CMSS WEBINAR SERIES:
Registry Science and Research

CMSS Presents:

Advancing FHIR in Clinical Registries and Research

August 29, 2022

CMSS WEBINAR SERIES:

Registry Science and Research

ABOUT THE SERIES:

As part of CMSS' Digital Transformation strategic priority, the Registry Science and Research Initiative will advance CMSS member knowledge and expertise in clinical registries and research through shared learning and collaboration with stakeholders in the broader clinical and research environment.

An advisory committee comprised of specialty society staff, society volunteer leadership, and federal agency representatives will advise on and seek to address key topics of interest to specialty societies in clinical registries and research.

KEY GOALS:

- Advancing CMSS member knowledge and expertise
- Informing future collaborative CMSS activities
- Identifying issues that require more focused development

STAY UP TO DATE:

Sessions are being planned for July 2022 through Winter 2023. Visit the website for more details on the series and be sure to follow **@CMSSMed** on Twitter for updates.

CMSS

CMSS WEBINAR SERIES:

Registry Science and Research

Today's Webinar:

Advancing FHIR in Clinical Registries and Research

August 29, 2022

1:00 - 2:30 pm ET

Panelists:

Brian Bialecki
Director of IT Standards and Interoperability, American College of Radiology

Aneesh Chopra
President, CareJourney

Christopher Treml
Director, Data Standards Institute, American College of Radiology

Marti Velezis
Data Standards and Interoperability Consultant (FDA), Chair/Coordinated Registry Network (CRN) Architecture Task Force (MDEpiNet)

Through a Regulated Path:

FHIR-enabling Clinical Registries & Research

August 29, 2022

Aneesh Chopra
@aneeshchopra

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A Hunch Analytics Company

Memory Lane: HIT Investment in Context

PROPOSED STRATEGY FOR EXECUTION OF THE HEALTH INFORMATION TECHNOLOGY INVESTMENT PROGRAM

Draft, February 24, 2009

EXECUTIVE SUMMARY

The $19 billion health information technology (HIT) investment authorized in the American Recovery and Reinvestment Act (ARRA) represents a landmark opportunity to improve health care. In considering how best to execute on this opportunity, it is critical to understand that to treat the HIT investment program as a pure technology implementation program is to effectively guarantee its failure. HIT is not magic. In the absence of provider payment reform and care delivery innovation, it is all too easy to imagine spending $19 billion on HIT adoption and producing little tangible social benefit. However, there is a clear path to victory:

- If we avoid focusing the HIT investment program narrowly on HIT adoption and instead focus it explicitly on the actual improvement of population health, and
- If we use the HIT investment to catalyze a "virtuous cycle" of (1) provider payment reform, (2) care delivery innovation, and (3) HIT adoption
- Then: the HIT investment can literally transform health care as we know it.

"Low HIT adoption cripples the ability to pursue provider payment reform, which is necessary to create a business case for care innovation by providers, which is necessary to drive demand by providers for HIT to support care innovations, which is necessary to drive large-scale HIT adoption. It's a "cycle of futility."

1. Establish clear population health goals
2. Link incentive payments to clinical outcomes
3. Establish an "HIT bullpen" aligning CMMI and ONC
4. Create "deployment infrastructure" to accelerate provider adoption and use
5. Seed "radical innovation" akin to X-Prize for delivery reform

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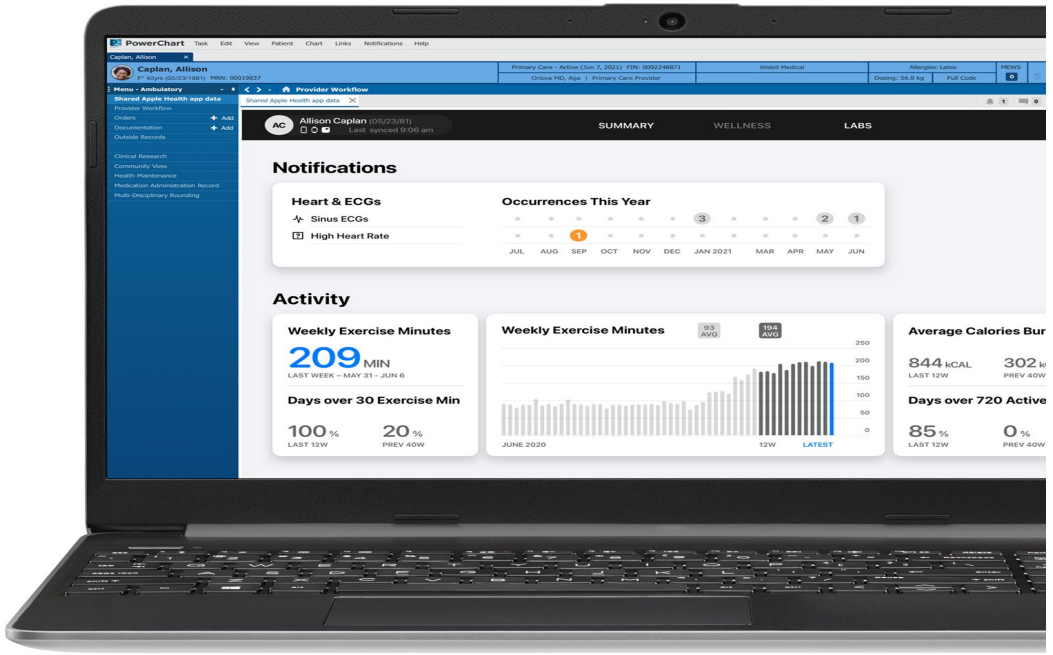
Public/Private Collaboration Drives Standards

After dramatic reduction in aircraft manufacturing following WWI, then-Secretary Hoover encourages industry collaboration on engine, wing standards, commercialized on popular DC-3, Boeing 247

Apple Health



Handshakes & Handoffs

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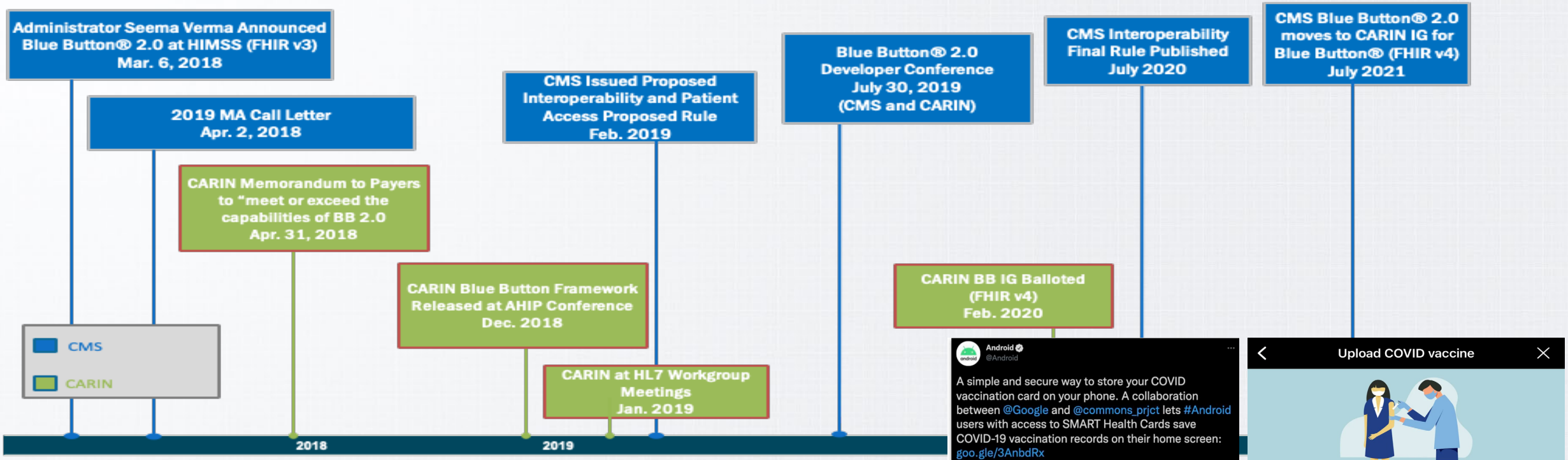
Source: http://argonautwiki.hl7.org/index.php?title=Main_Page

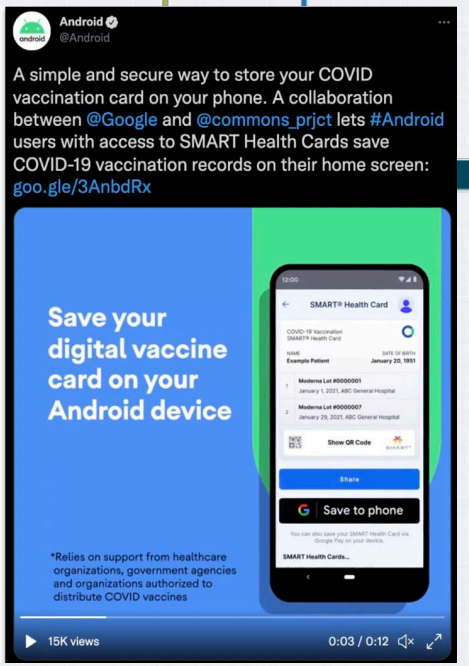
“Deep-Dive” on Patient Access API

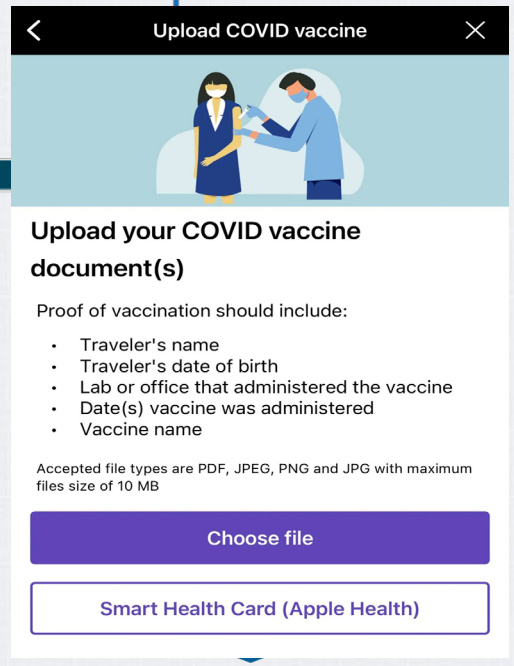


HL7® FHIR®
ARGONAUT PROJECT

carin
Creating Access to Real-time Information Now through Consumer-Directed Exchange

CMS issues call to action, industry responds (voluntarily) to meet it via standards, commits to real-world testing, validation; CMS scales via regulation (rinse, repeat)





Source: CARIN Alliance; argonautproject.org; SMART Health Cards

A “Public Option” for Health Networks

Institutions that support health records on iPhone (beta)

A growing list of healthcare institutions support health records on iPhone, enabling you to view important data such as immunizations, lab results, medications, and vitals directly in the Health app.

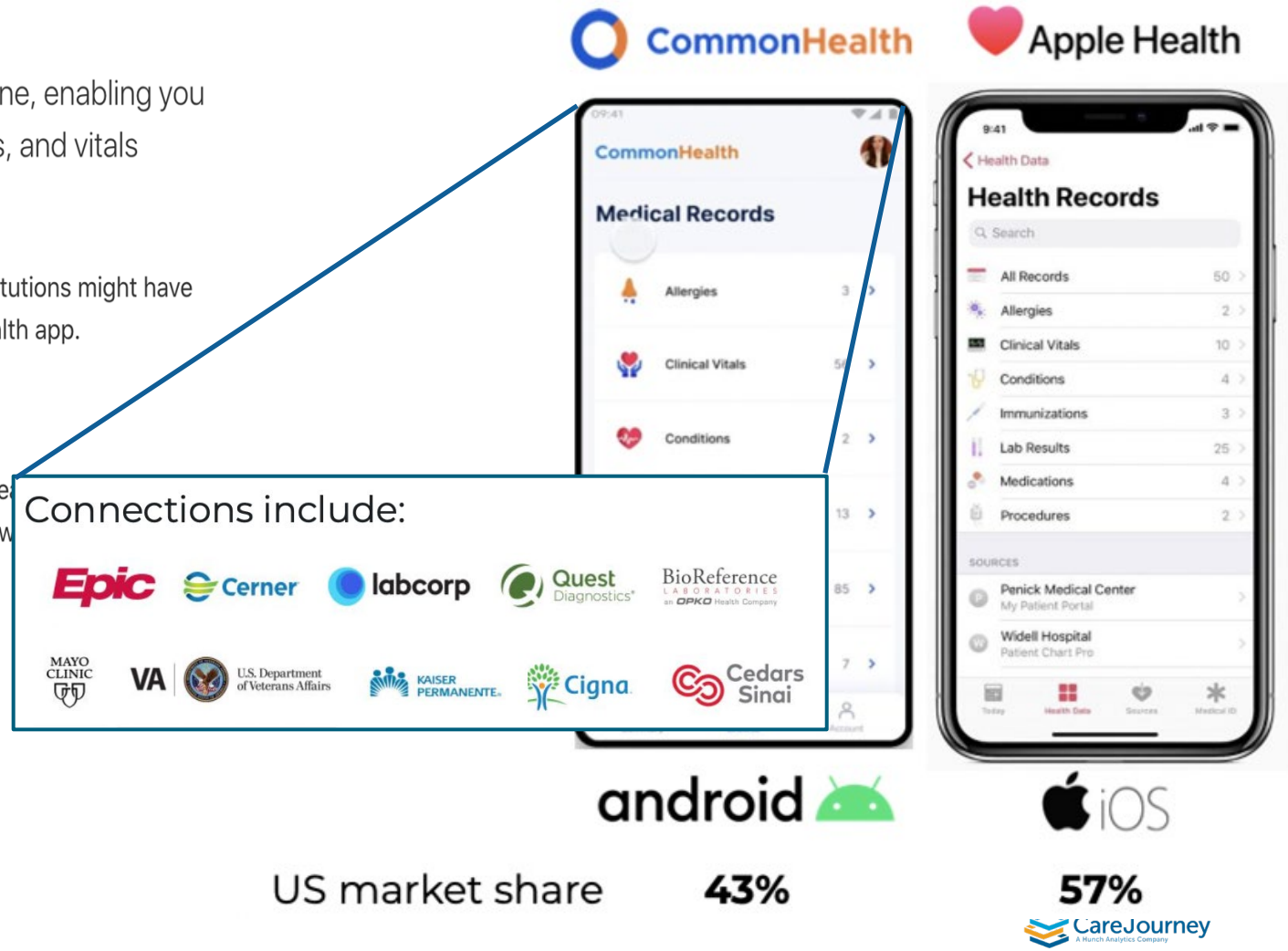
We’re working with more hospitals and clinics to support health records. Health institutions might have multiple hospitals and clinics that support health records, which are listed in the Health app.

Richard M. Adams, DPM - Family Foot Care (Texas)
https://www.richardadamsdpm.com

Community Health Systems (nationwide) - including AllianceHealth (OK), Bayfront He
Commonwealth Health (PA), Lutheran Health Network (IN), Merit Health (MO), Northw
Physicians Regional (FL), Tennova Healthcare (TN)
http://www.chs.net

Cone Health (North Carolina)
https://www.conehealth.com

Apple Health connected to ~800+ FHIR endpoints
CommonHealth connected to ~800+ FHIR endpoints



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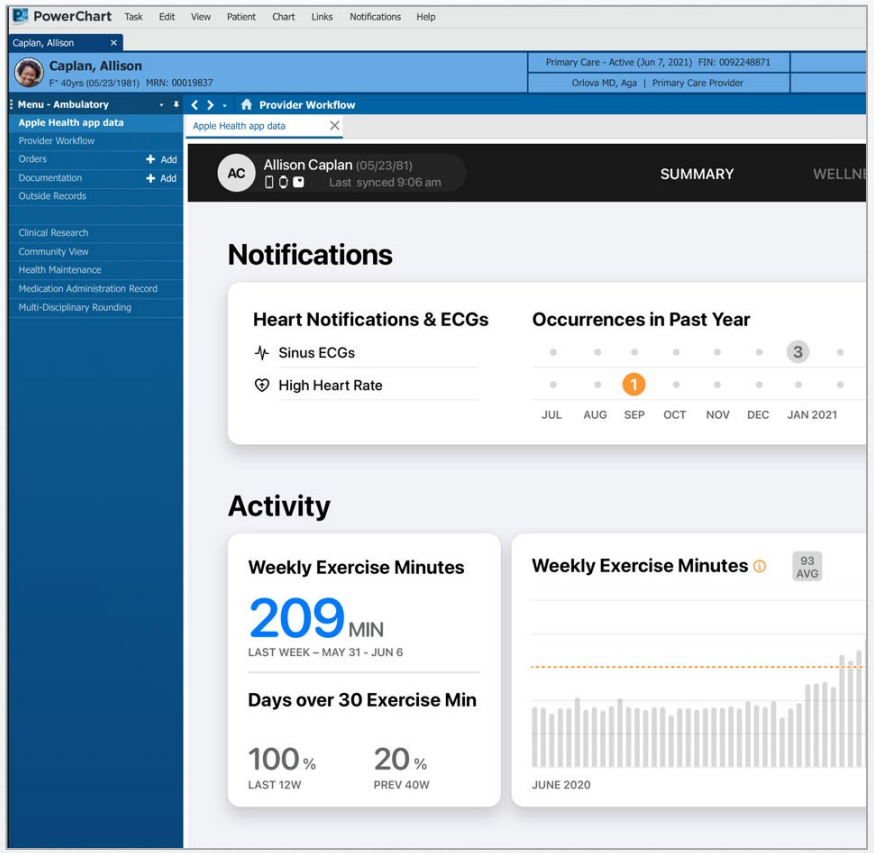
Era of “Physician—Designated” Apps

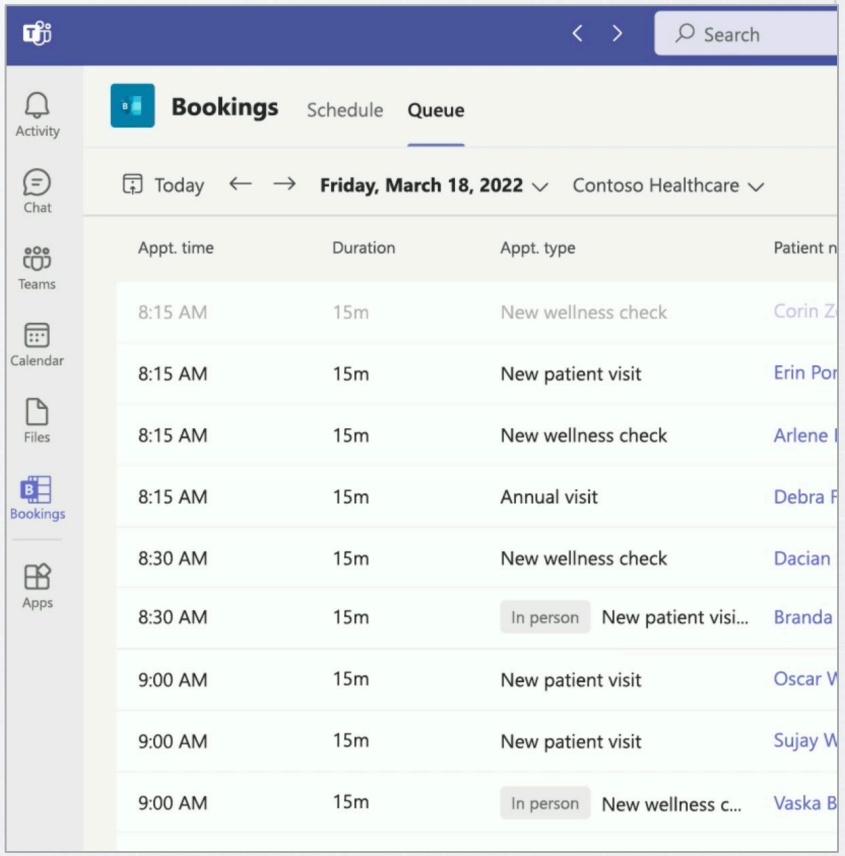
Right to Install Any 3rd Party App in EHR

Works with Apple Health



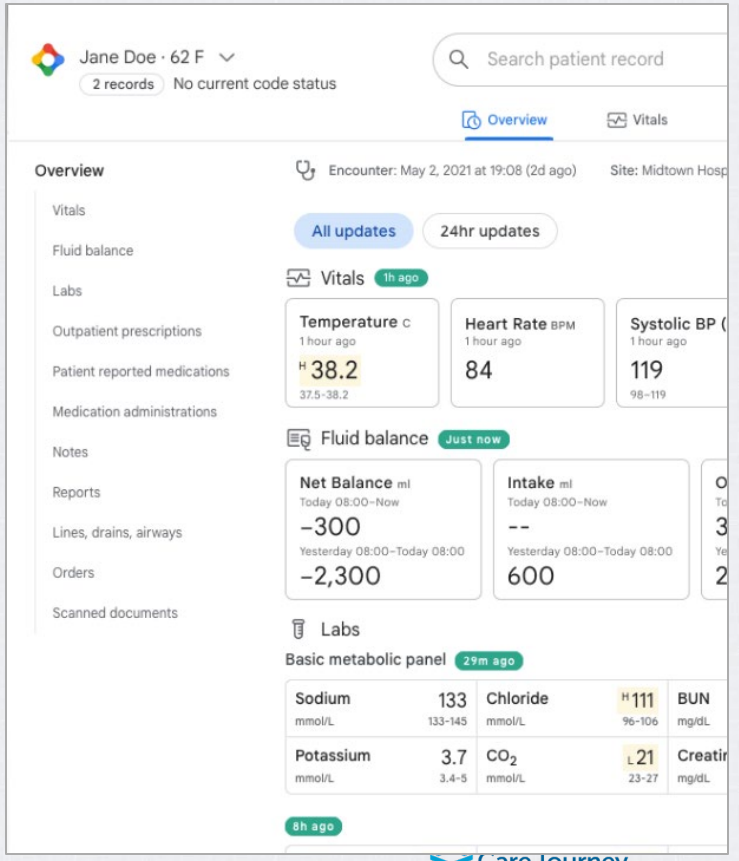
Right to Access Hospital ADT Feeds

Microsoft Teams EHR connector



Right to Access Longitudinal Records

Google Health



Source: Apple, Microsoft, Google

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Technology Failures Hinder Progress

News Release
July 13, 2021

NAACOS Statement on CMS's Proposed 2022 Medicare Physician Fee Schedule

Attributed to Clif Gaus, Sc.D., President and CEO of the National Association of ACOs

The Centers for Medicare & Medicaid Services (CMS) today took the appropriate step by proposing to roll back changes that the agency finalized last year in how accountable care organizations (ACOs) report and are measured on quality. Specifically, the agency proposes to allow Medicare Shared Savings Program (MSSP) ACOs to continue to use the Web Interface reporting option in 2022 and 2023, phasing in the new electronic clinical quality measure (eCQM) reporting requirement over three years as opposed to requiring eCQM reporting starting in 2022. NAACOS over the last year has cited potential negative consequences to patient care among the many reasons why such a rapid shift to eCQM reporting was bad policy. NAACOS is pleased that the Biden Administration listened to these concerns and is taking action. Delaying last year's changes is the right thing to do. The healthcare industry, including ACOs, electronic health record (EHR) vendors and government payers, need more time before mandating electronic quality measures, and we are pleased to see CMS provide this necessary transition time. We look forward to continuing to work with the new administration to make improvements to the way ACOs are assessed on quality in the future, among other important MSSP changes.

Advanced Explanation of Benefits

Under the CCA, once the provider sends the health plan the "good faith estimated amount" for a given patient, the health plan is then obligated to send enrollees an "Advanced Explanations of Benefits" ("AEOB") prior to scheduled care (or upon patient request). The health plan must provide the AEOB by mail or electronically (based on patient preference) either within three business days of receiving a request or a notice that a service has been scheduled if the service is scheduled at least 10 business days later, or within one business day of receiving the notice if the service is scheduled within 10 business days of receipt.

This requirement was set to take effect on January 1, 2022, but the Department noted that compliance is likely not possible by that time; therefore, the Departments intend to undertake notice and comment rulemaking in the future to implement this provision and in the meantime, will defer enforcement.

Good Faith Estimates

Beginning January 1, 2022, the CCA requires providers (individual practitioners and facilities) to send an individual's health plan a "good faith estimated amount" of scheduled services, including any expected ancillary services and the expected billing and diagnostic codes for all items and services to be provided. In the case that the individual is not enrolled in a health plan or coverage, the provider must provide this notification to the individual.

The FAQs state that the complexities of this requirement make it virtually impossible for providers to comply by January 1, 2022. Therefore, the Departments decided to defer enforcement of this requirement until future rulemaking.

Building (FHIR-based) Data Networks

Interoperability

Marching Forward: The Path to Operationalize TEFCA

Elise Sweeney Anthony; Liz Palena Hall and Mariann Yeager, CEO, The Sequoia Project (the TEFCA Recognized Coordinating Entity) | MAY 16, 2022

"And, be on the lookout soon for more information about upcoming plans for Health Level Seven (HL7®) Fast Healthcare Interoperability Resource (FHIR®) standards pilots, in alignment with our FHIR Roadmap for TEFCA Exchange."

Planned Stages of FHIR Availability in TEFCA

Timeline: pilot requests open, announcements EOY

Stage 1
FHIR Content Support

- ✔ FHIR exchange possible within QHINs' own networks
- ✔ IHE exchange of FHIR payloads between QHINs is possible with "out-of-band" coordination.

Stage 2
Network-Facilitated FHIR Exchange

- ✔ QHIN-facilitated FHIR-based exchange available as an option under TEFCA.

Stage 3
Network-Brokered FHIR Exchange

- ✔ QHIN-facilitated FHIR-based exchange available as an option under TEFCA.
- ✔ QHIN-brokered FHIR API exchange optionally available.

Source: Rock Health

Evolution to Network Connectivity Models

Consumer Driven Access + Physician Driven Access + **Network Driven Access**

HIE+

Description:
Existing HIEs adding FHIR-based sharing services (less friction)

Optimal / Designed For
Stable HIEs (trusted governance) focused on lowering access burdens via FHIR APIs

Minimum Necessary Governance
TEFCA principles, QHIN requirements

New Entrant Networks

Description:
Work with a new entrant that wishes to come in FHIR first

Optimal / Designed For
Organizations who wish to engage in TEFCA FHIR roadmap activities

Minimum Necessary Governance
TEFCA principles, QHIN requirements

Intranet

Description:
Launch an intranet version without officially pursuing QHIN status

Optimal / Designed For
CINs engaged in VBC contracts that need to share data within network

Minimum Necessary Governance
"QHIN-like" governance negotiated via data sharing agreements

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The Journey Begins

TEFCA draftt QHIN applications go live

End of Q1 2022

Cures Act EHI is no longer limited to USCDI data elements via information blocking rule

Oct 6, 2022

Cures Act EHRs must certify & provide all three CURES Act APIs (consumer, physician, population "bulk")

December 2022

CMS IP Rule (final) physician fee schedule (proposed) Providers must adopt the 2015 Cures Update edition for an EHR reporting period in CY 2023

September 2023

Cures ACT EHI Export must be made available

12/31/2023

Transparency in Coverage information for 500 shoppable services

January 2023

Transparency in Coverage information for all shoppable services

January 2024

Cures Act
(EHI Definition)

October 6th, 2022

Cures Act
(EHR Certification)

December 2022

Provider Adoption
(Cures Update)

September 2023

Transparency in Coverage
Shoppable Services Tool

January 2023 & 2024

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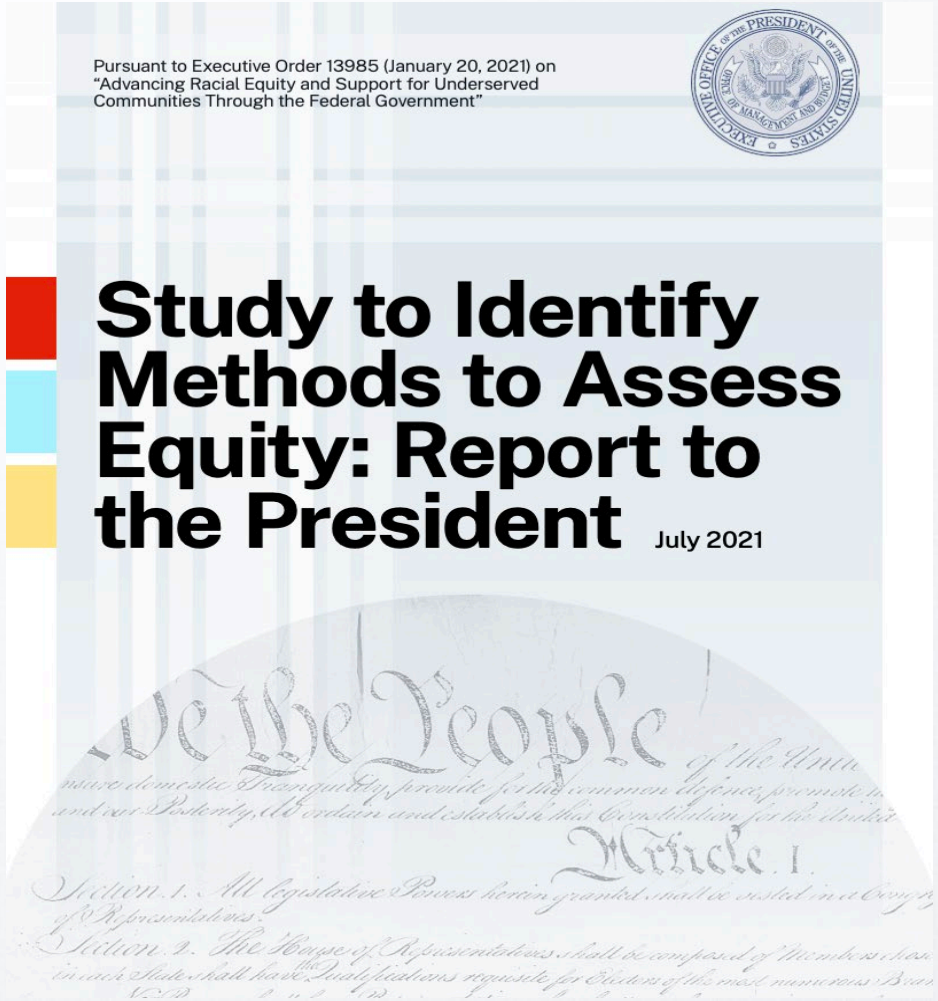
Listening for Public Demand Signal



1. "Bulk" FHIR for Quality, Cancer Moonshot
2. FHIR Questionnaire (CDC, CMMI, SDoH)
3. SMART on FHIR apps for Prior Auth
4. Automated EHI Export (NIH, SSA)
5. FHIR Subscription for Public Reporting

https://www.whitehouse.gov/wp-content/uploads/2021/08/OMB-Report-on-E013985-Implementation_508-Compliant-Secure-v1.1.pdf;
Open source app now available on GitHub; ResearchKitOnFHIR

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Transformation @ Pace of Trust

Popular Latest

The Atlantic

TECHNOLOGY

Google's Totally Creepy, Totally Legal Health-Data Harvesting

Google is an emerging health-care juggernaut, and privacy laws weren't written to keep up.

SIDNEY FUSSELL NOVEMBER 14, 2019

FIRST OPINION

Creating a digital Hippocratic oath for the 21st century

By Ries Robinson and Aneesh Chopra Feb. 15, 2022 Reprints

The development of the digital Hippocratic oath must extend to the broader health

"Beyond HIPAA:" Contractually bind 3rd-party vendors and contractors to our privacy policies and prohibit use or disclosure of user information (including de-identified…data) for any undisclosed purposes without express consent from the user.

NEWS | REFORM

Defense Innovation Board Recommends AI Ethical Guidelines

NOV. 1, 2019 | BY DAVID VERGUN

4 Reliable

DOD AI systems should have an explicit, well-defined domain of use, and the safety, security and robustness of such systems should be tested and assured across their entire life cycle within that domain of use.

5 Governable

DOD AI systems should be designed and engineered to fulfill their intended function while possessing the ability to detect and avoid unintended harm or disruption, and for human or automated disengagement or deactivation of deployed systems that demonstrate unintended escalatory or other behavior.

Source: https://www.carinalliance.com/wp-content/uploads/2019/05/2019_CARIN_Code_of_Conduct_05082019.pdf; Atlantic; STAT

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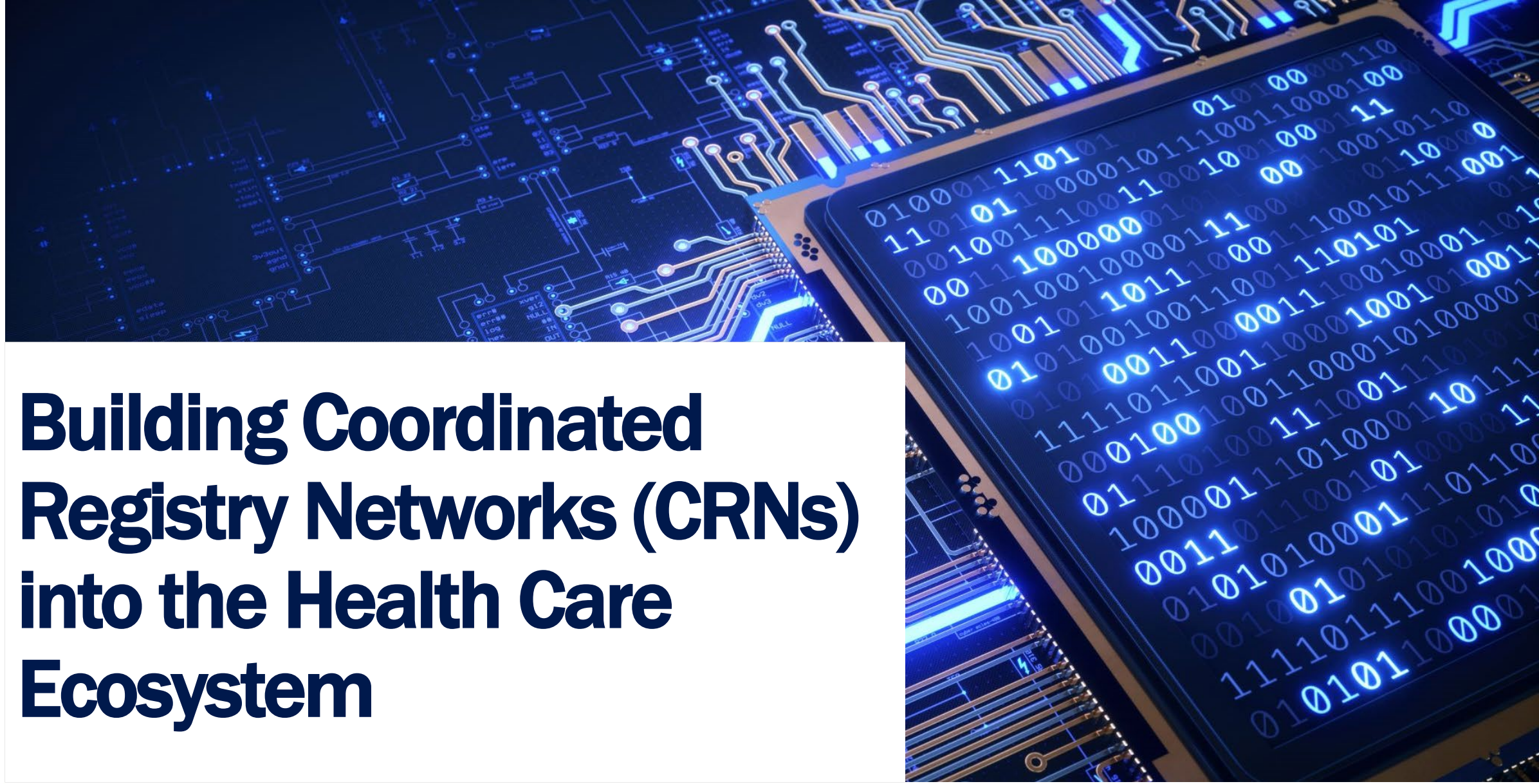


Building Coordinated Registry Networks (CRNs) into the Health Care Ecosystem

MDEpiNet

U.S. FOOD & DRUG ADMINISTRATION

CRNs : Leveraging Real-word Data from Existing Sources

ASPE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION | OFFICE OF HEALTH POLICY

OS PCORTF OFFICE OF THE SECRETARY PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

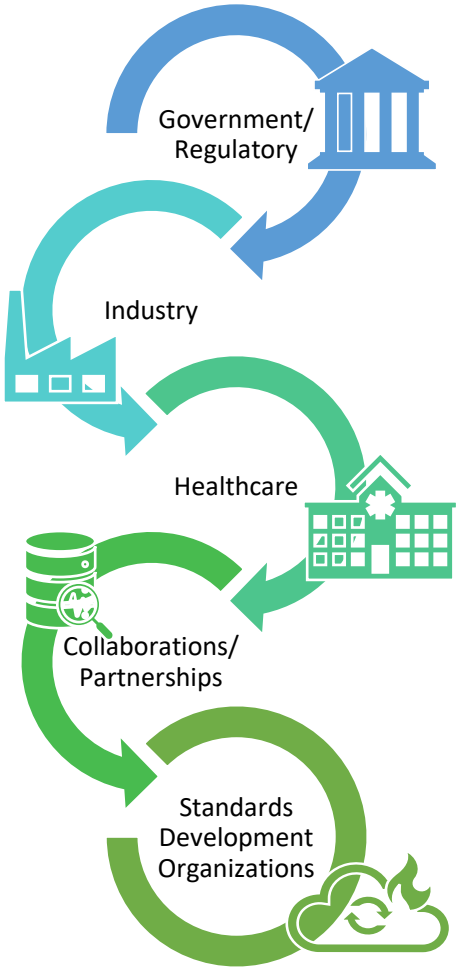
Funding for the CRNs was provided by the Assistant Secretary for Planning and Evaluation (ASPE) Office of Health Policy and the Building the Data Capacity for Patient-Centered Outcomes Research Grant.

CRNs are Part of the Health Care Ecosystem

Real-world Data reduces data collection burden for patients, providers, researchers and regulators

- **Data exists everywhere**
  - Leverage data where it is collected
  - Enable interoperability standards to ensure data is used correctly
- **Data Use and Reuse**
  - Systems need to enable provider to deliver improved care
  - Mitigate information overload and information inconsistencies
  - Support the analysis of patient outcomes
  - Additional information will be available to patients, health care providers, researchers and regulators

Modernizing National Infrastructure



Coordinated Registry Network

*Connecting "complementary" existing registries and electronic non-registry data sources (e.g., EHR, administrative data) each correcting the deficiencies of the other (device identifiers, operator proficiency, outcomes ascertainment, duration of follow up). Broad range of interoperability solutions for systems flexibility customized to device specific CRN objectives (e.g., benefit/risk, safety surveillance) and available existing resource, if any (e.g., existing registries, EHR data fields, standardized definitions) - Evolution of a National System based on systems flexibility able to continuously adapt to both rapid changes in electronic modalities of health care data collection and the rapid pace of medical device innovation (e.g., a learning National System)**

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

Example: Level 5 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)

Coordinated Registry Networks

*Maturity Criteria***

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

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

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

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

***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

*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.

CRNs: Use Cases to Advance Use of Real-World Data

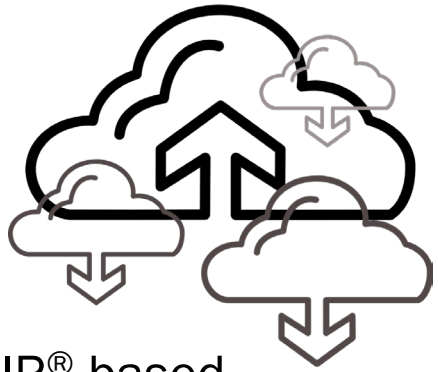
EXAMPLES : UDI and Device Usage

USING STANDARDS TO ENSURE WE HAVE THE DATA NEEDED FOR PATIENT SAFETY

- **Devices are everywhere**
  - How do we accurately identify the devices in use or placed into patients?
  - Why do we need a better way to identify devices (i.e., capturing the Unique Device Identifiers (UDIs))?
    - Patient safety
    - Patient outcomes
    - Supply management and cost containment
- **Devices collect, transmit and store Data**
  - Data needs to be managed for its use
  - More devices are communicating clinical information real-time and needs to be reliable
  - Devices are set to deliver treatments (e.g., medication, blood products, ventilation, etc.)

FHIR® in the MDEpiNet CRNs

How FHIR® is leveraged in the MDEpiNet clinical domains



- **Vascular Implants Surveillance and Outcomes Network (VISION)**
  - Began to collect UDIs to identify vascular implants
  - Moving to improve post-op follow-ups and imaging studies and can leverage FHIR® based exchanges
- **Women's Health Technologies**
  - Demonstrated use of FHIR for various women's health technologies including the device identification information
  - Developed SMART on FHIR® Application
- **Venous Access National Guideline & Registry Development Coordinated Registry Network (VANGUARD-CRN)**
  - Begun development of FHIR® Implementation Guide to address the use case of venous access insertions (specifically catheter tip placement) and risk of infections

Medical Devices in the Health Care Ecosystem

We need to lead the way with interoperable solutions to improve patient safety

- What is our WHY?
  - To deliver care to patients safely
  - Ensure data is used to improve how we deliver care (i.e., faster, cheaper, equitably)
  - Improve our understanding about patient outcomes
- How do we do this?
  - **Together.** Engage all stakeholders involved in the generation of health care data
    - CRNs are built on the foundation of patients, providers, researchers, regulators and manufacturers all coming together
  - **Utilize the standards.** In order to improve how we navigate within complex the health care data ecosystem

Future demand for medical devices requires that we have a fast, interoperable way to exchange data.

THANK YOU

Case Study

ACR and FHIR

Breakdown

- Background
- ACR Connect
- Simple Example
- Current State

Background

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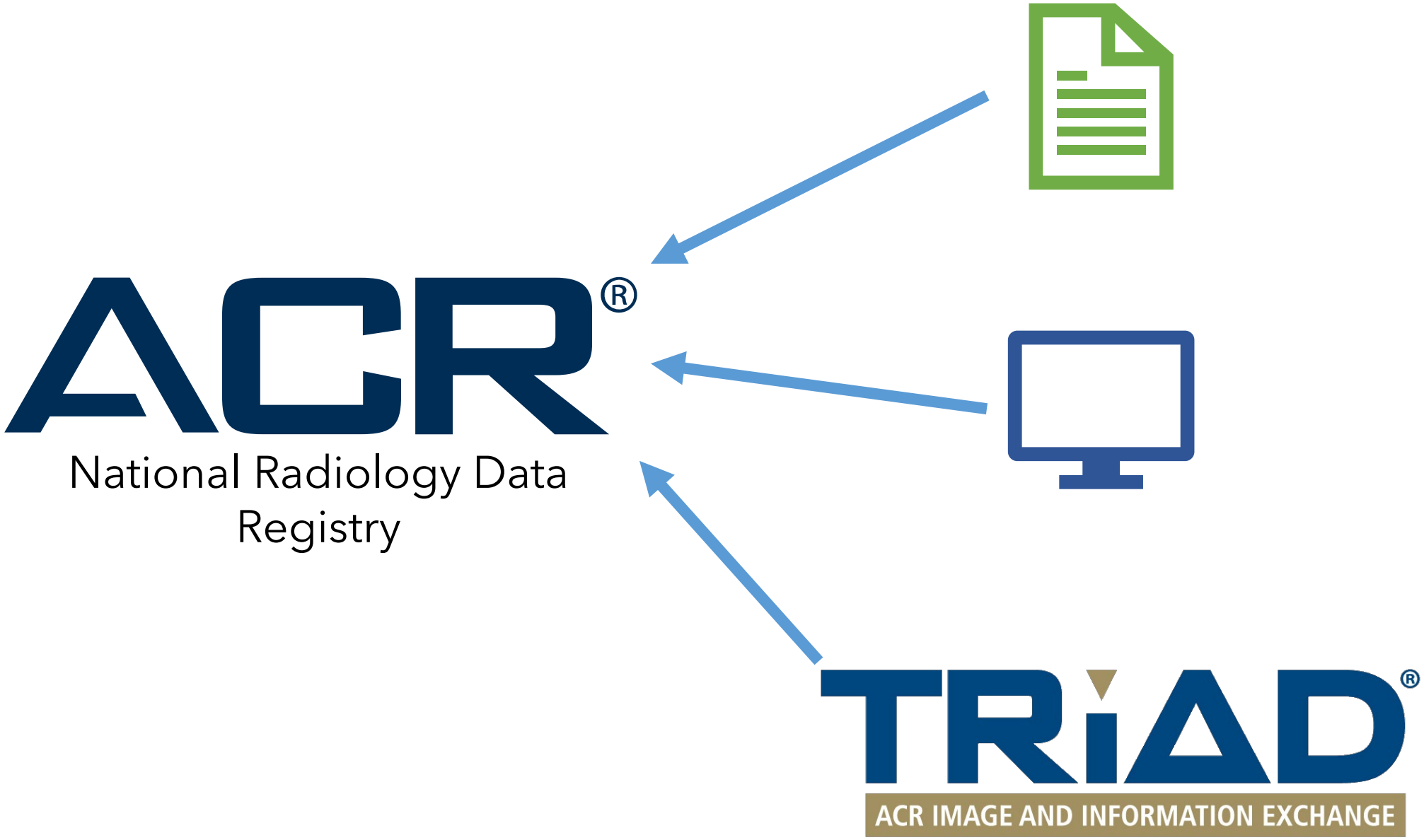
ACR®

National Radiology Data Registry


ACR®
National Radiology Data Registry
TRIAD®
ACR IMAGE AND INFORMATION EXCHANGE

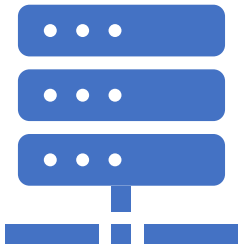
ACR®

National Radiology Data Registry

TRIAD®

ACR IMAGE AND INFORMATION EXCHANGE

DICOM℠



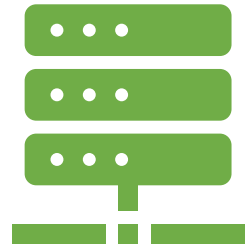
ACR Connect

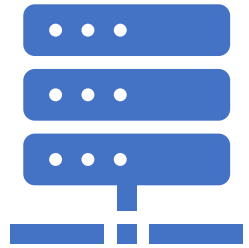
ACR®

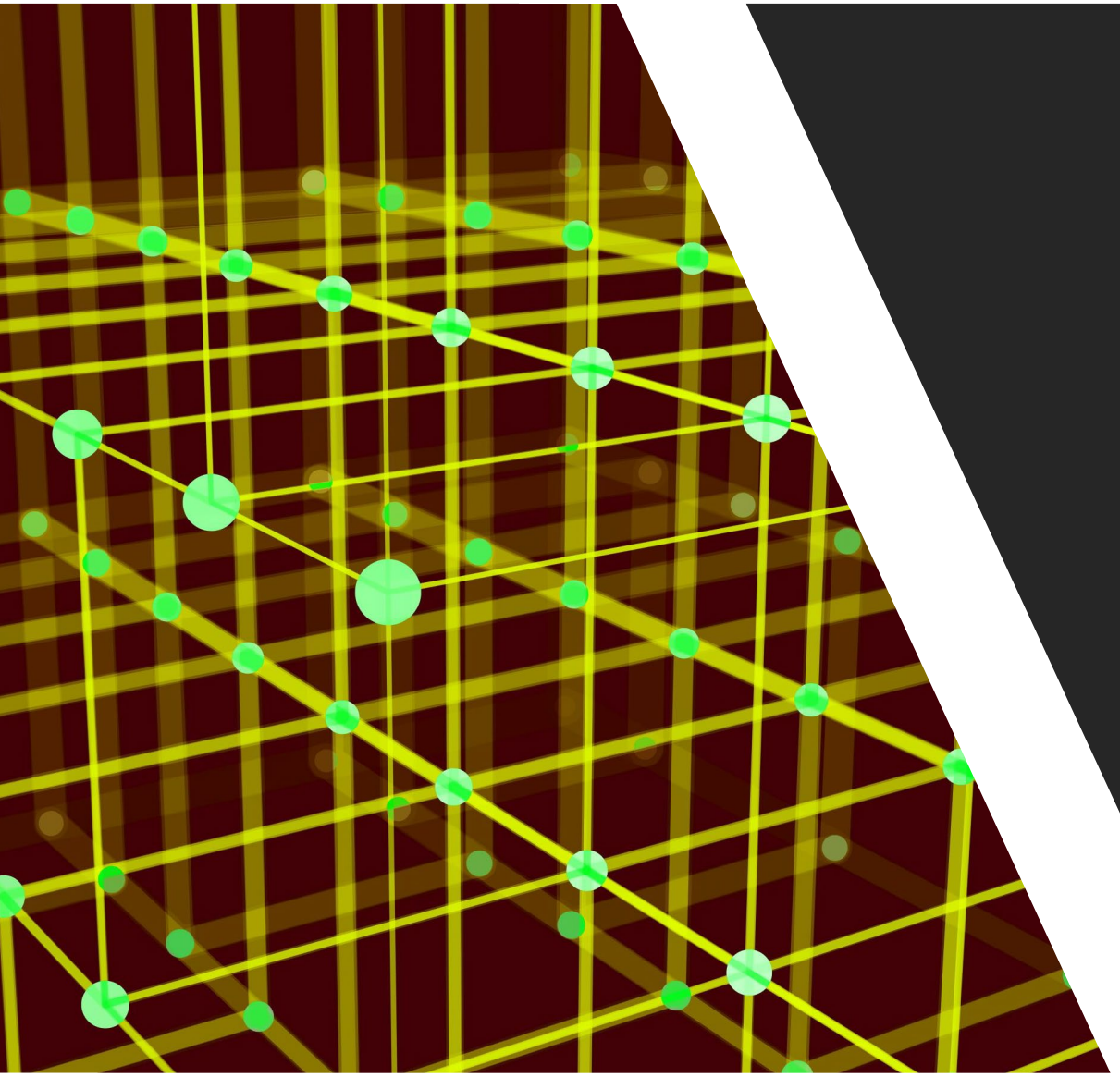
National Radiology Data Registry

ACRconnect®

DICOM







Simple Example

Simple Example – DIR Reason for Exam

- Want to collect the “Reason for Exam” element
- Not trusted to be in DICOM
- Lives on the procedure/order
  - RIS or EHR
- Clinical Data
  - HL7v2 or FHIR
- FHIR
  - Query-Retrieve Model

ACR®
National Radiology Data Registry

6. Upload

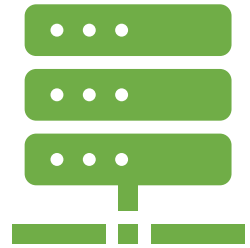
3. Normalize
4. Anonymize
5. Package

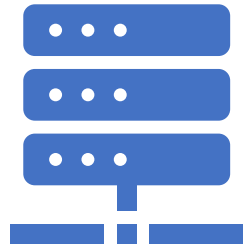
ACRconnect®

2. Query ServiceRequest

1. Incoming DICOM

DICOM





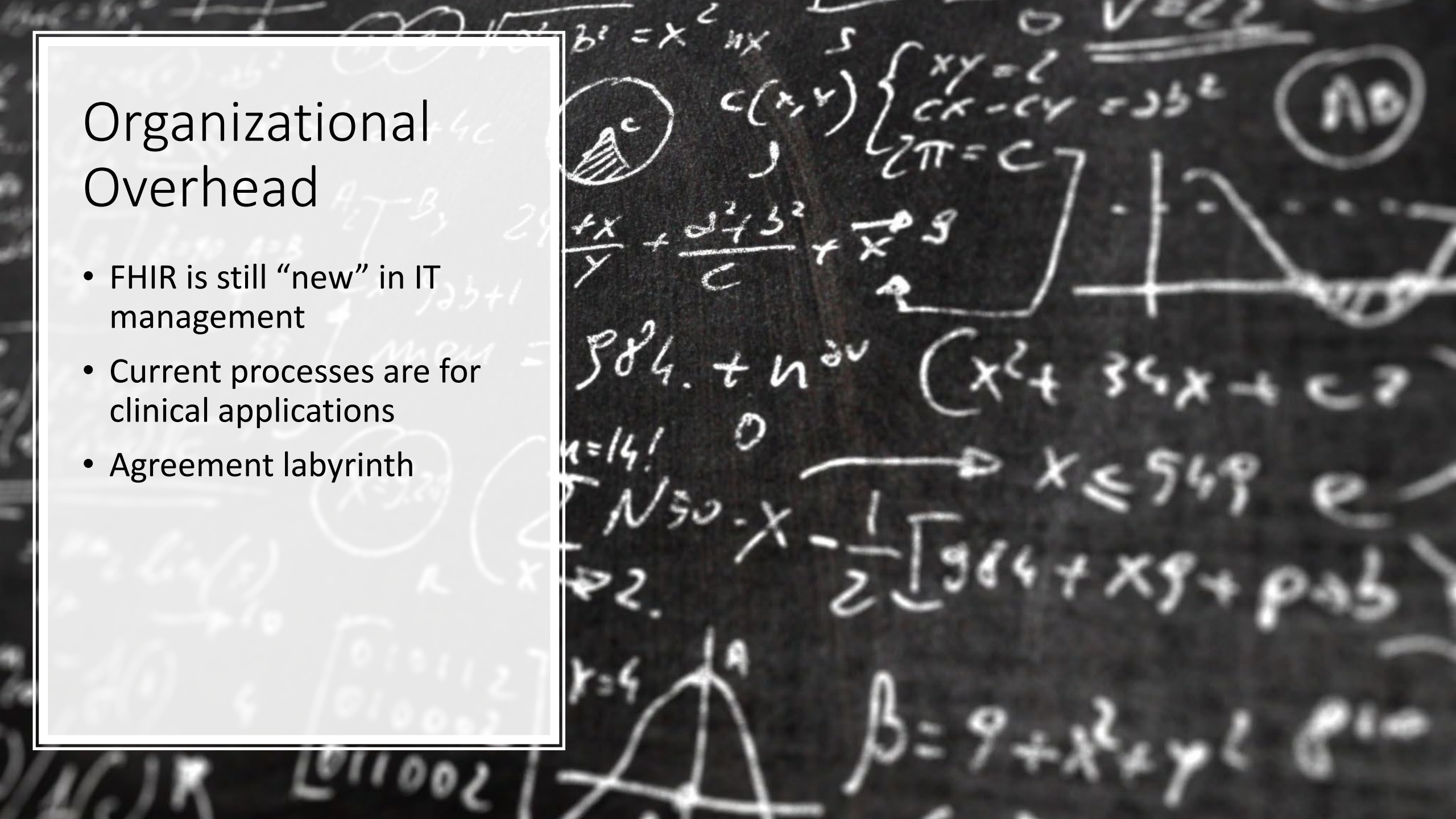
Steps

- Technically straightforward
- Tested with public servers
- Issue in working with organizations

Current State

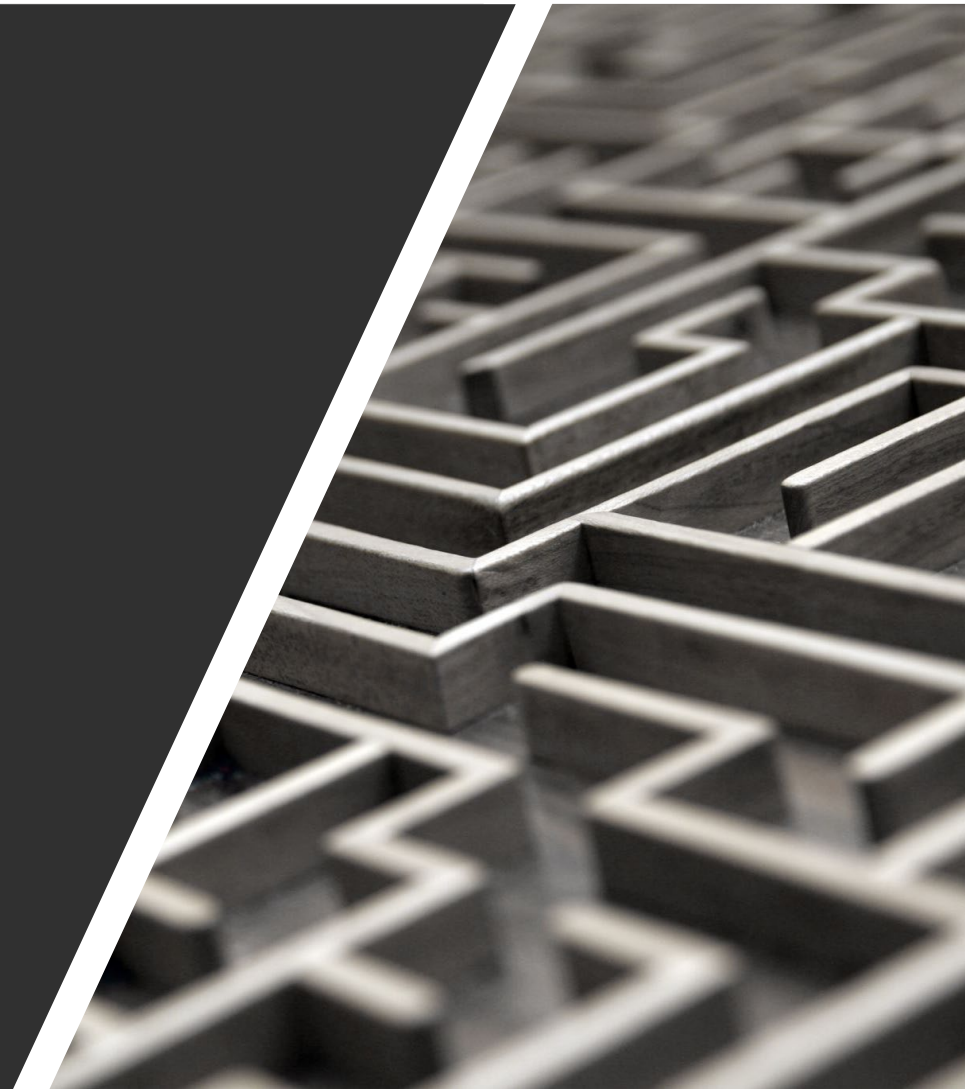
Organizational Overhead

- FHIR is still “new” in IT management
- Current processes are for clinical applications
- Agreement labyrinth



Agreement Labyrinth

- FHIR used to be behind paywalls with vendors
  - Join their developer program
  - Eventually was made free to use
- Many orgs adopted the following policy
  - **You must be in our vendor's developer program to connect with FHIR**
- Back to square one
  - Financially programs don't make sense



FHIR’s Standing for Registries

- Scope aimed at clinically workflows
- Works for some registry/research work
  - Square peg – round hole
- Example - CDSR registry
  - AUC criteria code used
  - AUC vendor
  - Operational details not in FHIR

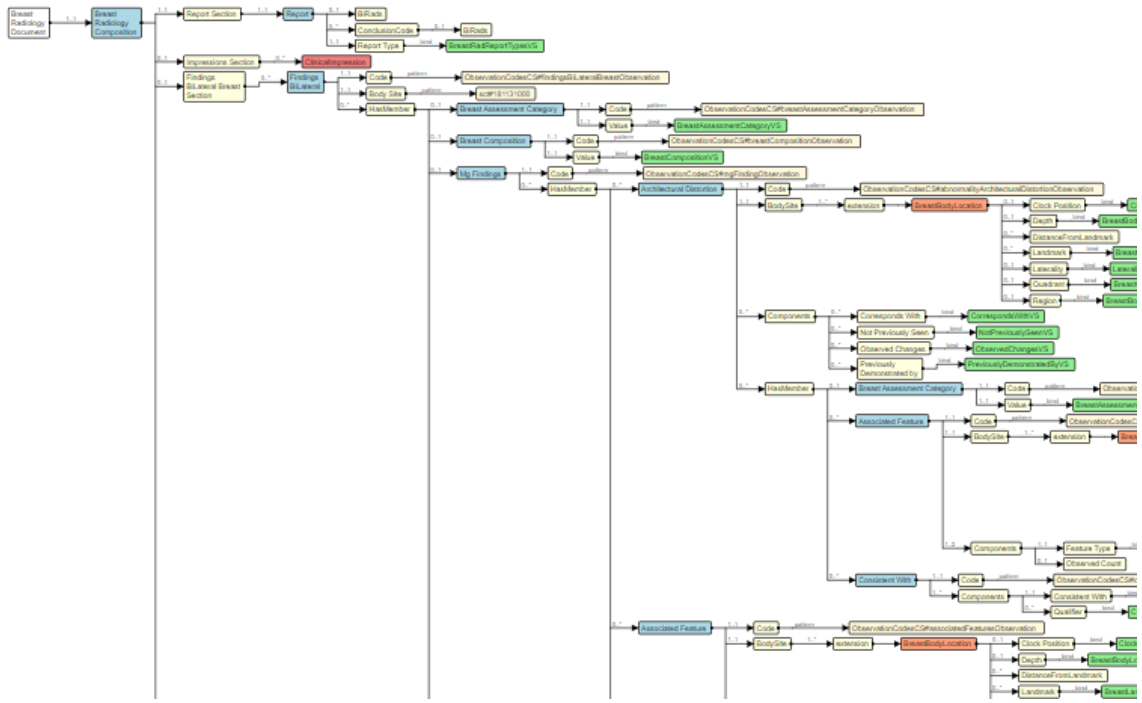
FHIR (Fast Healthcare Interoperability Resources)

Contain a set of structured data items as described by their definition

- Patient
  - Demographics and other administrative information about an individual
- ServiceRequest
  - A record of a request for service such as diagnostic investigations to be performed
- ImagingStudy
  - Representation of the content produced in a DICOM imaging study
- Observation
  - Measurements and simple assertions made about a patient
- DiagnosticReport
  - The findings and interpretation of diagnostic tests performed on patients

Using FHIR resources

- FHIRcast
  - Synchronizes healthcare applications in real time to show the same clinical content to a common user
- FHIR IG (Implementation Guide)
  - National standards, vendor consortiums, clinical societies, etc. publish "implementation guides" that define how the capabilities defined by the FHIR specification are used in particular data exchanges, or to solve particular problems

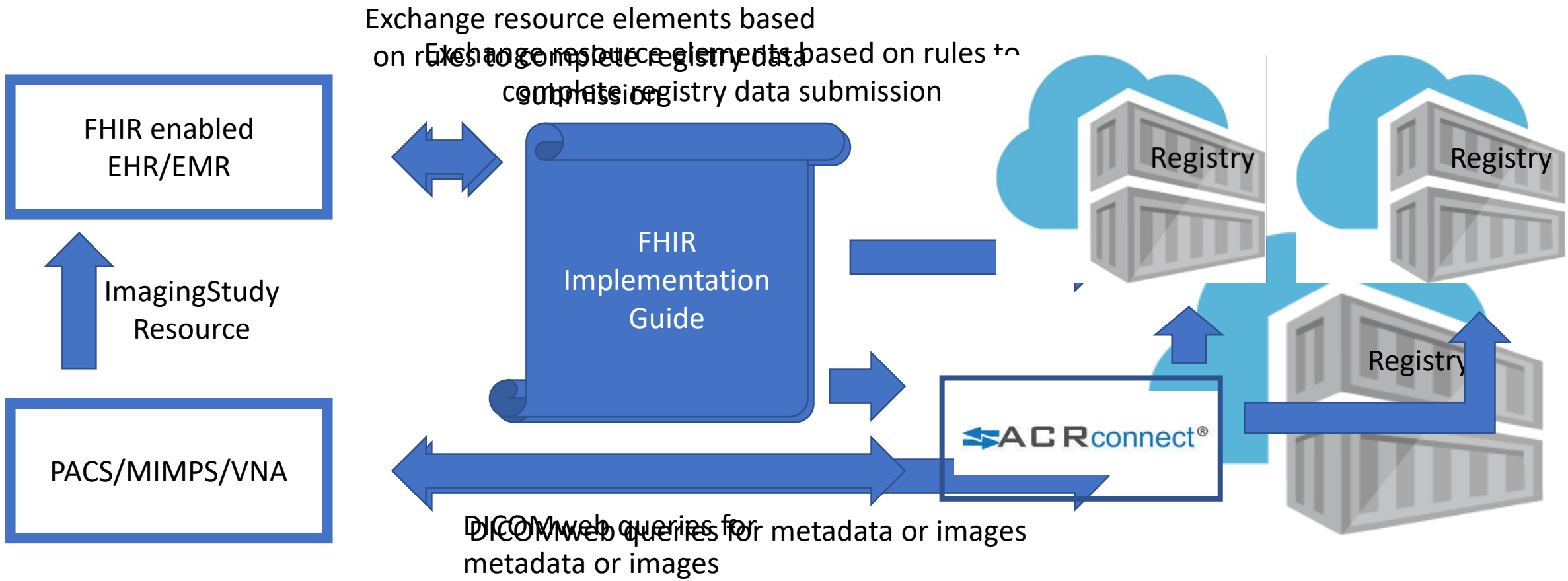
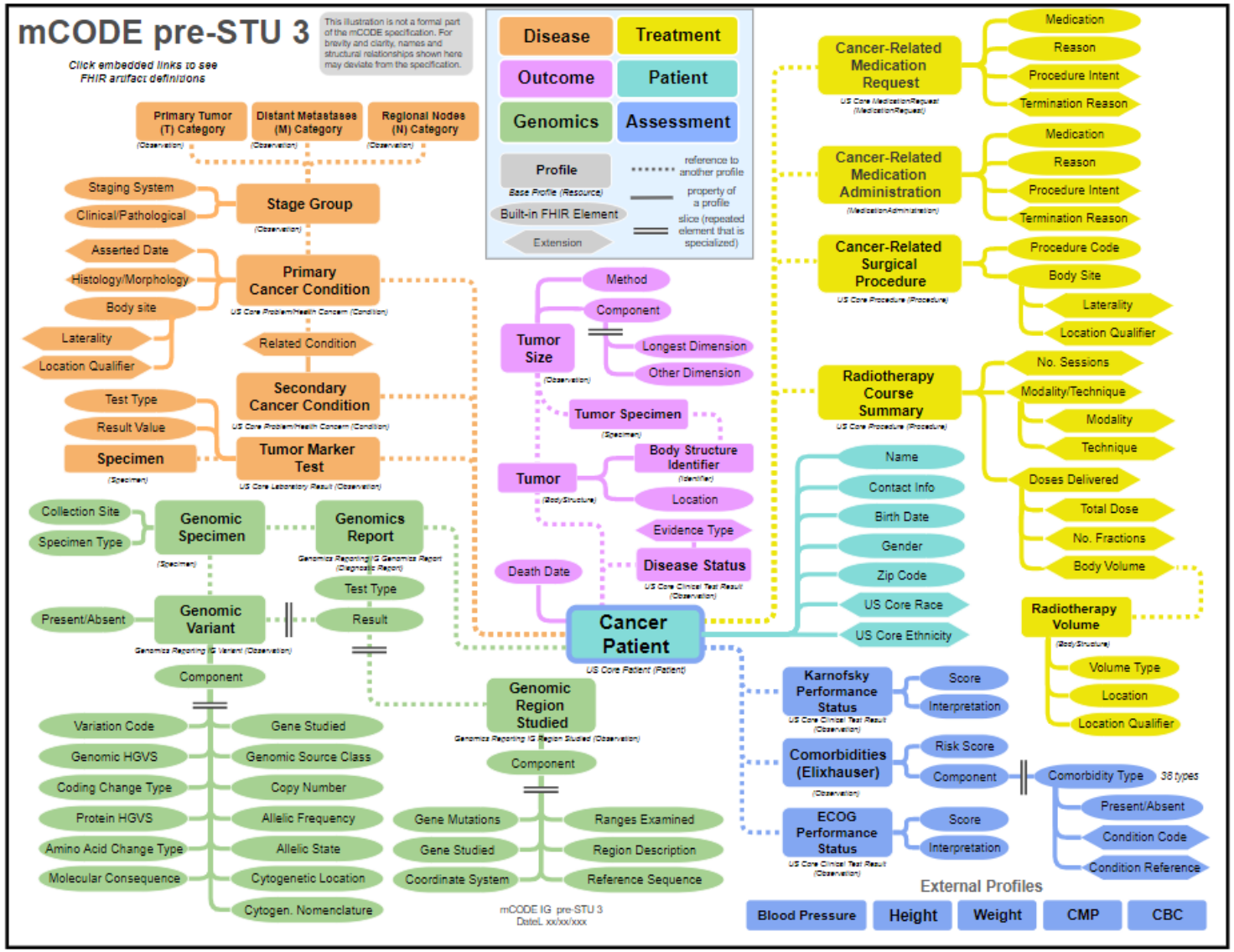


Call to Action – Vendor Support

- ImagingStudy resource support from EMR/EHR vendor
  - Limited to no support today
- ImagingStudy population by PACS (picture archiving and communication systems) / MIMPS (medical image management and processing systems) / VNA (vendor neutral archive) vendor
  - Currently no known clinical implementations
- DICOMweb support by imaging vendors
  - Supported in many VNA implementations but may have limited exposure, although DIMSE operations are more prominent

Call to Action – Societies / Registry Providers / CMS

- Publish a FHIR Implementation Guide for registries and quality measures that can automated data submissions



Example from mCODE