Sharing Medical Images with Patients & Providers with RSNA Image Share Validation

David S. Mendelson, MD FACR | Senior Associate – Clinical Informatics
Vice Chair Radiology IT | Mount Sinai Health System
Professor of Radiology |Icahn School of Medicine at Mount Sinai
Co-Chair Integrating the Healthcare Enterprise (IHE)- International

In collaboration with

Objectives

- Why Imaging Interoperability?
- How are images and reports currently shared?
- What are some of the emerging solutions to sharing images?
- Standards, Standards, Standards…..
- ONC- Shared Nationwide Roadmap
- The RSNA Image Share Validation Program
  - A partnership with The Sequoia Project

Image sharing- Why?

- Benefit of historical exam during interpretation
- Rapidly growing cost of healthcare especially growing utilization of imaging
  - Overutilization- Inappropriate Utilization
  - Prevent duplicate exam because a recent exam is inaccessible
- Radiation exposure- reduction
- Quality
  - Expedites clinical care through easy availability of imaging examination

Inappropriate Utilization

Up to 20% of imaging exams may be inappropriate

- Defensive Medicine – Liability concern
  - Tort Reform
- Patient Demand
- Financial Incentives
  - Self referral
- Pressures to minimize overall cost of an episode of care
- Physician lack of knowledge
- Duplicate exams
  - Results not easily available
  - Patient lack of understanding of exams already performed
  - Fragmented care – no coordination of care

Image Sharing vs. Image Exchange

View Only (sharing)

- File format can vary
- EMR- easier
  - Enterprise viewers
- Lighter process

Exchange

- DICOM payload
- Requires PACS or PACS viewer
- Greater workflow requirements
  - Import and Reconciliation
- Greater power to deliver care
  - Easier for comparisons, surgery, long term longitudinal imaging record

Network based Clinical Sharing - Exchange

Methods

- Local Healthcare Enterprise
  - EMR for most data
  - Radiology
  - Other Images-"..ologies"-----????? (VNA)
- Within an Extended Enterprise-Integrated Delivery Network (IDN)
- Within a Vendor network
- HIE
  - Proprietary
  - DICOM
  - Cross-Enterprise Document Sharing (XDS)
- Peer to Peer
  - NHIN Direct
  - Social Networking
    - Providers
    - Patients
- PHR- Patient directed on demand

Stakeholders

- Patients
- Provider groups- Professional Associations
- Integrating the Healthcare Enterprise (IHE)
- Government
  - ONC
  - State Health Departments and HIEs
- National Associations
  - The Sequoia Project (eHealth Exchange & Carequality)
  - CommonWell Health Alliance
  - Concert (IHE USA & IWG- Interoperability Workgroup)
- Vendors- cross many of these

Clinical Sharing- barriers

- Consent
  - Opt in
  - Opt out
- Rise of large Healthcare Enterprises
  - IDN- Integrated Delivery networks- sometimes reluctant to share content
- Vendors- a desire to have all exchange through themselves
- Disagreement regarding standards
  - JASON report
  - PCAST
  - RestFul
  - Web Services

Challenges to exchange

- Who pays for an exchange infrastructure
- What is the persistence of the information in the exchange
- Are images different from other forms of healthcare data
- Easy secure access is good for the patient
  - Does it endanger the provider?- is this an impediment?
  - Economic adjustments and evolution are likely to occur
    - Balance of cost control vs. Quality
    - Reduction in Radiation exposure
  - Not all patients agree

Useful IT tools - Standards are Fundamental building blocks

- Ontology- RADLEX, SNOMED-CT
- DICOM
- HL7 (FHIR-Fast Healthcare Interoperability Resources)
- IHE-Integrating the Healthcare Enterprise
  - Organizes the existing standards into practical efficient workflows
- Expose Information in a Computable format

IHE: A Framework for Interoperability

- A common framework for harmonizing and implementing multiple standards
  - Application-to-application
  - System-to-system
  - Setting-to-setting
- Enables seamless health information movement within and between enterprises, regions, nations
- Promotes unbiased selection and coordinated use of established healthcare and IT standards to address specific clinical needs

IHE: A Framework of Interoperability

- IHE uses an open, consensus-based process to engage users, providers and suppliers of health IT solutions to identify and solve interoperability problems
- an international SDO of users and vendors
- Profiles formally recognized by ISO though being Liaison A
- Sponsoring and fostering a robust interoperability testing ecosystem (cross-standards, open source tooling, process rigor across entire lifecycle)
- Directly supportive of ehealth projects (use cases, conformity assessment, projectathon, national certification)

IT-Infrastructure

- XDS, XDS- I Cross Enterprise Document Sharing
- XCA, XCA-I Cross Community Access
- XDR, XDR-I Cross-Enterprise Document Reliable Interchange
  - Document sharing in the absence of a registry and repository
- XDM Cross-enterprise Document Media Interchange
- XUA Cross Enterprise User Assertion Integration
- XDS-SD Cross-Enterprise Sharing of Scanned Documents
- BPPC Basic Patient Privacy Consents
- ATNA Audit Trail and Node Authentication
- XCF Cross-Community Fetch
- XCPD Cross-Community Patient Discovery
- XDW Cross-Enterprise Document Workflow
- MHD Mobile Health Documents

Radiology Specific

- PDI Portable Documents for Imaging
- IRWF Import Reconciliation Workflow
- TCE Teaching File and Clinical Trial Export
- IOCM Imaging Object Change Management
- BIR Basic Image Review
- MIMA Multiple Image Manager/Archive
- IID Invoke Image Display
- MHD-I Mobile Access to Health Documents – Imaging
- MMRT Management of Radiology Report Template
- WIC Web based Image Capture

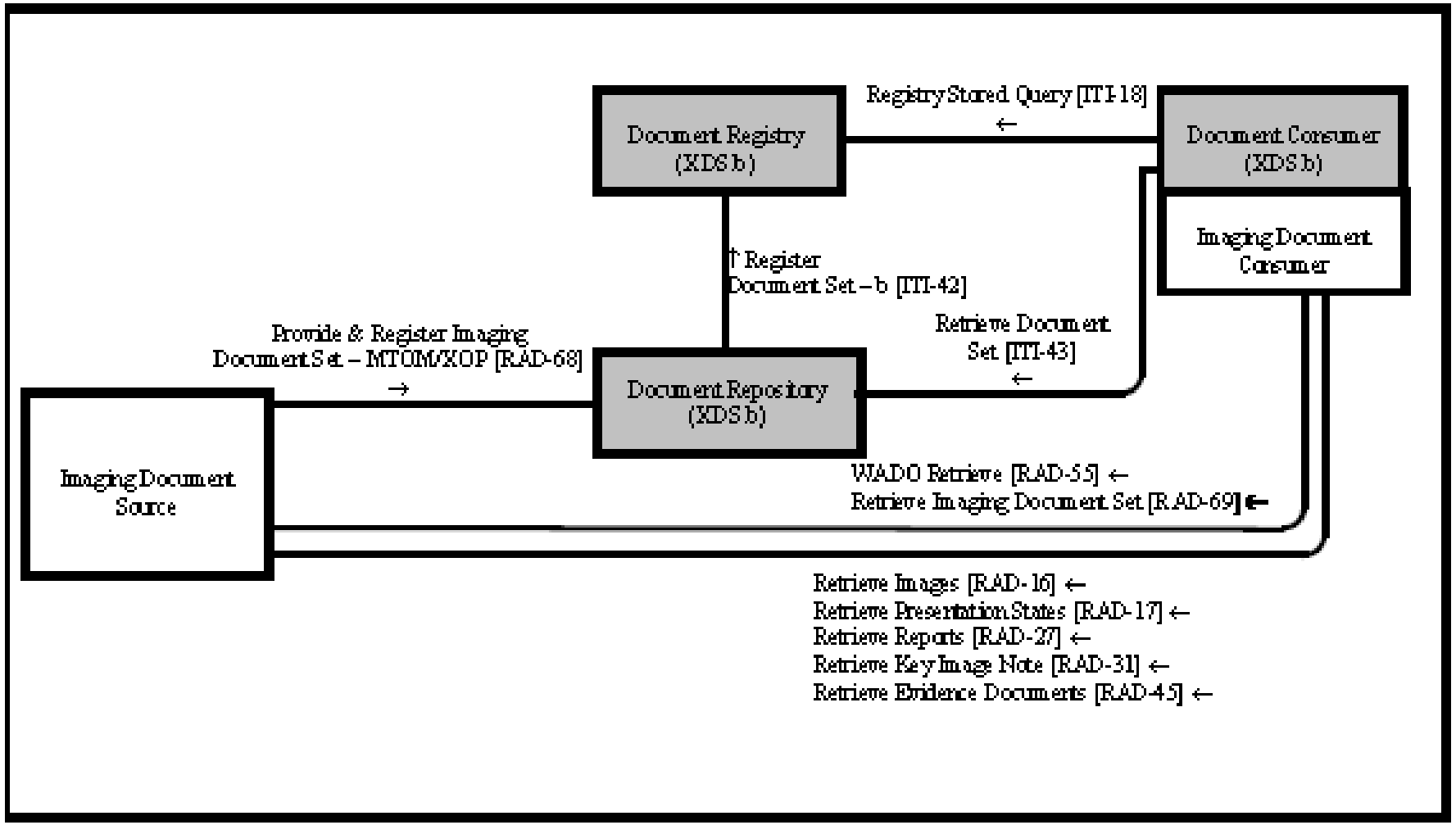
www.ihe.net
Ihe.wiki.net

FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir)

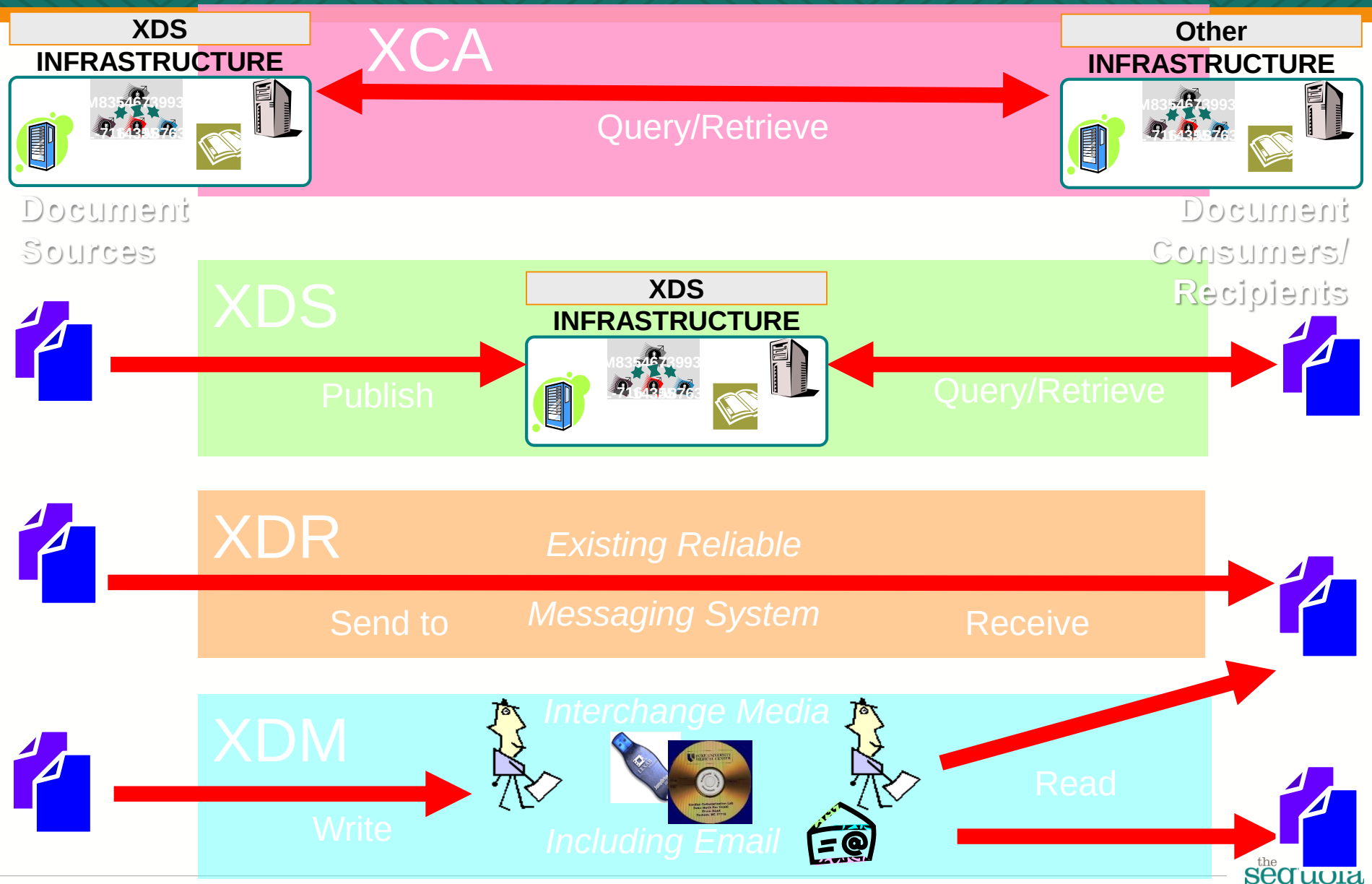
- A strong focus on implementation – fast and easy to implement (multiple developers have had simple interfaces working in a single day)
- Multiple implementation libraries, many examples available to kick-start development
- Specification is free for use with no restrictions
- Interoperability out-of-the-box– base resources can be used as is, but can also be adapted for local requirements
- Evolutionary development path from HL7 Version 2 and CDA – standards can co-exist and leverage each other
- Strong foundation in Web standards– XML, JSON, HTTP, Atom, OAuth, etc.
- Support for RESTful architectures and also seamless exchange of information using messages or documents
- Concise and easily understood specifications
- A Human-readable wire format for ease of use by developers
- Solid ontology-based analysis with a rigorous formal mapping for correctness

http://hl7.org/implement/standards/fhir/summary.html

XDS-I.b



Health Document Exchange Options
Flexible Infrastructure



Courtesy of Don Dennison

NIBIB/RSNA Image Sharing Project A **Standards** Based Solution

- Consumer controls the flow of information –Patient Engagement
  - Diminishes the need for BAAs between enterprises
    - Imaging Site to Clearinghouse
    - Clearinghouse to PHR
- Bootstrap an IHE based network
  - IHE generally has not focused on consumer driven solutions but rather on institutional and enterprise workflow
  - Primary emphasis is Consumer Control through PHRs
  - Can be extended to other forms of sharing
    - Health Information Exchange (HIE)

- Security and Confidentiality are drivers
- Replacement / Alternative to CD

- 5 Academic Institutions
- Develop a solution for all Radiology Sites
- Establish a clearinghouse
- Engage PHRs

Image Share Architecture

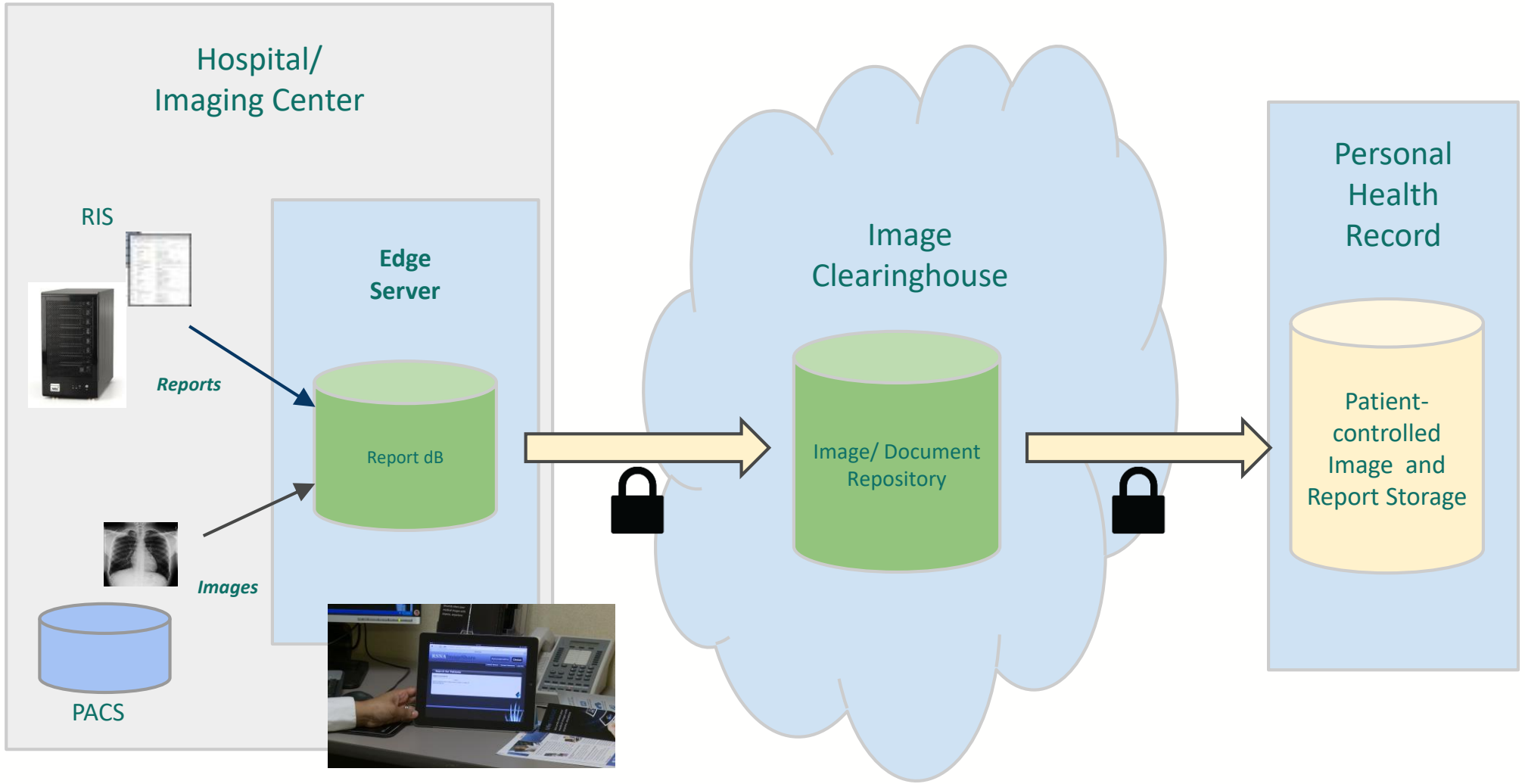


Image Sharing/Elements of Solution

- Edge Server
  - Register a patient
  - Listens to a Radiology Information System (RIS)- looking for a complete exam
  - Retrieves Image set from PACS and Report from RIS
  - Send both to clearinghouse
    - PHI hidden; an RSNA ID and 2nd factor security token are used to identify the patient
- Clearinghouse (XDS-I) – functions as a secure router
  - Transiently hold encrypted patient data
- PHR
  - Consumer controls upload and future access
    - Must have RSNA ID available and know answer to 2nd factor question
  - Develop web based viewers
  - Download full DICOM data set
- Misc Consumers

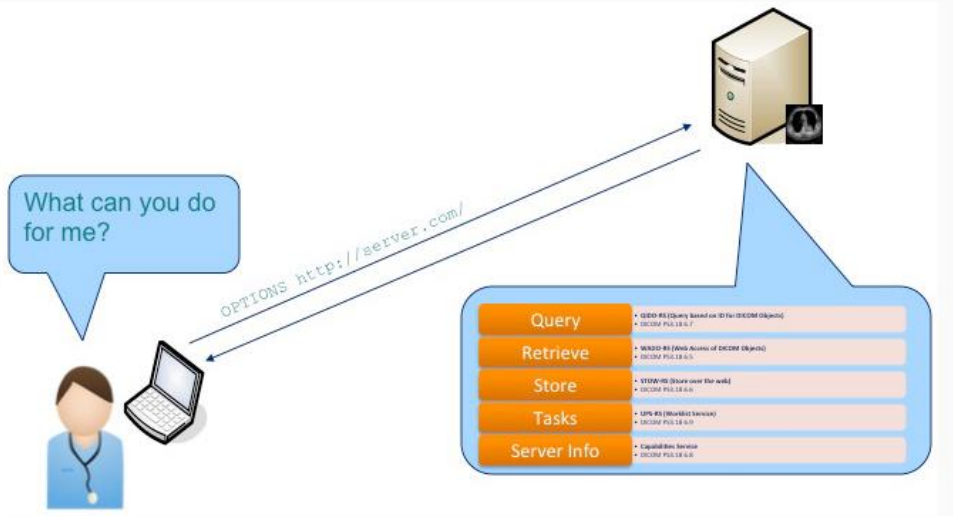
How to move large DICOM exams efficiently?

- DICOM historically is not a communication protocol; not a web protocol
- Every Image contains metadata
  - Redundant thousands of times

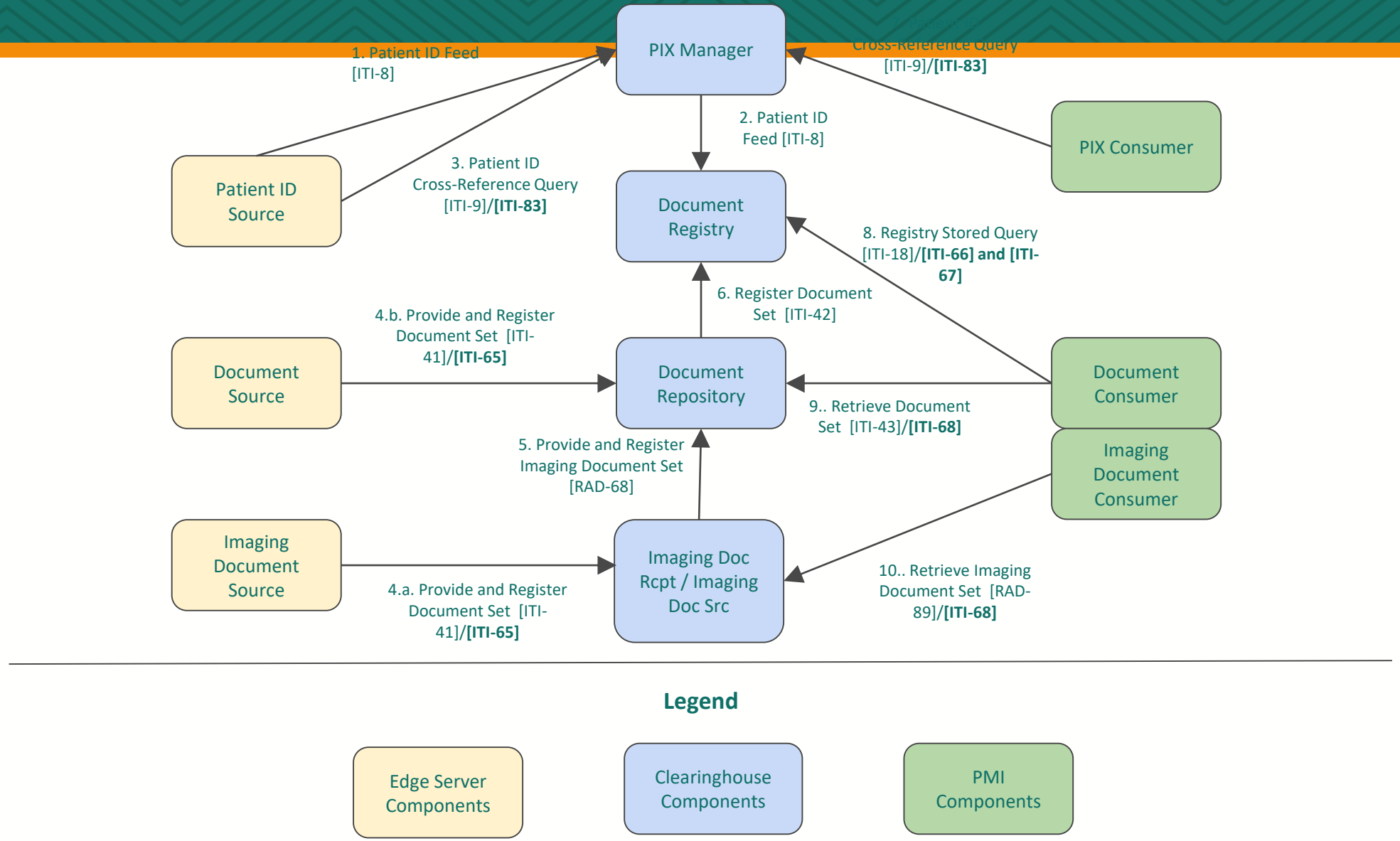
- Solutions
  - Segregate the pixel data from the metadata
  - Web Services
  - move to RESTful services

DICOMweb Services

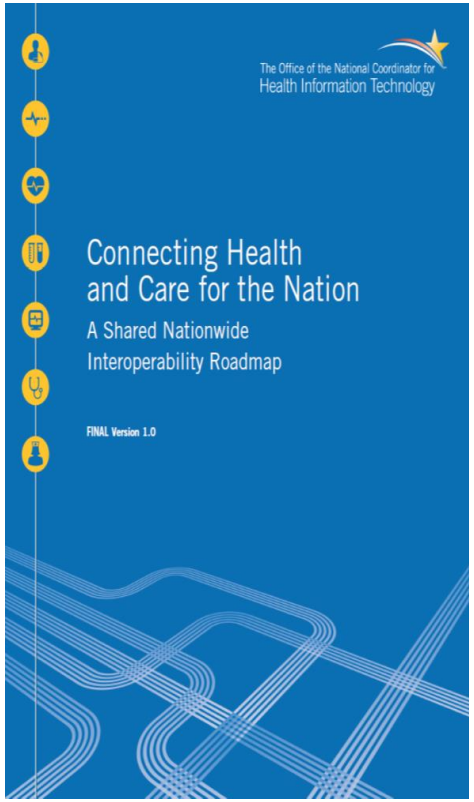
Service	Description	Details	Specs
Query	QIDO-RS (Query based on ID for DICOM Objects)	Link	DICOM PS3.18 6.7
Retrieve	WADO-RS (Web Access of DICOM Objects)	Link	DICOM PS3.18 6.5
Store	STOW-RS (Store over the web)	Link	DICOM PS3.18 6.6
Tasks	UPS-RS (Worklist Service)	Link	DICOM PS3.18 6.9
Capabilities	Service information	Link	DICOM PS3.18 6.8



http://dicomweb.hcintegrations.ca/#/home

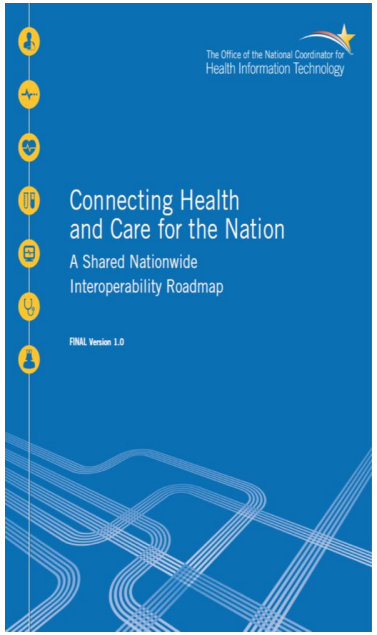


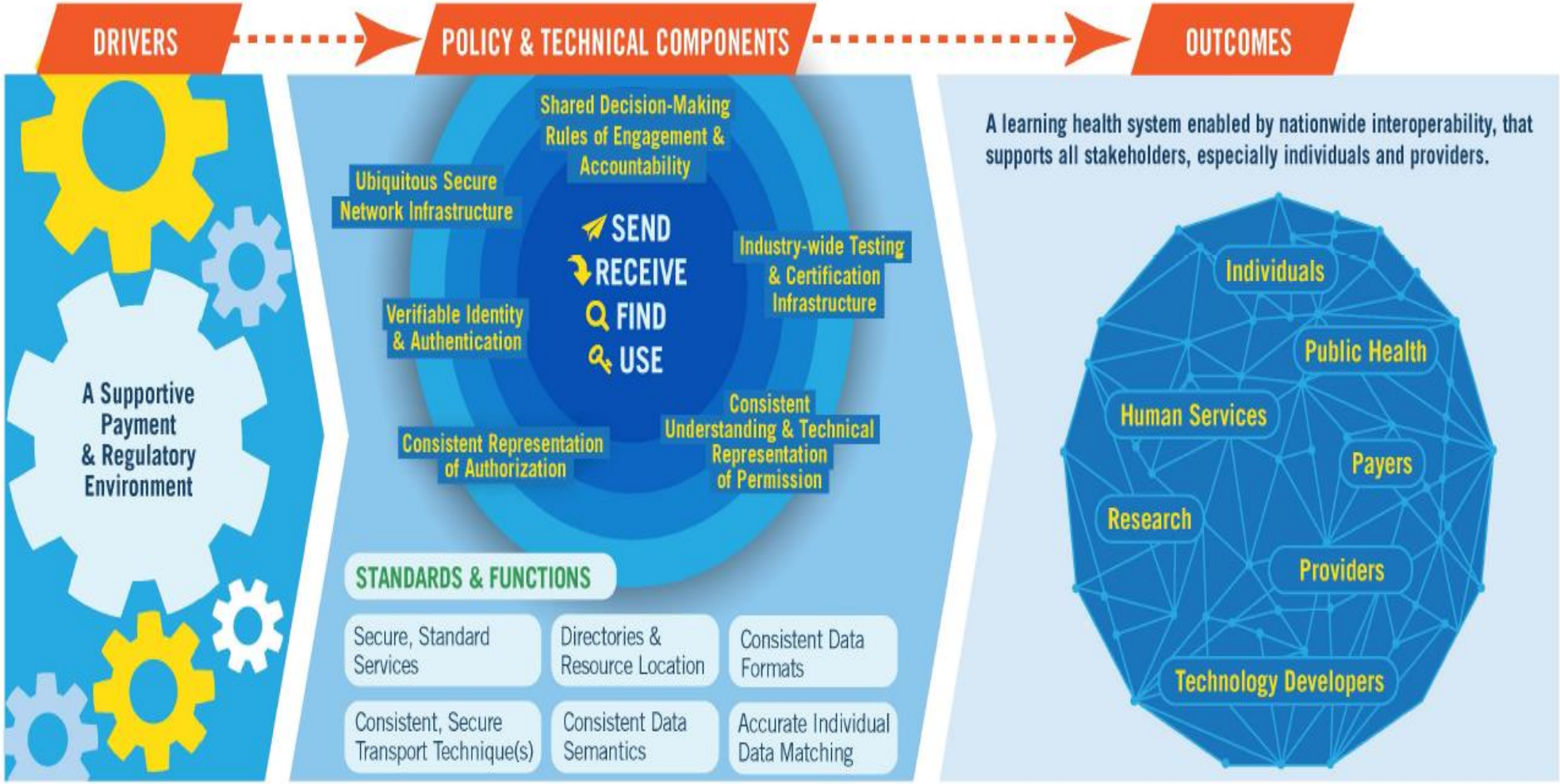
PMI Sharing - Overlaying MHD/PIXm on Model

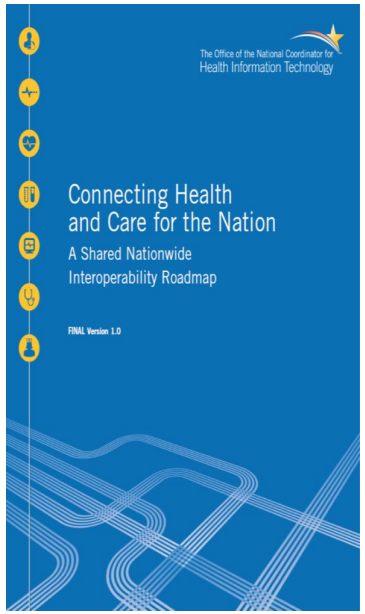


The goals are:

- **2015-2017:** Send, receive, find and use priority data domains to improve health care quality and outcomes.
- **2018-2020:** Expand data sources and users in the interoperable health IT ecosystem to improve health and lower costs.
- **2021-2024:** Achieve nationwide interoperability to enable a learning health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access.





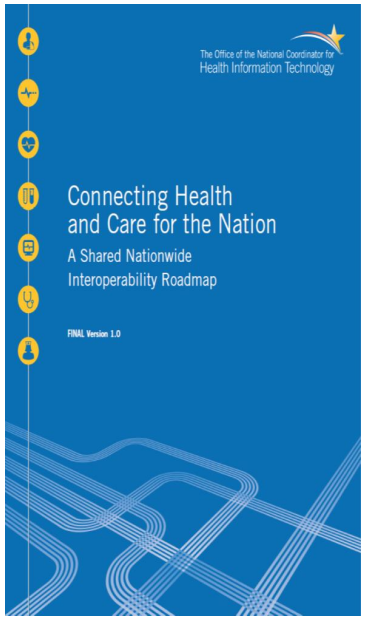


G. An Industry-wide Testing and Certification Infrastructure

A variety of health IT testing tools and resources must be broadly available to stakeholders to support technology from development through deployment. Testing and certification programs must provide health IT users with reasonable assurance that health IT is interoperable.

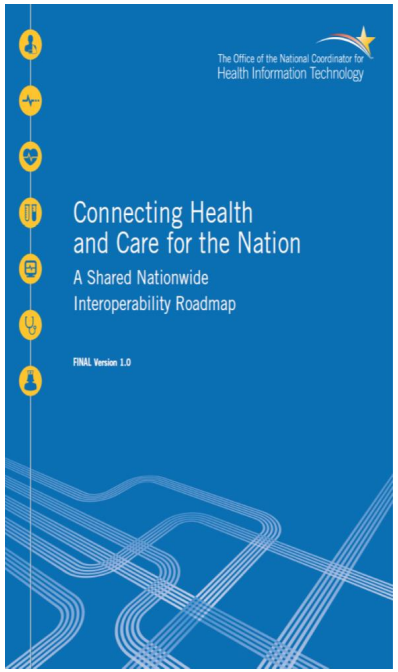
Certification

Certification programs, including but not limited to ONC's, should be established and based on health IT users' need for assurance about the performance of certain health IT products and services. To advance interoperability, certification programs should include a sufficient level of testing rigor around core interoperability functions, such that stakeholders derive a tangible benefit from the certification. The addition of transparent surveillance processes can protect purchasers of certified products and services as well as keep them up-to-date regarding poor performing or non-compliant products.



Standards Development Organizations and Implementation Guidance

Standards Development Organizations (SDOs) act as convening bodies for the stakeholder communities that collaboratively develop, curate and maintain standards and information models including those mentioned above. These organizations include, but are not limited to: Health Level 7 (HL7), the National Council for Prescription Drug Plans (NCPDP), Integrating the Health care Enterprise (IHE), Clinical Data Interchange Standards Consortium (CDISC), Regenstrief Institute, International Health Terminology Standards Development Organisation (IHTSDO) and International Organization for Standardization (ISO). In addition to publishing standards, these organizations also create profiles or implementation guides that provide additional implementation instruction and examples for developers. For instance, the HL7 2.5.1 messaging standard is a content standard for which several different implementation guides have been created to address specific purposes ranging from laboratory result receipt to immunization submission.



Another commonly used transport technique today is web services. Documentation or profiles from Integrating the Healthcare Enterprise (IHE) often use Simple Object Access Protocol (SOAP)-based web services to support transport for queries, as well as services like public health reporting. The eHealth Exchange also uses SOAP-based web services in its implementation. This approach is also currently deployed by many EHR developers as it allows XML-based, system-to-system transactions to be constructed easily. Another type of web service approach includes RESTful implementations, which are growing in interest as they are leveraged by HL7's Fast Healthcare Interoperability Resources (FHIR) project.

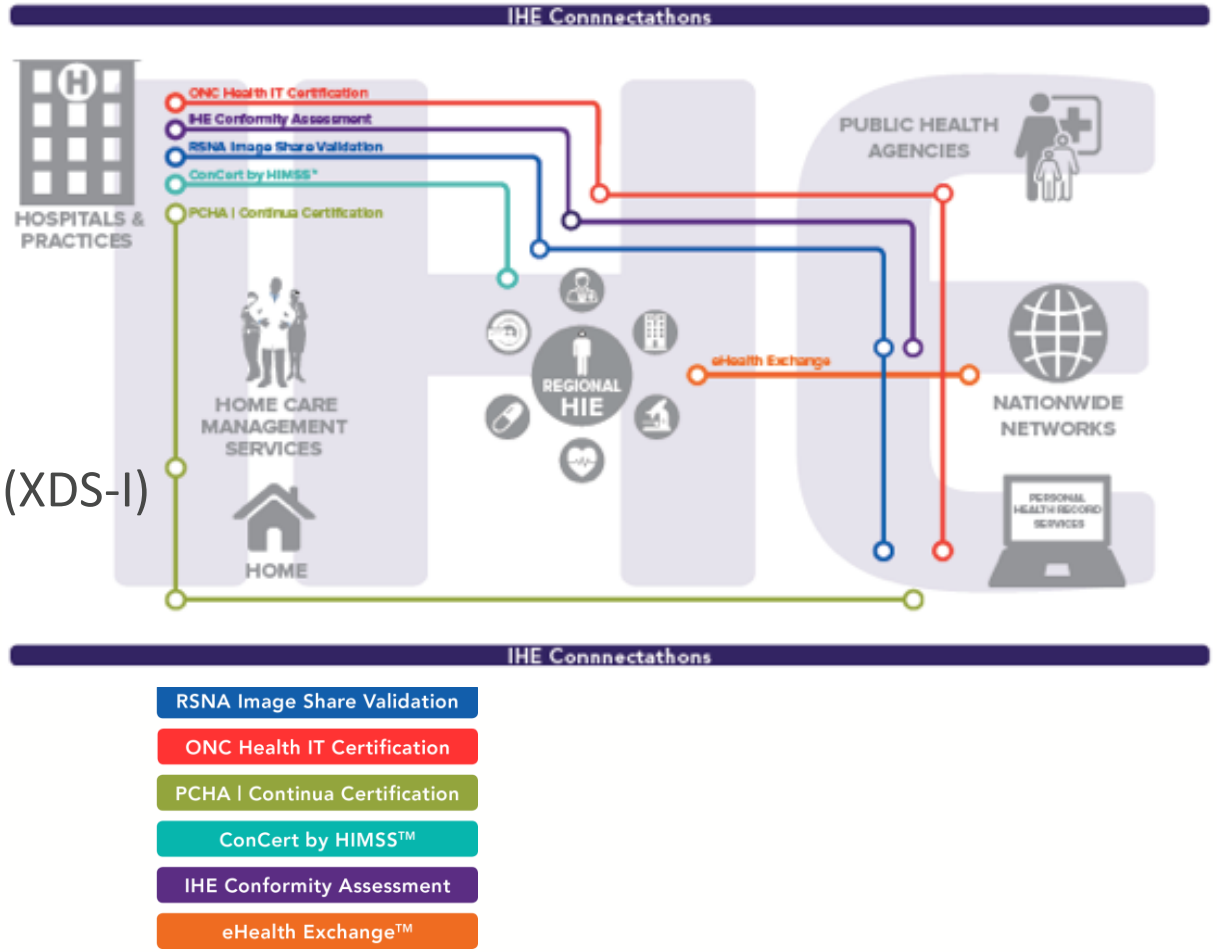
Web services based on SOAP and RESTful approaches for more automated transactions, including query/response and some publish/subscribe transactions, will also be important standards in this suite. Where technology developers have SOAP-based implementations that work well,[73] they should continue to leverage those investments, while exploring RESTful transport approaches that may scale more easily and nimbly over time.

ONC Interoperability Building Blocks

- Core technical standards and functions
- Certification to support adoption and optimization of health IT products and services
- Privacy and security protections for health information
- Supportive business, clinical, and regulatory environments
- Rules of engagement and governance

RSNA Image Share VALIDATION

- Fills a national Standards Gap
  - International Conformity Assessment
- IHE profiles provide the basis
- Modular
  - Cross-Enterprise Document Sharing for Imaging (XDS-I)
    - Document Source and Document Consumer
    - Registry and Repository
  - Cross-Community Access for Imaging (XCA-I)
  - RSNA Image Share PHR



The Sequoia Project's Role

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

Works to address the challenges of secure, interoperable nationwide health information exchange (HIE).

Proposed Timeline

- Dec. 1, 2015 – Image Share Validation Program Announced
- Jan. 4, 2016 – Registration for Pilot Testing Program Opens and Detailed Test Plans Published
- Mar. 1, 2016 – Valid Testing Sessions Begin
- Sept. 30, 2016 – Pilot Validation Testing Sessions Completed
- July 29, 2016 – Enrollment of all interested vendors; ongoing testing
- Nov. 27 – Dec. 1, 2016 – Image Share Demonstration at RSNA 2016

- Improved efficiency
- Reduced costs
- Standards-based interoperability to spur innovation
- International IHE Conformity Assessment program

- **Enhanced quality of care!**

Lesson Learned from 7 Years of Production

Rigorous Testing is essential to enable interoperable data sharing at national-level scale

- Multi-level testing
  - Profile-level testing
  - Product testing and 3rd party validation of interoperability
  - Production-level testing to assure production configuration interoperates
- Automated, self-service approach
- Tightly constrained tests
- Focus on known interoperability issues and security
- Testing eco-system with feedback loop into tightly constrained implementation specifications

eHealth Exchange Validated Products

Vendor	Validated Product
Browsersoft Connected Health	OpenHRE™ from Browsersoft
Cerner	Clinical Exchange Platform
CONNECT	CONNECT
Epic	Care Everywhere (2012, 2014, 2015)
Greenway Health	Greenway Exchange
ICA The Interoperability Experts	CareAlign 3.0

Vendor	Validated Product
IOD	PRISM
InterSystems	InterSystems HealthShare
LTS Health Exchange	LTS HEX
Medicity A Healthagen Business	Network v5 and v7
OPTUM	Optum HIE 2.0
ORION HEALTH	Exchange Gateway v3

Validated eHealth Exchange

Health IT systems complete rigorous set of tests to validate:

- Conformance to underlying standards and specifications
- Systems are free from known interoperability issues - transport, security, transactions and content (if not MU certified)
- Configured and operate securely (negative security tests)

How does a Validation program work?

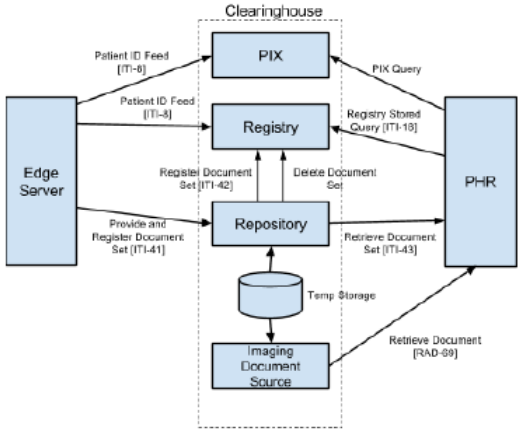
- Implementation Guides
- Testing Scripts

RSNA Image Sharing Network Implementation Guide

Implementation Guide

1.0 Introduction

The RSNA Image Sharing Network (ISN) defines an architecture that allows imaging centers to upload patient images (DICOM format) into a centralized storage system termed a Clearinghouse. A patient creates an account in a Personal Health Record (PHR) system and uses that system to retrieve images from the Clearinghouse in a secure manner. The diagram below shows the architecture of the RSNA Image Sharing Network.



The Clearinghouse is composed of several IHE defined actors and participates in different transactions with the Edge Server and PHR. In the model shown above, the internals of the Clearinghouse are shown for illustrative purposes. The implementation requirements are defined by the exchanges with the Edge Server and PHR systems.

2.0 Definition of Roles

2.1 Clearinghouse

An implementation of a Clearinghouse exists as a resource on the public Internet that participates in system to system communication with Edge Server and PHR systems. It receives patient feed

3.0 Image Sharing Network PHR Based Sharing Use Case

3.1 Background

This use case describes the actors, transactions and requirements to enable a patient who has had an imaging exam to retrieve the imaging data and reports from that exam into a Personal Health Record system in a secure manner.

3.2 Use Case: Image/Report Upload and Image Retrieve (RSNA ISN)

In this use case, an imaging center uploads radiological images and a final report to a centralized clearinghouse that will hold that data for a limited period. A user (patient) acting through a PHR retrieves that data into the PHR and can manage the data in the PHR. At a minimum, the PHR provides the user the ability to view the images and report.

3.2.1 Actors

1. Edge Server (multiplicity of 1)
2. Clearinghouse (multiplicity of 1)
3. PHR (multiplicity of 1)

3.2.2 Assumptions

1. The Edge Server and Clearinghouse agree on transport level details (specified elsewhere in this document) that allows for the following:
    a. Secure messaging over TLS.

3.2.3 Pre-Conditions

1. The imaging center where the Edge Server is located has completed an imaging exam. The Edge Server has access to those images by means not specified here.
2. Nominal flow: The imaging center has completed a radiology report for the imaging exam and makes that report available to the Edge Server. The report is nominally in HL7 V2 format, but can be in other formats.

3.2.4 Use Case Steps - "Nominal Flow"

1. This use case begins when the Edge Server has gained access to DICOM images acquired during an imaging exam and to the final report, if the report is available.

XDS-I.b Conformity Assessment Tests: Imaging Document Source

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Validation Test

TC:XDSI:IDS:1001.0: Imaging Document Source PnR KOS: Single Image Study

Purpose / Context

The Imaging Document Source is required to submit a DICOM KOS object that references an imaging study with a single image. The test points are:

- Imaging Document Source can execute a proper Provide and Register transaction per the XDS.b requirements.
- Imaging Document Source includes metadata specified by the RAD-68 transaction.
- Imaging Document Source includes metadata specified by this test as part of data requirements in a typical Affinity Domain.
- KOS object is a legal KOS object per DICOM specifications.
- KOS object contains
  - correct references to the single input image
  - correct demographics, patient identifiers, Study Instance UID
  - a Series Instance UID that is different from the Series Instance UID in the input image; the KOS can be in the same study as the original image but it must be created in a separate series per DICOM requirements.

Test Steps

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Setup

1. Imaging Document Source: Import the imaging study with patient ID **IDS-DEPT001-x** (where x is the extension a, b, c, …)
2. Imaging Document Source: Generate one KOS object per the XDS-I profile that references the single image in this study. Submit that KOS object using a RAD-68 transaction to the Repository/Registry simulator configured for your Imaging Document Source (e.g.: acme__rep-reg). Use the following patient identifier with the RAD-68 submission:
   `IDS-AD001-x^^^&1.3.6.1.4.1.21367.2005.13.20.1000&ISO`
   (where x is the extension a, b, c, …)
3. Imaging Document Source: This test does not retrieve images using the RAD-16, RAD-55 or RAD-69 transactions. Other tests will use the same configuration/setup and will retrieve images using those transactions.

Validation

1. Test Manager: After the KOS is submitted by the SUT, run the following script on the testing platform:
   `perl $XDSI/tests/ids/ids-single-image/ids-single-image-10.pl label extension rep-reg-sim`
   This perl script does the following:
   - Evaluation 1: Verify that the format of the RAD-68 Provide and Register transaction is legal per standard Provide and Register requirements. Perform this verification using the NIST tools.
   - Evaluation 2: Verify that the content of the RAD-68 Provide and Register transaction contains metadata defined by the RAD-68 transaction. Retrieve the metadata from the XDS.b Document Registry and perform this evaluation.
   - Evaluation 3: Retrieve the KOS object from the XDS.b Document Repository. Verify that the KOS object is formatted properly per DICOM specifications (Clunie tools).
   - Evaluation 4: Retrieve the KOS object from the XDS.b Document Repository. Verify that the KOS object contains the proper demographics and references to the single image that was created as input to this test case.
   - Evaluation 5: KOS object uses the same Study Instance UID and same Patient Identifier values as the input image. KOS object uses a different Series Instance UID than the input object.
   - Evaluation 6: Extract all UIDs from the KOS object and place them in $XDSI/results/$label/ids-single-image/data/kos.txt. Evaluator is told to perform manual inspection of the Series Instance UID and SOP Instance UID of the KOS object to determine if they appear to have been derived from a legal UID root.
2. Test Manager: Look for the validation output from stored in **$XDSI/results/$label/ids-single-image/validation**. Ensure that all validation steps have been

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successfully completed. Upload the validation output (**full_report.txt**) into Gazelle as evidence of this step.

3. Test Manager: Examine the a dump of the KOS file found in **$XDSI/results/$label/ids-single-image/data/kos.txt**. By visual inspection, ensure that all UIDs appear to have been generated with a proper UID root. Upload the uid file into Gazelle as evidence of this step.
4. Test Manager: Assuming that all validation steps are completed successfully, apply the appropriate test result for this test instance in Gazelle.

Successful Participants awarded Validation Seals November 2016

CONGRATULATIONS!

	Testing Key	XDS-I Source/Consumer		XDS-I Registry/Repository		XCA-I Gateways		PHR
		Source	Consumer	Registry	Repository	Initiating	Responding	Edge
Agfa	z2	X	X	X	X			X
DICOM Grid/Ambra	z1	X	X	X	X	X	X	X
GE	w1	X	X	X	X	X	X	
Lexmark	x1	X	X	X	X	X	X	
lifeIMAGE	x	X	X	X	X	X	X	X
Mach 7	w2	X		X	X			
Novarad								X

http://sequoiaproject.org/resources/rsna-image-share-validation-program
http://www.rsna.org/image_share.aspx

Thank You!

the sequoia project

In collaboration with RSNA Radiological Society of North America