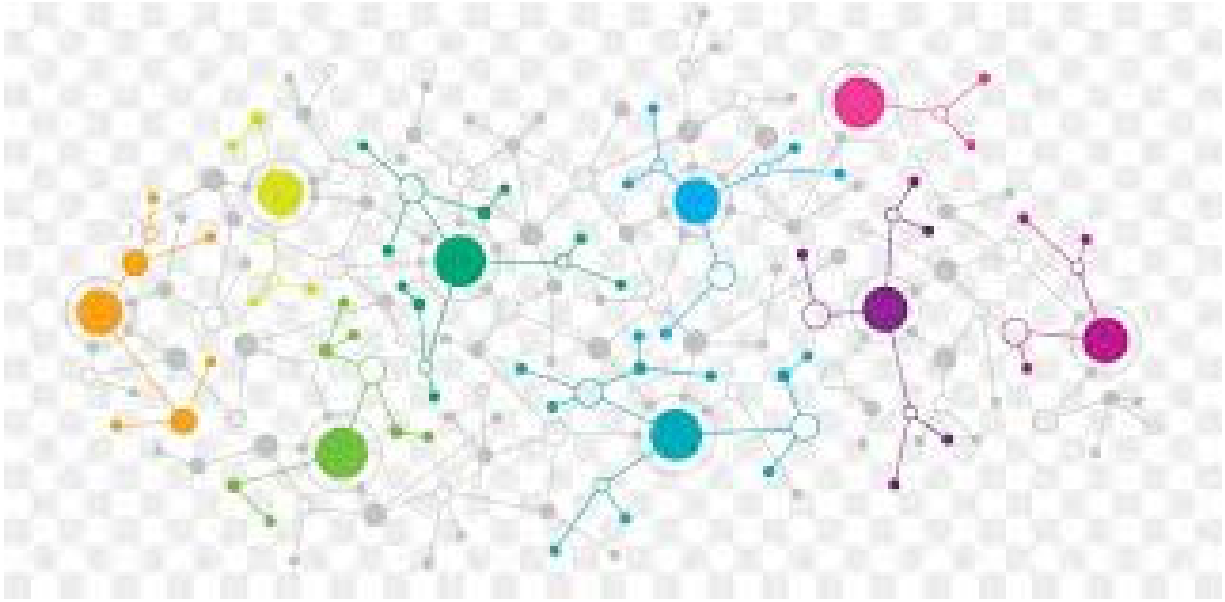
CRN Methods: Data sources and linkage

SVS | VQI

In collaboration with NCDR®

Based on a rich literature lead by MDEpiNet

Creation of a data network = CRN

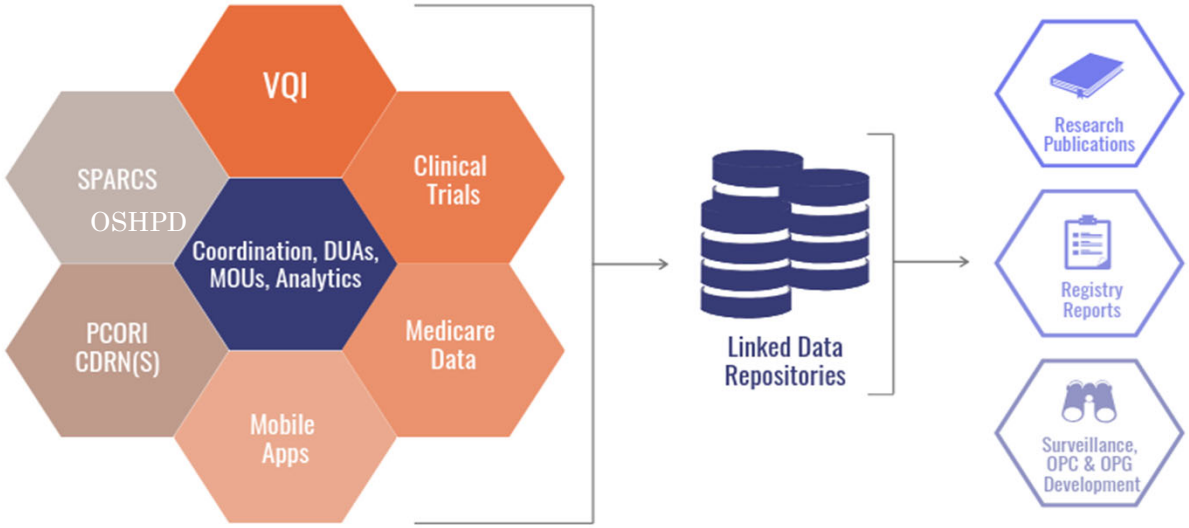


Add PRO from apps, add EHR, add data from wearables, add data out of medical devices, add mortality statistics.

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.



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

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*:**
***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 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

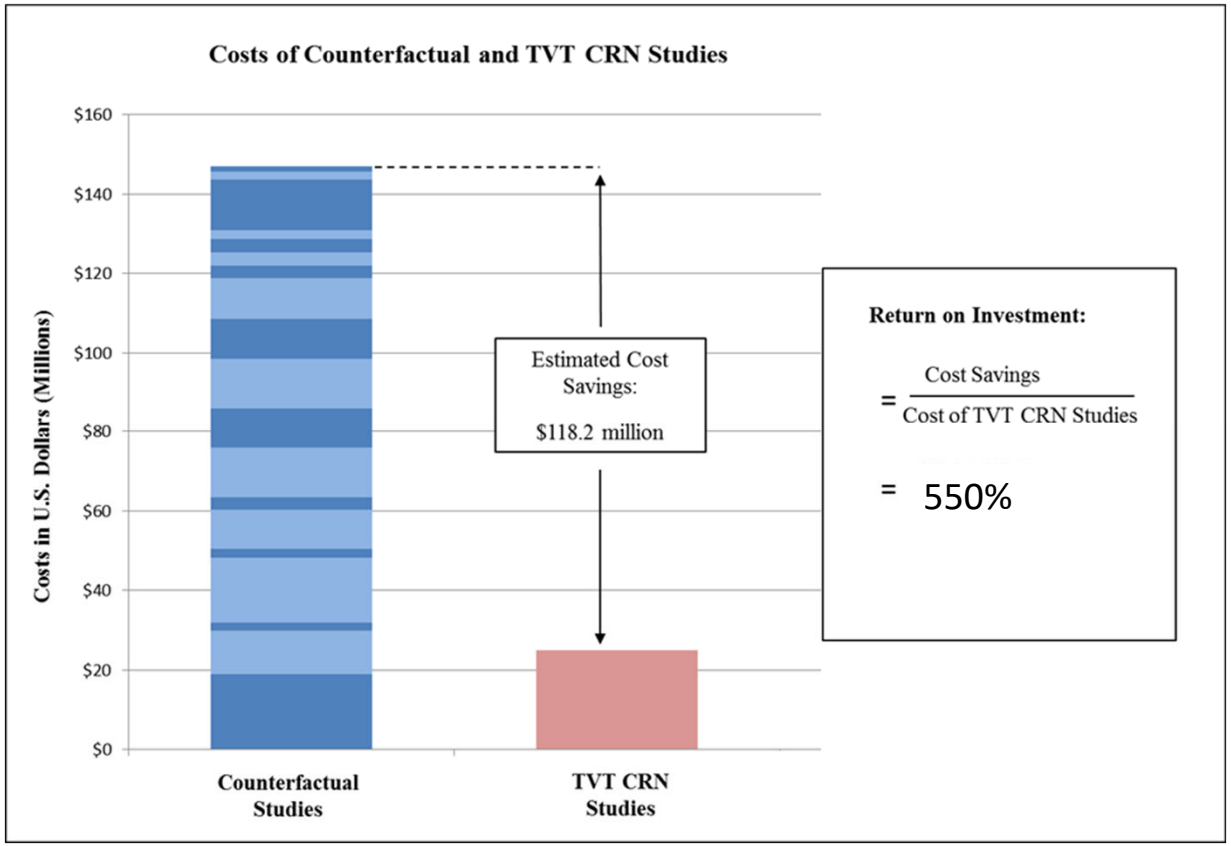
Three case studies document the value created by the CRN; this is the basis for a broader framework to guide future work

Pappas, Gregory, et al. "Determining value of coordinated registry networks (CRNs): a case of transcatheter valve therapies." BMJ Surgery, Interventions, & Health Technologies 1.1 (2019).

Cronenwett, Jack L., et al. "Use of data from the Vascular Quality Initiative registry to support regulatory decisions yielded a high return on investment." BMJ Surgery, Interventions, & Health Technologies 2.1 (2020).

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

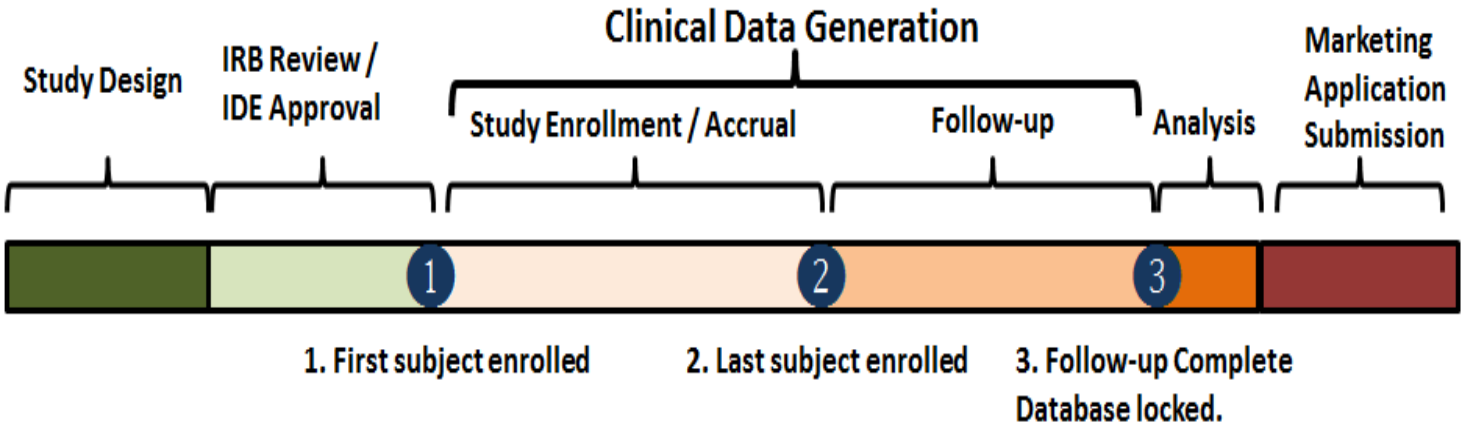
Value created by CRN has been documented*



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



"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

- Medical product industry
- Patients
- Clinicians and their professional societies
- Regulatory Agencies
- Public Health

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

Support regulatory decision making	Research for improved product development –	Quality assurance/improvement –	Training
• Improved determination of safety and efficacy – FDA, industry, clinicians, public health • Support evidence of reimbursement – CMS, industry • Support evidence of value for cost – CMS, industry • Support negotiation of price based on contribution of public/federal to products – CMS, industry, patients, health care providers	• patients, clinicians, industry	• clinicians and their associations, medical systems, and patients	• clinicians and their associations

Operationalize the value proposition in three buckets: key performance indicators (metrics and case studies)

CHEAPER

FASTER

BETTER

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

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-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

As public health doctor, this is the most important to me. Safety first!

-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.

To increase the use and value of the CRN, they need to mature.

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

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.

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