Trusted Convener of US Industry & Government to Address Health IT Interoperability Needs & Testing Requirements Overview for Greek Task Force

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the sequoia project

The Sequoia Project's Role

The Sequoia Project is a trusted, independent convener of industry and government

Supports multiple independent initiatives, each with their own mission, governance, membership and structure.

SECURE

INTEROPERABLE

NATIONWIDE

Sequoia Provides Support Services to:

eHealth Exchange is a nationwide public-private health information network

Carequality operates a nationwide interoperability framework to link health information networks

Current Sequoia Project Initiatives

PULSE
Patient Unified Lookup System for Emergencies

PULSE is a system which provides disaster healthcare volunteers access to information to treat individuals injured or displaced by disasters

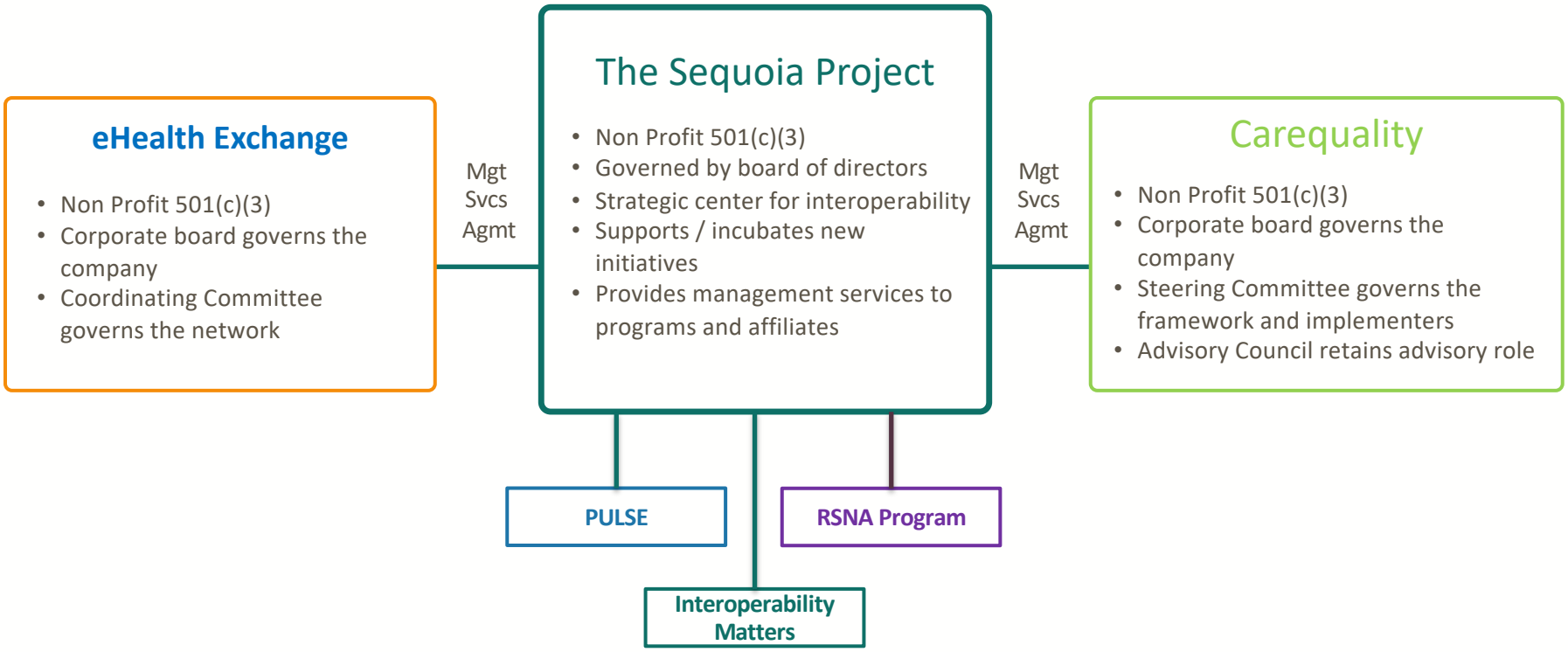
RSNA Image Share VALIDATION

RSNA Image Share Validation Program is an interoperability testing program to enable seamless sharing of medical images

Interoperability Matters

Interoperability Matters is an interoperability leadership forum

Corporate Structure Overview



21st Century Cures Act – Section 4003(b)

"[T]he National Coordinator shall convene appropriate public and private stakeholders to develop or support a ***trusted exchange framework*** *for trust policies and practices and for a* ***common agreement*** *for exchange between health information networks."* *[emphasis added]*

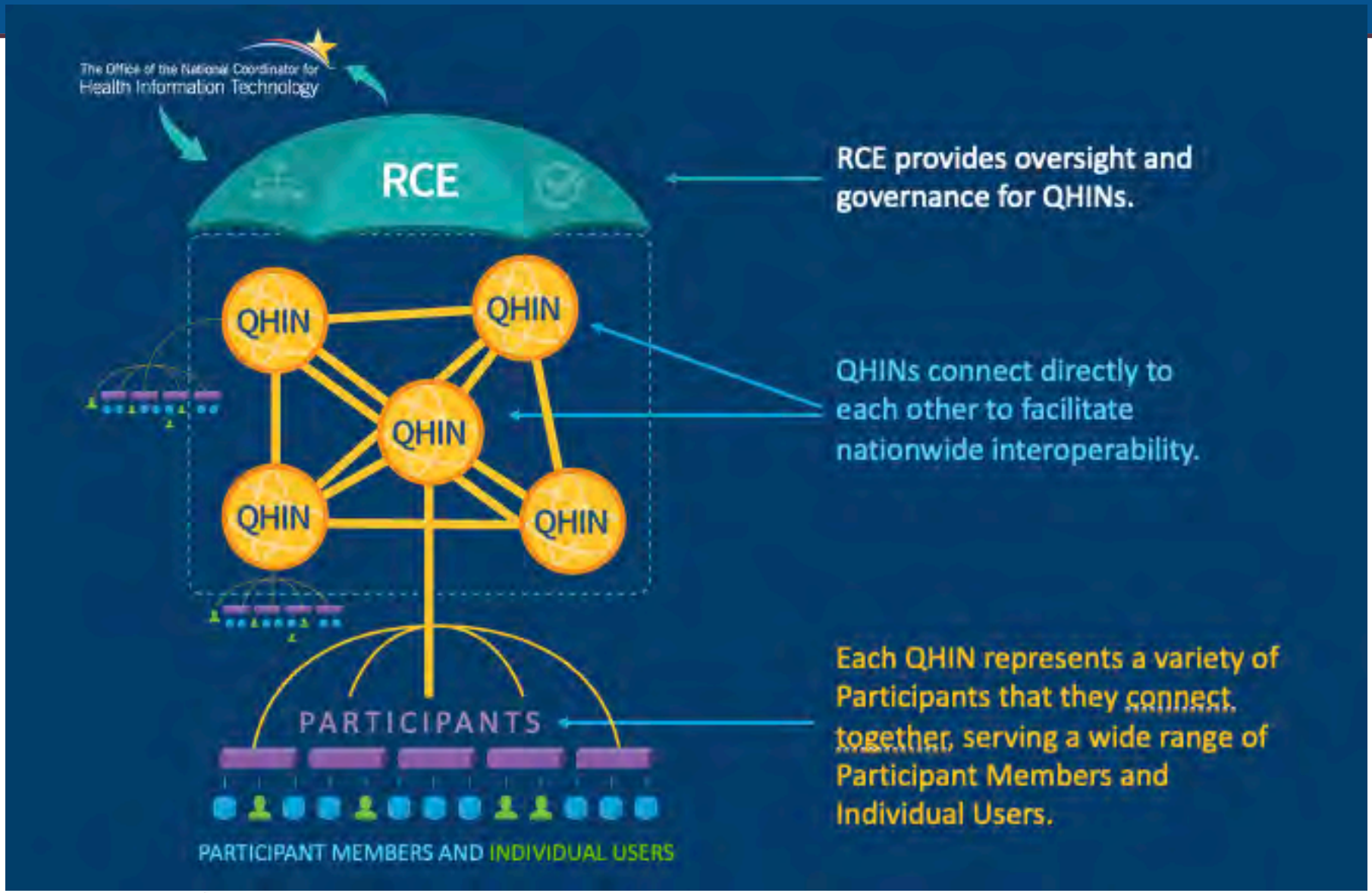
https://rce.sequoiaproject.org/wp-content/uploads/2019/10/RCE-Public-Kickoff-Call-10.7.2019-Web-Final.pdf

TEFCA Goals

Provide a single "on-ramp" to nationwide connectivity

Electronic Health Information (EHI) securely follows you when and where it is needed

Support nationwide scalability


The Office of the National Coordinator for Health Information Technology
RCE
QHIN
QHIN
QHIN
QHIN
QHIN
PARTICIPANTS
PARTICIPANT MEMBERS AND INDIVIDUAL USERS
RCE provides oversight and governance for QHINs.
QHINs connect directly to each other to facilitate nationwide interoperability.
Each QHIN represents a variety of Participants that they connect, together, serving a wide range of Participant Members and Individual Users.

ONC Selection of Recognized Coordinating Entity

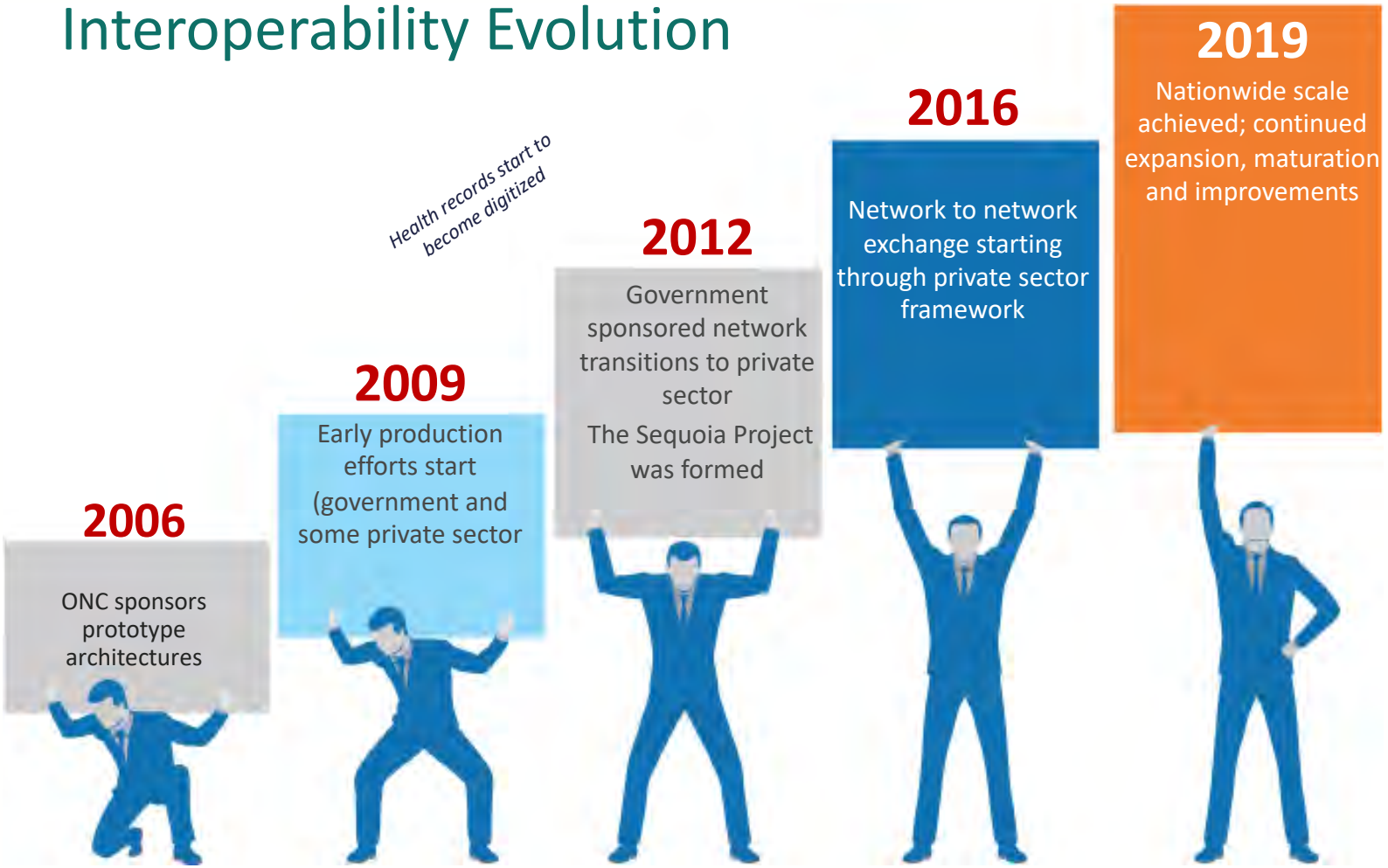
- ONC posted a Notice of Funding Opportunity
- The Sequoia Project applied, with support from 55+ organizations
- The Sequoia Project was selected 8/29/19
- News Release: https://www.hhs.gov/about/news/2019/09/03/onc-awards-the-sequoia-project-cooperative-agreement.html

www.rce.sequoiaproject.org

RCE Key Milestones

- Year 1
  - Planning and ramp up
  - Engage stakeholders and enlist input
  - Develop the Common Agreement
  - Update the QHIN Technical Framework (QTF) for production use
  - Develop a process to designate and monitor Qualified Health Information Networks (QHIN)
- Subsequent Years
  - Facilitate ongoing stakeholder engagement and input
  - Maintain Common Agreement
  - Maintain QTF
  - Designate and monitor QHINs
  - Propose sustainability strategies

Interoperability Evolution



Sequoia Interoperability Testing Platform (ITP)

Tooling Leverages Gazelle Platform Hosted by IHE Services

Content Testing VM

- Tooling updated 03/30/20 – Erratum, Value Sets, Reported Defects
- Working with Partner Organizations and Vendors to support Data Quality Improvements for Industry (RCE/USCDI Coordinated strategy)
- EVS Client (UI for Systems Under Test) https://gazellecontent.sequoiaproject.org/EVSClient/home.seam

Sequoia Transport & Security Testing VM https://validation.sequoiaproject.org/

- Gazelle Test Management (User Management)
- Gazelle Security Suite (Security Testing)
- Assertion Manager (Checklist Testing)
- EVS Client (UI for Systems Under Test)
- Patient Manager (PD Testing)
- Gazelle Webservice Tester
- XDS Toolkit (QD & RD Testing)
- Tooling updated 11/29/19 – Latest Versions

RSNA Image Share VALIDATION

IHE CONFORMITY ASSESSMENT

Validated eHealth Exchange

IHE GAZELLE eHealth test framework for interoperability

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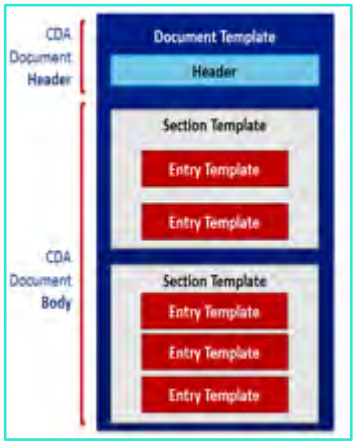
Content Testing Program Background & History



1. 2015/06 Testing Workgroup approved
2. 2016/07 Content Testing Pilot Completed
3. 2017/01 Requirements Effective
   - Meaningful Use 2011 Edition (HL7 CCD/C32)
   - Meaningful Use 2014 Edition (HL7 C-CDA R1.1) + Companion Guide
   - Meaningful Use 2015 Edition (HL7 C-CDA R2.1) + Companion Guide
4. 2018/02 Sequoia Interoperability Testing Platform Launched/Available – Content
5. 2019/10 All Existing and New Participants MUST Complete Initial Testing
6. 2021/04 All Participants have 18 months to remediate Reported Errors

Value Sets
https://vsac.nlm.nih.gov/

Requires UMLS license/account

C-CDA R1.1 (9 Document Types) and R2.1 Document Types (14 Document Types)

C-CDA R1.0/R1.1

- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

New as of C-CDA R2.0/R2.1

- Care Plan
- Referral Note
- Transfer Summary
- Clinical Note
- Patient Generated Summary

Content Testing Status

- **15 or 5%** of Eligible Participants organizations have **Passed**
  - https://ehealthexchange.org/participants/ 

- **95%** have Submitted and **Failed** for various reasons, the most common are:
  - Vocabulary issues such as incorrect code system reference or incorrect value from value set referenced in the Value Set Authority Center (VSAC)
  - Required fields missing such as Street Address or other required CCDS data classes – US Realm Header Requirements
- >9000 Documents Tested with >70% tested against HL7 C-CDA R2.1 Standards
- No known defects in the tooling at the present time
  - Issues as they are identified will be documented on the tooling home screen
  - Validators were last rebuilt and tested 03/30/2020
- Sequoia working with Vendors and their Customers to coordinate remediation

Sequoia Clinical Data Quality/Standards Feedback Loop

- Sequoia drives HL7 Specification Improvements Yearly since 2017
- HL7 C-CDA R2.1 Specification
  - Testing Tools Launched in 2018 with clean published specs
  - Sequoia Pushed for two 2018 Errata Publications (May, December)
  - Errata continues to be contributed to HL7 as spec issues are identified
- Value Sets 

  - HL7 published Value Sets for industry for first time in 2018
  - Sequoia worked with NLM who hosts the Value Set Authority Center (VSAC) to publish 2019 Value Set Updates June 28, 2019
  - Yearly Cadence for Value Set Updates
  - Working with ONC to provide increased funding to support VSAC
- Collaboration with industry groups for data quality improvement

PULSE

Patient Unified Lookup System for Emergencies

An initiative of the sequoia project

We Can’t Control Disasters; We Can Control Our Response

Disaster Healthcare Volunteers Deployed to Alternative Care Facilities

PULSE is activated and available for use

Volunteers use PULSE to request and access critical patient information to treat patients who are displaced or seeking care in Alternate Care Facilities

Key Healthcare IT Challenges During Disasters

- Physical
  - Disrupted access to electronic systems
- Staffing
  - Are disaster health volunteer's identity proofed and authorized to treat
- Information
  - Limited or disrupted access to key patient information (e.g. problems, meds, allergies)
- Reunification
  - Locating missing / related patients

(PULSE is designed to assist in certain aspects of the first three cases! In the fourth case, an enhancement is under consideration to allow for secure lost person reunification.)

Patient Unified Lookup System for Emergencies

What Does PULSE Do?

PULSE enables authorized disaster healthcare volunteers to access health records to treat people injured or displaced due to disasters

How Does PULSE Work?

- Disaster Healthcare Volunteers log into the PULSE portal and are authenticated against the state's credentialed volunteer database
- Authorized volunteers in alternative care facilities, search for patient records from all connected providers and networks
- Volunteers retrieve view patient records while treating them at the alternative care facilities

RSNA® Image Share VALIDATION

RSNA Image Share Validation Program

- **Fills a national Standards Gap**
  - Product conformity assessment testing
- **IHE profiles provide specifications for testing**
- **Modular Standards/Specifications/Test Cases**
  - Cross-Enterprise Document Sharing for Imaging (XDS-I)
    - Document Source and Document Consumer
    - Registry and Repository
  - Cross-Community Access for Imaging (XCA-I)
    - Initiating Gateway
    - Responding Gateway

RSNA Image Share Validated Products

RSNA Image Share VALIDATION

Acuo by Hyland

AMBRA

dicom systems

LifeImage

SIEMENS Healthineers

http://sequoiaproject.org/rsna/validated-products/

Industry Developed Trusted Exchange Framework and Common Agreement

Accelerating seamless, interoperable health information exchange among networks

Health Information Network Evolution

- Public policy and public good call for multiple health information networks
- Numerous health information networks evolved since 2009, each with different affinity groups, geographies, services, etc.
  - Regional and statewide health information networks
  - Consumer apps
  - Technology vendors
  - Service providers (e.g. gateway, record location service, etc)
  - Others
- Prior to 2016, these networks were not able to interconnect due to differing standards, policies, data sharing agreements and governance

The Challenge

What if you had a cell phone plan that only allowed you to call other customers of your carrier?

That's the situation for most healthcare providers today, when they join a health information network.

The Solution

Carequality creates a standardized, national-level interoperability framework to link all data sharing networks

Carequality has created a web of interconnected networks

Essential Elements

Common rules of the road: In order for the varied participants to trust each other with health information, everyone needs to have a legal obligation to abide by the same rules.

Well-defined technical specifications: Shared rules are not enough; clear standards must be laid out in an implementation guide that all implementers can follow.

A participant directory: To connect using the common standards, systems must know the addresses and roles of each participant.

The Carequality Process

Carequality Interoperability Framework

- Legal and Governance Documents:
  - Carequality Connected Agreement (11/04/2019)
  - Carequality Connection (CC) Terms (11/04/2019)
  - Dispute Resolution Process
  - Technical Trust Policy
  - Carequality Policy on Full Participation During COVID-19 Emergency
- Implementation Guides
  - Query-Based Document Exchange Implementation Guide
  - Proposed – Image Exchange Implementation Guide Supplement v0.2 (12.02.2019)
- Coming Soon…Implementation Guides
  - FHIR, Push Notifications and Electronic Case Reporting

eHealth Exchange™

Nationwide Health Information Network Started by Government and Supported by Private Sector

Formerly known as Nationwide Health Information Network (NHIN)

What is the eHealth Exchange?

- Facilitates electronic exchange of patients' medical information
- Improves the speed, quality, safety, and cost of patient care
- Informs clinical decisions **when seconds and minutes matter**

How are we different?

Incubated by the U.S. Department of Health and Human Services as an ONC initiative in 2006

The eHealth Exchange is now a non-profit Health Information Network (HIN) dedicated to the public good

Diverse Use Cases

The longest-standing nationwide network supporting diverse use cases

Federal Connectivity

The only network enabling providers & regional networks direct exchange with federal agencies

Vendor Agnostic

The only vendor-independent nationwide network

Out of Network Exchange

Provides exchange not only among eHealth Exchange Participants, but also with Carequality-enabled networks

The Largest Health Data Network in the U.S.

eHealth Exchange™

We connect:

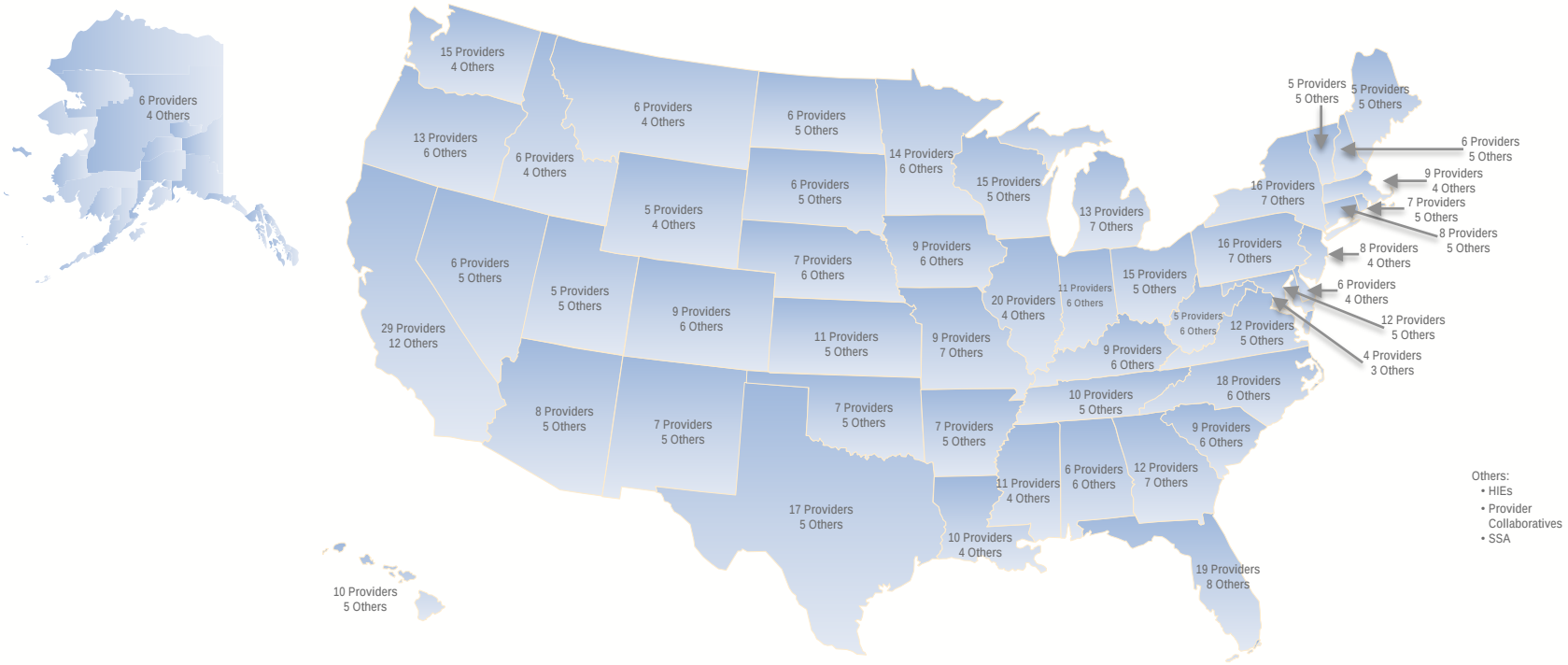
All 50 States	70,000 Medical Groups
Four Federal Agencies (DoD, VA, CMS, SSA)	5,200+ Dialysis Centers
75% of U.S. Hospitals	8,300 Pharmacies

Supporting more than 120 million patients

60+ Regional and State HIEs

279 Participants (75% US Hospitals)

(200+ Health System contracts + 61 State/Regional HIE contracts)



61 State & Regional HIEs

Patient-Centric Exchange Use Cases

Treatment / Care Coordination
Enables access to critical information to support improved care coordination for patients by their providers during transitions of care

Social Security Disability Benefits Determination
Automates the request and retrieval of records to support applicants' claims for disability benefits, accelerating determination process

Immunization
Enables the push of immunization data for treatment purposes *(not related to immunization registries)*

CMS End Stage Renal Disease Quality Reporting
Enables dialysis centers to send quality data to CMS to ensure kidney patients receive superior quality of care

Life Insurance Applications
Automates the request and retrieval of clinical records for life insurance applications

Consumer Access to Health Information
Enables clinical exchange between patient and provider, often via a Personal Health Record (PHR)

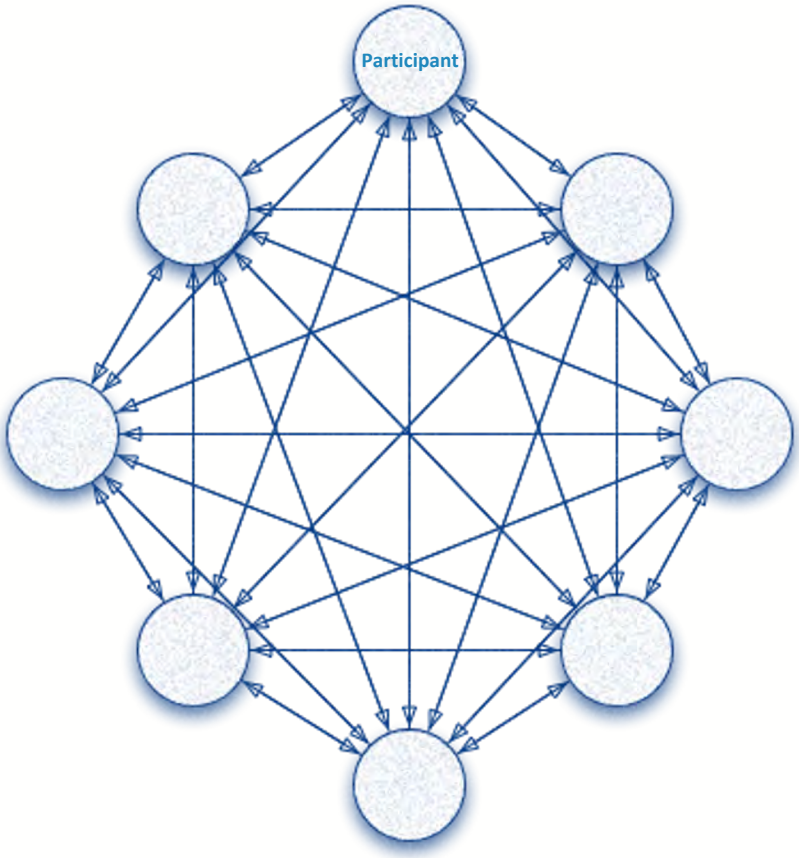
Image Share
Enables organizations to share images

Encounter Alerts
Enables event notification of clinical encounters to patient associated care team members

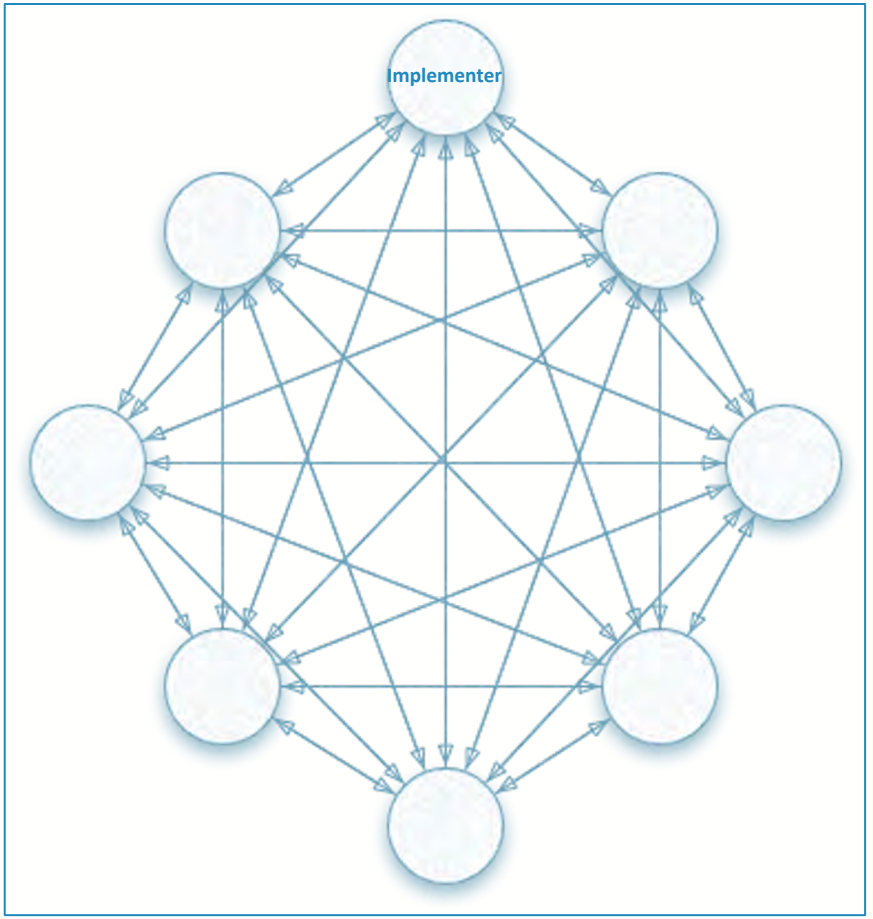
Prescription Drug Monitoring Program (PDMP)
Enables exchange of PDMP data

Syndromic Surveillance Reporting
Enables providers to report disease trends (including lab results) to public health agencies

Federated Architecture



eHealth Exchange Participants



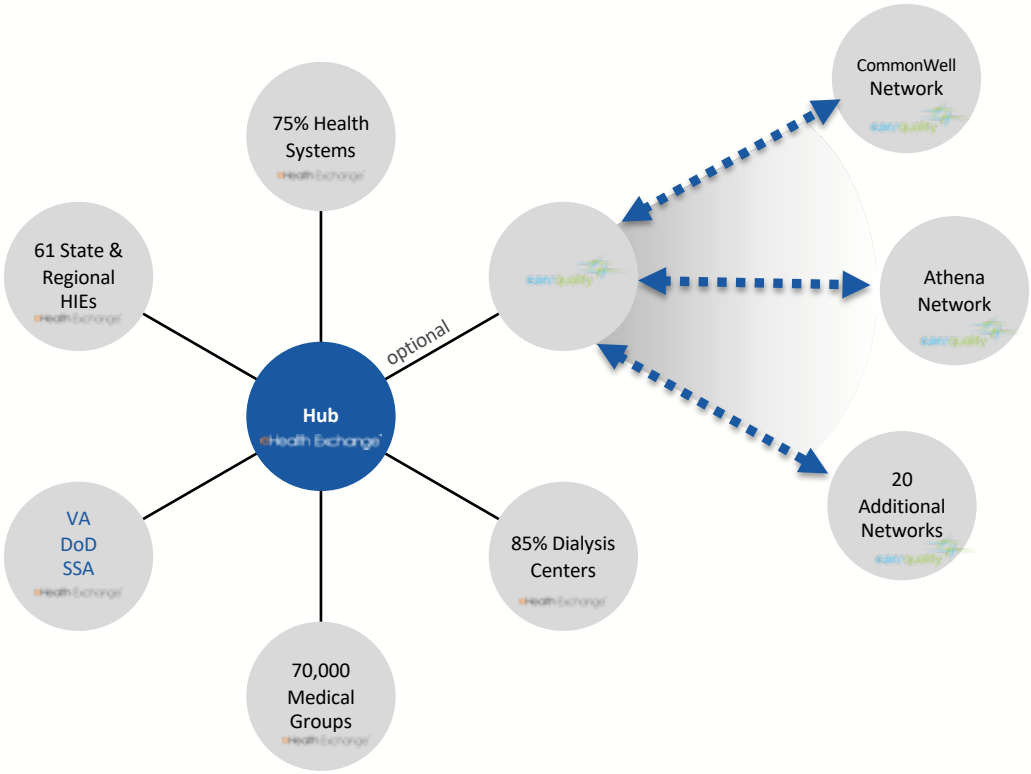
Carequality Implementers

Hub Accelerates Expanded Reach

carequality

- Surescripts
- CommonWell Health Alliance
- athenahealth
- NextGen Healthcare
- eClinicalWorks
- Epic Care Everywhere
- GE
- Netsmart
- Etc.

Single Connection to eHealth Exchange & 20+ Carequality Networks



What is the DURSA (Data Use and Reciprocal Support Agreement)?

A comprehensive, multi-party trust agreement:

- Establishes Participants' obligations, responsibilities and expectations
- Creates a framework for safe and secure health information exchange
- Promotes trust among Participants
- Expects Participants comply with Applicable Law
- Protects the privacy, confidentiality and security of the health data that is shared
- Assumes that each Participant has trust relationships in place with its agents, employees and data connections
- Evolves as a living document and modified over time

Signed by Veterans Administration, DoD, SSA, CMS, 200+ Health Systems, 61 HIEs

http://ehealthexchange.org/onboarding/dursa/

https://ehealthexchange.org/policies/

https://ehealthexchange.org/onboarding/how-to-apply/

eHealth Exchange Testing Program Overview

eHealth Exchange Participant Testing Program: This process verifies that Systems used by Applicants and Participants comply with the Specifications and satisfy the requirements established by the DURSA.

eHealth Exchange Validated Product Program: This process verifies that the Systems developed by Vendors that may be used by Applicants and Participants, comply with the Specifications prior to being implemented in the Applicant's and / or Participant's production environment. The objective is to establish built-in conformance and interoperability into these Systems to minimize variability in System compliance in production.

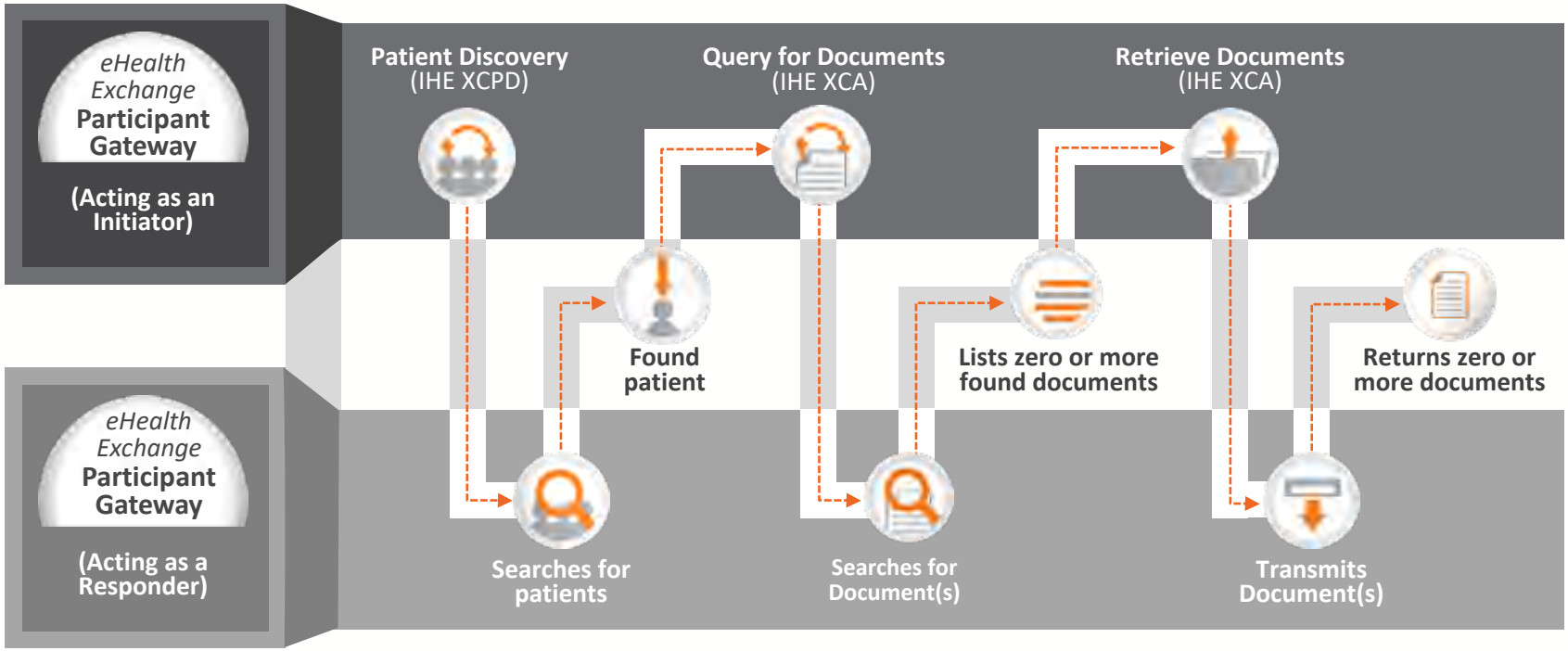
eHealth Exchange Content Testing Program: documentation, testing methodology, and test data that will be required for interoperability testing to enable the exchange of clinical content between eHealth Exchange Participants.

National Use Cases and Standards Supported
https://ehealthexchange.org/testing-program/exchange-specifications/

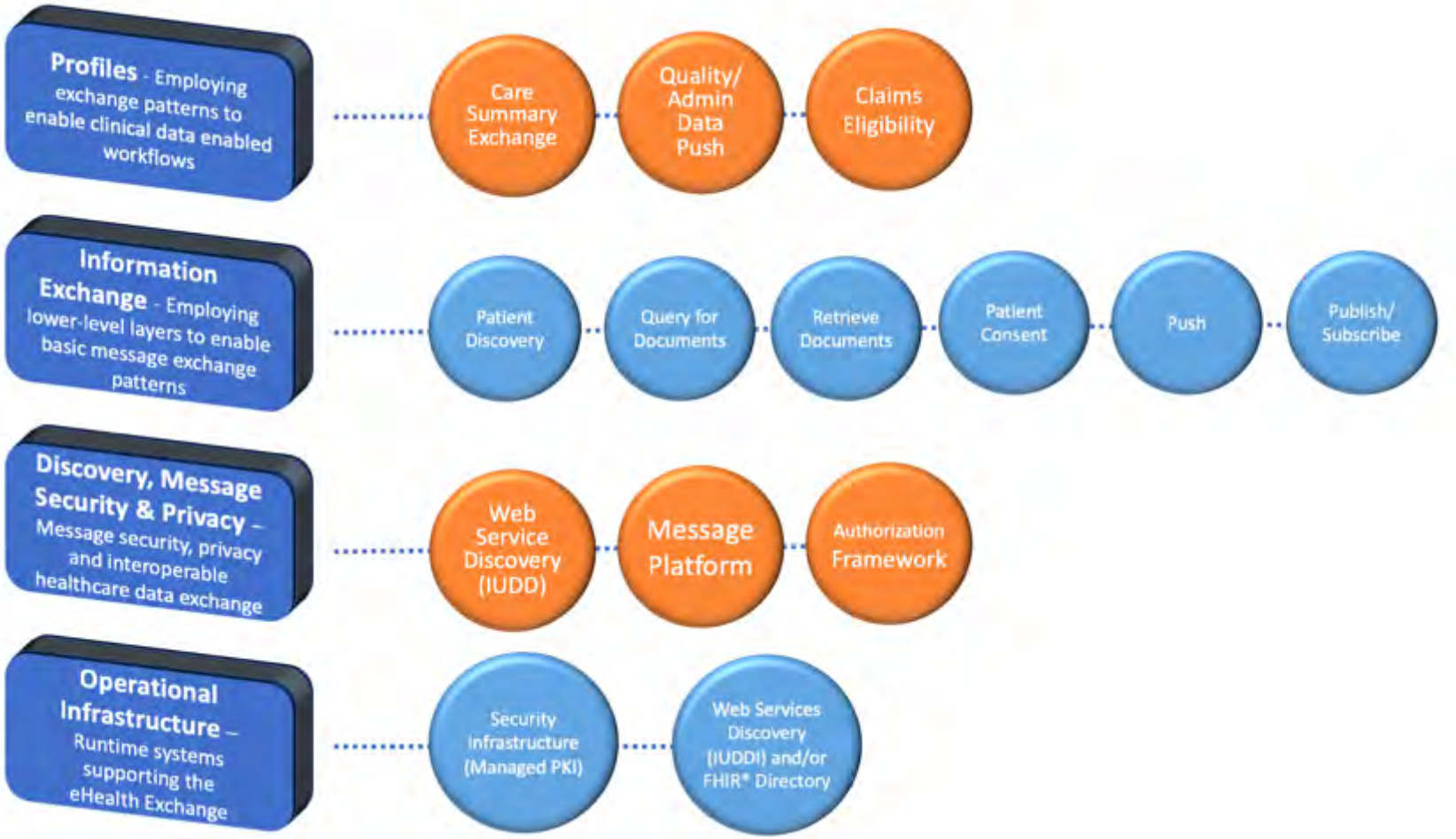
Specifications & Standards

- **Query Use Case: SOAP / SAML + IHE (XCPD, XCA, ATNA, XUA,)**
- Push: ONC NHIN Direct, Document Submission / Admin Distribution
- Content: HL7 CDA, CCDA, quality measures
- **HL7® FHIR®**
- **Imaging Exchange**
  - **Integrating the Healthcare Enterprise (IHE) - XDS-I, XCA-I)**
- Others added in 2016
  - VPN (transport)
  - HL7 v2 (content)
  - NCPDP, PMIX, SCRIPT

Query Workflow



eHealth Exchange Architectural Layers



Testing is the Backbone of Interoperability

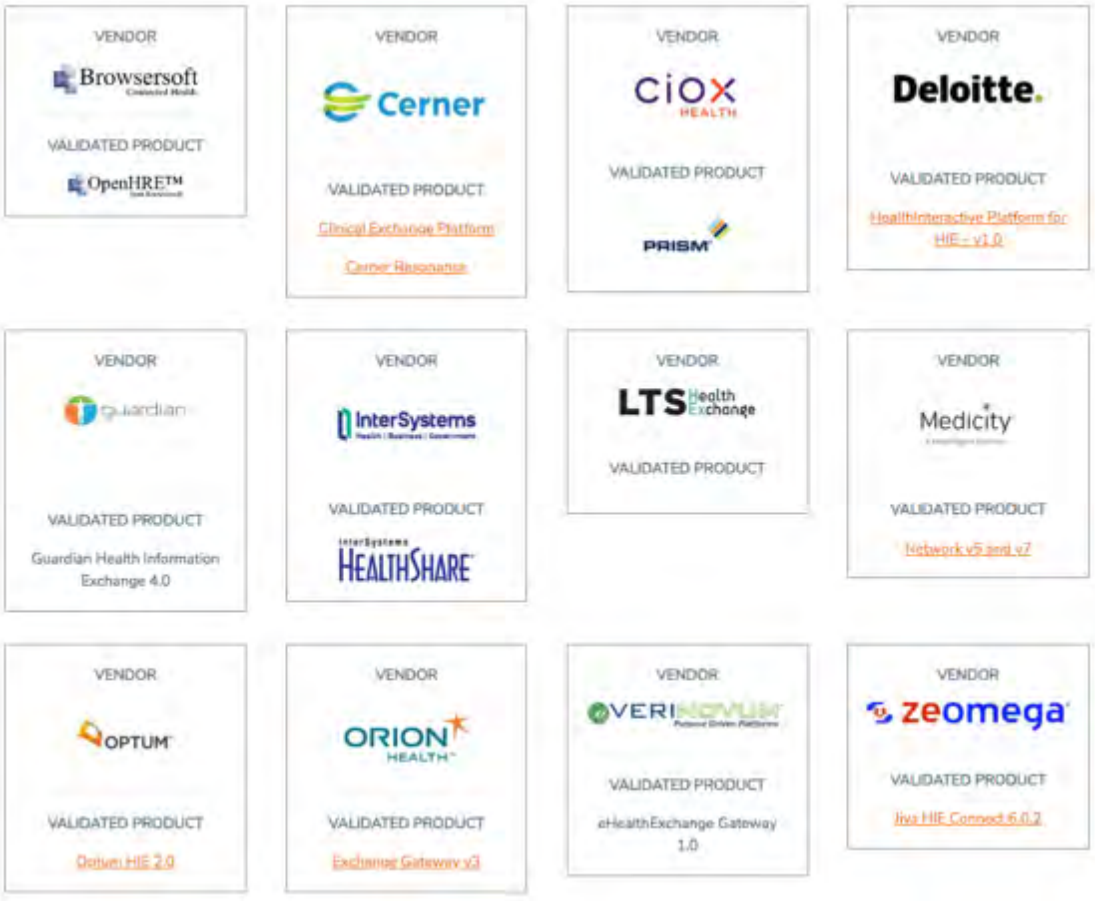
Provides testing of Products, Participants, and Content

- Validates interoperability compliance and HIE standards
- Ensures predictable and reliable exchange

Customers using validated products onboard to eHealth Exchange FASTER and CHEAPER

Validated products receive the eHealth Exchange Validated Products Seal

Validated Product Vendors:



Countless additional EHRs are also widely used on the eHealth Exchange

https://ehealthexchange.org/testing-program/validated-products/

Charting a Course for the Future

SOURCE: https://www.healthit.gov/infographic/shared-nationwide-interoperability-roadmap-journey-better-health-and-care

Appendix: Lessons Learned Operating a Nationwide Health Information Network

#1: Essential Building Blocks

- **Highly constrained specifications**
  - Transport, security, web services
  - Payload (e.g. clinical documents, images, etc.)
- **Robust Testing**
  - Well-defined test cases and automated tools that focus on known interoperability issues and security
  - Product testing to assure capabilities are “baked in”
  - Implementation-level testing of production configuration of system used in exchange
- **Workflow and best practices**
  - Patient matching
  - Consent
- **High-value use cases that drive adoption**
  - Meaningful use a start
  - Other high-value transactions essential to realize value from connectivity
- **Interoperability policies that work across networks**
  - Minimize barriers to exchange and foster trust
  - Need for clearly articulated responsibilities of parties to exchange
- **Interoperability eco-system and governance**
  - Accountability measures to promote and maintain compliance
  - Consequences for non-compliance

#2:Testing is Key

- **Multi-level testing**
  - Profile-level testing
  - Product testing and validation
  - Production-level testing to assure production configuration interoperates
- **Automated, self-service approach**
- Tightly constrained tests
- Focus on known interoperability issues and security, as well as “negative tests”
- Implementation-level testing essential to catch interoperability **issues introduced by systems configurations**
- Testing eco-system with **feedback loop** into tightly constrained implementation specifications

Thank You!

Convene

Collaborate

Interoperate

For more information on Sequoia http://www.sequoiaproject.org/

For more information on eHealth Exchange http://www.ehealthexchange.org/

For more information on Carequality http://www.carequality.org/

Join the interoperability movement:
https://sequoiaproject.org/interoperability-matters/

RCE Web Site: https://rce.sequoiaproject.org/