IHE MultiCountry WorkGroup (MCWG)

MCWG Recommendation on Standards Positioning for sharing imaging information at the national/regional level

Positioning HL7 FHIR and DICOM along with the related IHE profiles such as MHD(FHIR), XDS-I, XCA-I, WIA (DICOMweb).

Final Version Approved by MCWG Plenary on June 3, 2025

For use by MCWG Member Countries

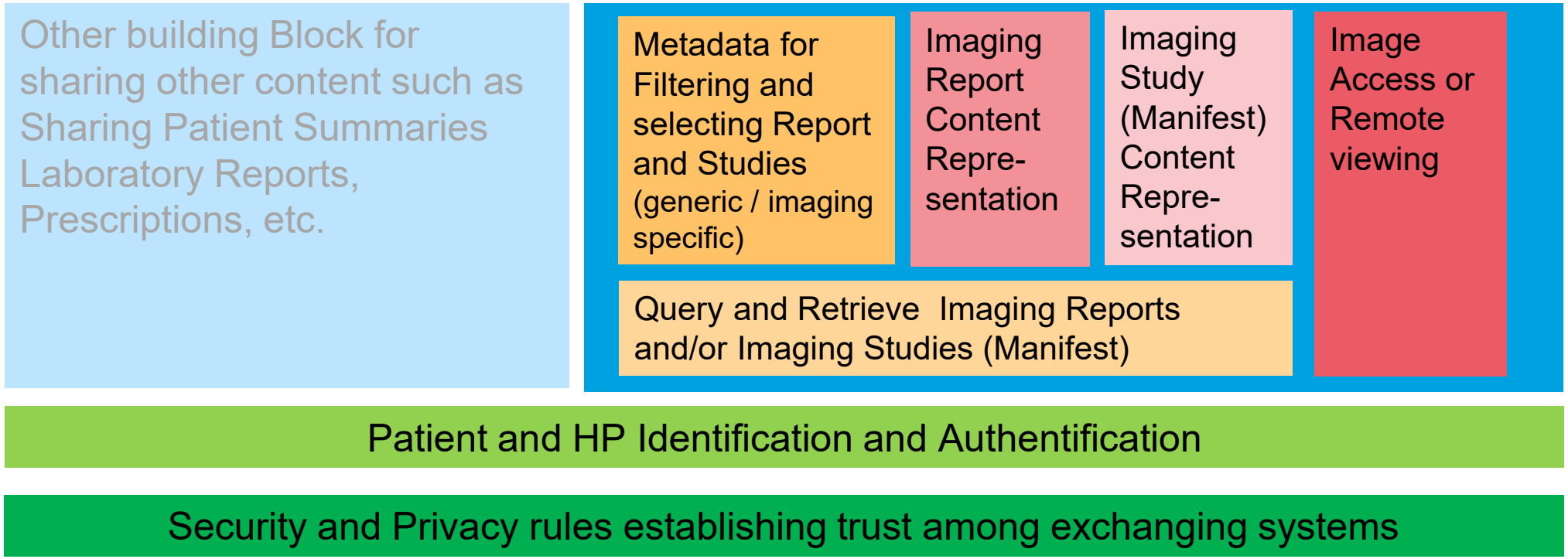
Objectives of this analysis on Standards Positioning by IHE-MCWG

- This recommendation was initially developed by a Focus Group of MCWG in September and October 2023 and submitted to the MCWG plenary for approval. In May 2024, it was extended with notes on the usage of DICOM QIDO. **The purpose of MCWG is to develop recommendations by national ehealth projects interested to facilitate their deployments while increasing consistency to ease market adoption and cross-border exchanges.**
- The scope of this MCWG recommendation is: *Positioning the role of HL7 FHIR in the sharing of imaging information architectures, choice of profiles and standards (e.g., MHD(FHIR), XDS-I, WIA), coexistence with XCA and FHIR/MHD, integration of Web Access to DICOM Objects (WADO) in XDS-I.*
- The Standards Positioning FG decided to reuse the "building block "structure that was developed by the European eHealth Network Task Force on Imaging, taking this structure a step further by:
  - Developing the content details of the Building Blocks specific to National/Regional imaging sharing deployments, whereas those of the eHN TF focus on NCP to NCP cross-border imaging exchanges.
  - Expecting that this format would facilitate the understanding of the complementary roles of the eHN Imaging Guideline published early 2024.
  - Adding sufficient technical details to make the recommendation at least 90% implementable and interoperable (see slide 18).

Assumptions Made in this Recommendation on Standards Positioning

1. The use case scope is the **sharing of imaging information within a country or a region** between:
   - imaging systems and their professionals that create such imaging information in the form of imaging reports and imaging studies available nationally and/or regionally and need to view, process and analyze images across time,
   - any health professional and patient that need to access imaging reports and view related imaging studies
2. The focus is on the standards positioning in relationship to the sharing of imaging information. The national/regional environment unique identification of patients and health professionals involved, along with the necessary security and privacy framework are assumed to be in place.
3. It is also assumed that the sharing of other types of information (patient summaries, laboratory reports, hospital discharge summaries, etc.) may already be in place or is intended to coexist in the future along with the sharing of imaging information.
4. The approach proposed is first to identify "information exchange building blocks" that need to be assembled to create operational transactions between the communicating systems, then to make recommendations in terms of standards and profiles positioning depending on the deployment environment (e.g., federated regional registries, single registry country-wide, etc.)

Business requirements for shaping the Standards and Profiles Positioning



Overview of the proposed building Blocks related to Sharing Imaging Reports and Imaging Studies

Five Imaging Information Sharing Building Blocks – Overview
They enable transactions between consuming & imaging information source systems

Making Metadata for Filtering ***a distinct building block*** *from* imaging study *due to concerns to keep it minimal but efficient*

2-Filtering and returned Report and Studies Metadata (generic / imaging specific)

3-Imaging Report Content Repre-sentation

4-Imaging Study (Manifest) Content Repre-sentation

5-Image Access or Server-side viewing

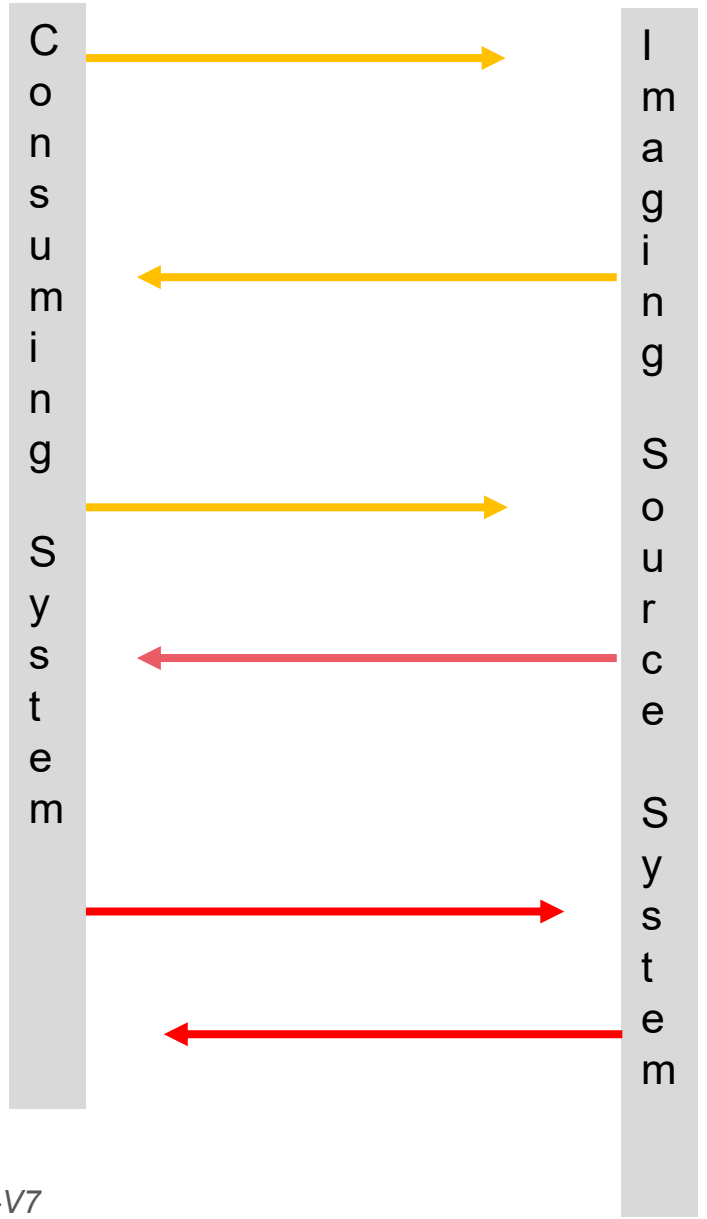
1-Query and Retrieve Imaging Reports and/or Imaging Studies (Manifest)

Covers and distinguishes (1) access to native acquired images and (2) server-side viewing

Patient and HP Identification and Authentification

Security and Privacy rules establishing trust among exchanging systems

We assume that these building blocks are reused



Five Imaging Information Sharing Building Blocks Mapped to Transactions between consuming & imaging information source systems

2-Filtering and returned Report and Studies Metadata (generic / imaging specific)

3-Imaging Report Content Repre-sentation

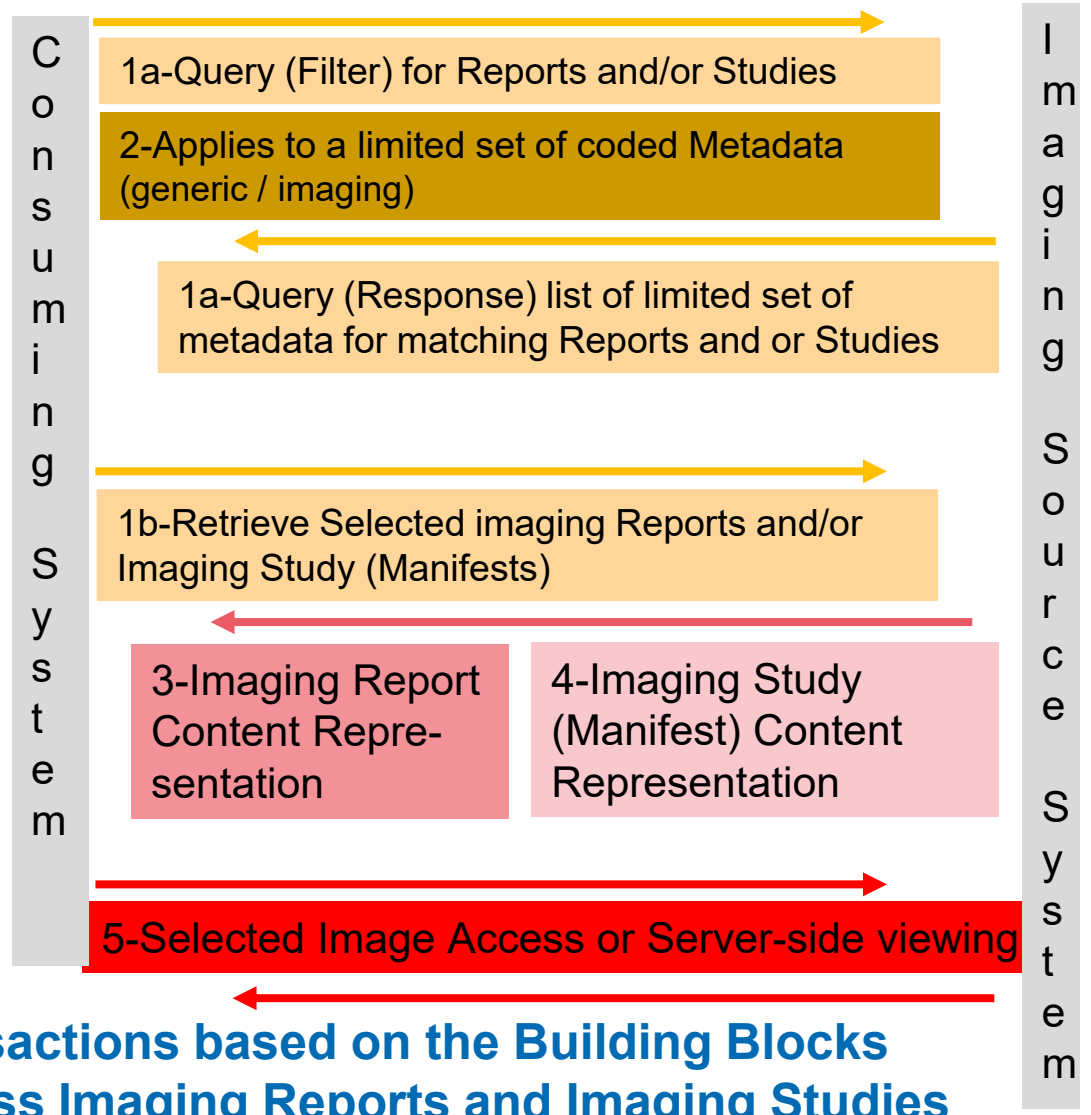
4-Imaging Study (Manifest) Content Repre-sentation

5-Image Access or Server-side viewing

1-Query and Retrieve Imaging Reports and/or Imaging Studies (Manifest)

Patient and HP Identification and Authentification

Security and Privacy rules establishing trust among exchanging systems



Transactions based on the Building Blocks to Access Imaging Reports and Imaging Studies

Clarifications on the scope of the 5 building blocks (1)

1- Query and Retrieve Imaging Reports and/or Imaging Studies (Manifest)

Discover the existence and location of all imaging reports and DICOM studies for a given patient, using three levels of interactions.

a) The initial query request with an associated predefined set of contextual information parameters (metadata) that can be used by the end user to interactively make an initial request to obtain a shorter and more relevant list of matching studies or reports. The metadata used for this query is defined by the second building block “2-Filtering and returned Report and Studies Metadata (generic/ imaging specific)”.

b) The user-friendly, intuitive and reliable selection among the elements of the above initial list with more information on each matching study manifests or reports to quickly select among them the desired ones and request their download. The metadata used for this query is also defined by the second building block “2-Filtering and returned Report and Studies Metadata (generic/ imaging specific)”.

c) In the case of imaging studies, use the information contained within the “3-imaging study manifest“ building block, to request the download of selected images of an imaging study(identified by the Imaging Study UID and possibly the Series Instance UID). This is addressed by the 5-Image Access or Server-side viewing Building Block.

Clarifications on the scope of the 5 building blocks (2)

2 - Filtering and returned Report and Studies Metadata (generic / imaging specific)
Support the efficiency of the discovery process by defining metadata that can be used across regions/nationally to describe the main traits of imaging reports and DICOM studies available in order to filter what is most relevant:

- A small number of metadata classification properties to most effectively filter – e.g., modality, anatomical region and date range.
- A few globally unique identifiers - e.g. Study UID, Accession Number, Order Placer number - that are shared by imaging reports and imaging studies to accommodate complex n-m relationships - e.g. all reports related to the same imaging study, all imaging studies related to the same report, all imaging reports and imaging studies related to the clinical request.

- Minimize the number of entries for classifications in the value set for each metadata property to simplify selection, avoid misfiling, keep deployment efficient - e.g. about 10 coarse anatomical regions values.

Further set of recommendations about such metadata elements and the link between various entities has also been approved and published by MCWG.

Clarifications on the scope of the 5 building blocks (3-4)

3- Imaging Report Content Representation
Define the data elements and format that represents the information in the imaging report – whether structured (made of elementary data elements that are coded textual) or unstructured (a display formatted body such as PDF plus a few key data elements in the header such as metadata elements defined in the building block). This building block ensures the exchange of imaging reports among many content consumers using the Query and Retrieve Imaging Reports and/or Imaging Studies building block.

4- Imaging Study Manifest Content Representation
Define the data elements and format that represents the key information about an imaging study, including pointers to its image content. It acts as a manifest or summary for the actual imaging study that is large (typically megabyte or gigabyte size) and complex (hundreds of data elements). It organizes this information according to the well establish model of an imaging study made of one or more series and each series made of instances or images. This building block ensures the exchange of information about imaging studies among many content consumers using the Query and Retrieve Imaging Reports and/or Imaging Studies building block.

Such a manifest should allow a clinician to understand the overall content of an imaging study and decide whether this study is likely of interest or not, and if so, which part of the study the clinician need to be viewed or processed first using the image access or server-side viewer building block.

Clarifications on the scope of the 5 building blocks (5)

5- Image Access or Server-side viewing

This building block allows a clinician that has decided that an imaging study is of interest to access its imaging content. It offers two strategies in realizing this access:

- "***Image access***" which allows the requesting system to request copies of image instances available remotely. This way, the full information richness of a native acquired DICOM format is directly usable in the requester's environment for further processing (e.g., for AI algorithm, 3D volume rendering and co-processing with locally acquired studies). This type of access is often used by imaging professionals such as radiologist, nuclear medicine, surgeon, orthopedist, etc., who need to use their own specialized software.

- "***Server-side viewing***" which allows the requester, with a simple web browser, to request
  - either that the server where the imaging study is stored renders the images based on a local integration with the source PACS/VNA,
  - or that a centrally hosted viewer renders the images by accessing copies of the images from the source PACS/VNA through the primary imaging sharing infrastructure.

  Requesting the launch of such a viewing application on a specific study managed by the server is typically done through invoking a URL. More than one URL may be in the same imaging report when several imaging studies may be associated to a single report. This type of access is often used by health professionals that mostly need to review imaging reports and want a basic web-viewing of the corresponding imaging study(ies). It also fits quite well the need for patient access to imaging information.

Listing Each Building Block with Candidate Standards/Profiles

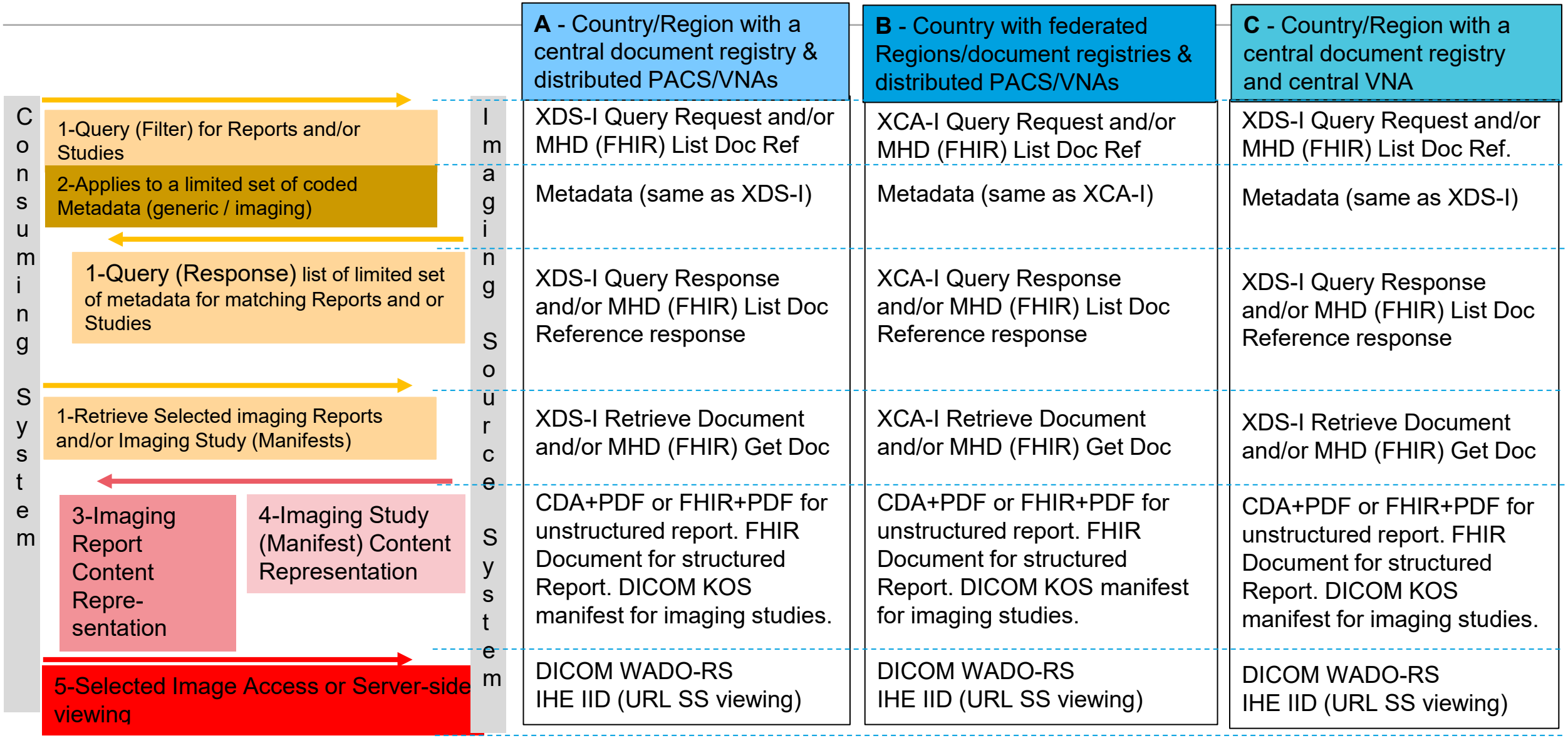
- Country and Regional Deployments can follow different architecture, depending on governance, funding, operational responsibilities, etc. So, the recommendation needed for positioning the best fit standards and profiles needs to account for these deployment architectures.

- All deployment architectures considered are based on the sharing of documents (structured images, structured and unstructured imaging reports, imaging study manifests) between systems (PACS, VNA, RIS, DICOM Workstations, Patient and Professional Portals, etc.). Except for central shared PACS and/or central VNA deployments, all existing or planned regional or national deployments rely on document-sharing architectures.

- Three columns of deployment architectures are addressed in this version of the standards and profiles positioning recommendations.
    A. A Country (or a single stand-alone Region) with a central document registry both with distributed PACS and or VNAs
    B. A Country with federated regional document registries and regions with distributed PACS and or VNAs
    C. A Country (or region) with a central document registry and a central VNA

  Note: Document Repositories whether centralized or distributed should be possible in all above architectures.

Building Block with Candidate Standards and profiles depending on deployment architecture for the primary imaging sharing infrastructure



	A - Country/Region with a central document registry & distributed PACS/VNAs	**B** - Country with federated Regions/document registries & distributed PACS/VNAs	**C** - Country/Region with a central document registry and central VNA
1-Query (Filter) for Reports and/or Studies	XDS-I Query Request and/or MHD (FHIR) List Doc Ref	XCA-I Query Request and/or MHD (FHIR) List Doc Ref	XDS-I Query Request and/or MHD (FHIR) List Doc Ref.
2-Applies to a limited set of coded Metadata (generic / imaging)	Metadata (same as XDS-I)	Metadata (same as XCA-I)	Metadata (same as XDS-I)
1-Query (Response) list of limited set of metadata for matching Reports and or Studies	XDS-I Query Response and/or MHD (FHIR) List Doc Reference response	XCA-I Query Response and/or MHD (FHIR) List Doc Reference response	XDS-I Query Response and/or MHD (FHIR) List Doc Reference response
1-Retrieve Selected imaging Reports and/or Imaging Study (Manifests)	XDS-I Retrieve Document and/or MHD (FHIR) Get Doc	XCA-I Retrieve Document and/or MHD (FHIR) Get Doc	XDS-I Retrieve Document and/or MHD (FHIR) Get Doc
3-Imaging Report Content Repre-sentation 4-Imaging Study (Manifest) Content Representation	CDA+PDF or FHIR+PDF for unstructured report. FHIR Document for structured Report. DICOM KOS manifest for imaging studies.	CDA+PDF or FHIR+PDF for unstructured report. FHIR Document for structured Report. DICOM KOS manifest for imaging studies.	CDA+PDF or FHIR+PDF for unstructured report. FHIR Document for structured Report. DICOM KOS manifest for imaging studies.
5-Selected Image Access or Server-side viewing	DICOM WADO-RS IHE IID (URL SS viewing)	DICOM WADO-RS IHE IID (URL SS viewing)	DICOM WADO-RS IHE IID (URL SS viewing)

Key Rationale (1) on the standards & profiles recommended for the primary imaging sharing infrastructure

1. In all three deployment architectures, imaging reports and imaging study manifests (DICOM KOS) are shared in the same document sharing infrastructure.
2. FHIR based document sharing (MHD) is offered in two slightly different ways:
   a) in the first and third column, the FHIR based document sharing (MHD) provides Query/retrieve capabilities between care delivery systems and the central registry and (central or distributed) repositories in a way equivalent to XDS-I.
   b) in the second column, the FHIR based document sharing (MHD) provides Query/retrieve capabilities between gateways a way which is equivalent to XCA-I ensuring the federation of affinity domains each made of:
      - a regional document registry and document repositories (central or distributed)
      - central or distributed PACS and or VNAs for image storage
3. The recommendation proposes the use of WADO-RS rather than WADO-URI for the retrieval of DICOM study data. WADO-RS allows the retrieval of an entire study or series of DICOM (image) data in a single transaction request.

   Note: In the context of large-scale image information sharing (regional or national scope), requesting systems shall only be required to used WADO-RS to retrieve DICOM Objects as part 10 files. Responding systems may not be required to respond to other WADO-RS requests other than retrieving DICOM Objects as part 10 files (e.g. metadata or bulk pixel, rendered images). This is a strategy where partial implementations are permitted as they serve a clear immediate need, but the longer-term vision is to encourage complete WADO-RS implementation within a few years.
4. Use of a DICOM KOS based manifest instead of a FHIR Imaging Study resource. This provides a better alignment for the DICOM viewers when processing the imaging study manifests. In addition, such documents are typically created by PACS systems that already handle DICOM Key Image Notes which are almost identical to a DICOM KOS Objects.

Key Rationale (2) on the standards & profiles recommended for the primary imaging sharing infrastructure

5. The large-scale sharing of structured information needs to be done with documents (like it is done for the International Patient Summary), whose exchange is performed by encapsulation within a FHIR Document Reference resource (see MHD) rather than the use of a REST API on the FHIR Imaging Study resource (See Note)

   Note: This avoids making gateways “relay” FHIR GET Operations on multiple, potentially distributed, Imaging Study resources which would require fetching significant amounts of clinical data (all imaging studies information of a patient) to perform a FHIR GET operation directly on every attribute across the set of imaging studies. The use of the FHIR Document Reference resource per the IHE MHD Profile is much more consistent with the proven functioning of the current XCA gateways (XCA on FHIR).

6. For Imaging Reports, both CDA based reports or FHIR Document based reports (bundle of FHIR Resources) can be used to encapsulate unstructured reports (PDF). For imaging reports with structured content, a FHIR document (vs CDA Level 3) is preferred.

   Note that DICOM SR is widely used for image analysis outcome (e.g. for AI). In that case, such SR instances should be treated like any other DICOM instance for registration and retrieval, therefore referenced in the KOS object. However, exchanging Imaging Reports in a DICOM SR format is not proposed as although used in some implementation, it is not in wide use. It has also been pointed out that imaging reports, if in DICOM SR format, are part of a DICOM Study, would require a very different approach to query and retrieve only imaging reports.

7. It is proposed to explicitly distinguish the case of unstructured imaging reports (PDF content) from the case of structured imaging reports. The later are not widely used today and will require a long transition to be introduced. This may imply that, to support structured imaging reports, they may be recorded both in structured and unstructured formats (XDS/XCA Transform relationship).

Key Rationale (3) on the standards & profiles recommended for the primary imaging sharing infrastructure

8. When XCA-I is used to federate imaging affinity domains, it is important to use XCA's optimizations for cross-domain queries:
   - Use the Patient Data Location Query transaction, with national patient IDs, in the XCPD profile (supplement).
   - Cache patient IDs mapping to either HomeCommunityIDs or directly to end-points that represent registries, repositories and (imaging) document sources.
   - Cache HomeCommunityID mapping to end-points.

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9. Recommended use of QIDO: In the three deployment architectures (A, B & C), covered by this recommendation, MCWG has decided to not use DICOM QIDO for the primary imaging sharing infrastructure.

   Note: Adding a QIDO query could simplify the content of the manifest, as the use of QIDO offers the means to supplement information obtained from the manifests of imaging studies directly from the source. However, it has not been found effective by MCWG because:

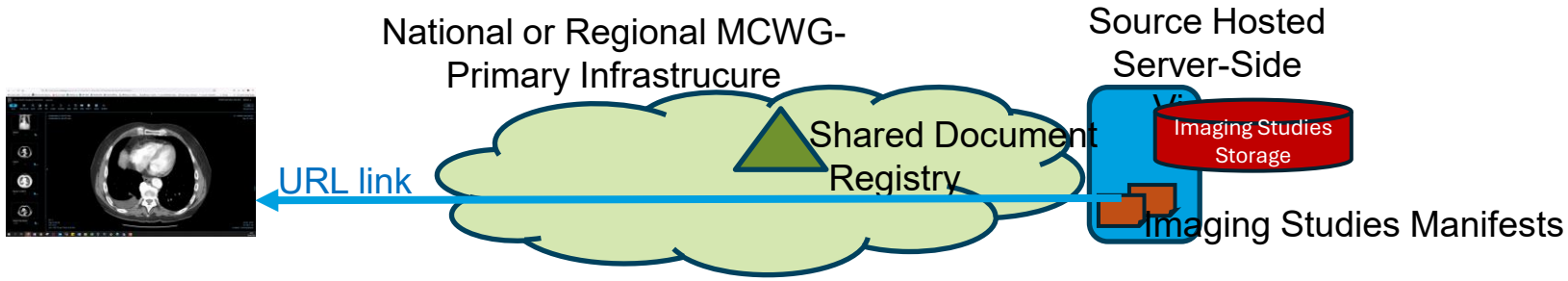
   - It adds as many QIDO queries as there are manifests that have been retrieved. This impacts the user with delays to the imaging study access as they target in general different sources of imaging studies (imaging studies repositories such as PACS/VNA) with different response delays.
   - Such QIDO queries need to be restricted to a single imaging study to avoid exposing all studies for a patient on such sources. This creates a privacy risk, despite providing the most recent snapshot of the image content of a study.

   Note: Likewise, the use of WADO-RS/Metadata, to supplement a simplified manifest is not recommended as it returns duplicate metadata from all image headers and induces slower performance on most sources not designed to access image headers without accessing the pixel data.

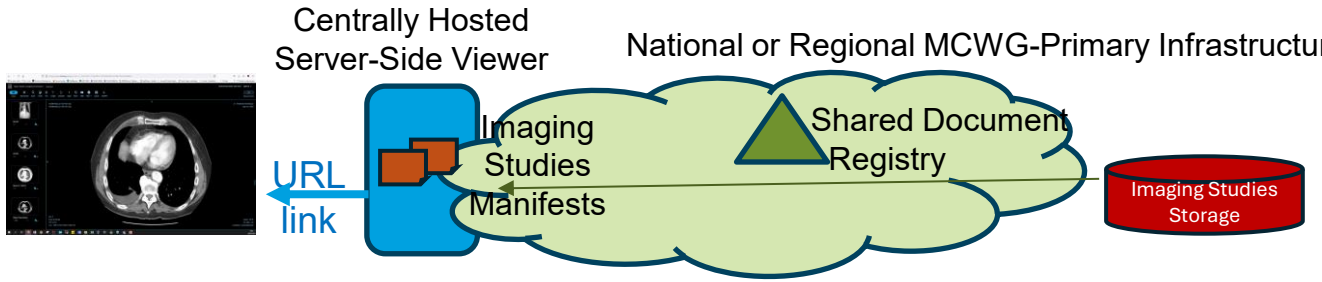
Deployment Architectures for the Source Server-Side Viewer

For each one of the three deployment architectures for the primary imaging sharing infrastructure (A, B & C), two **different deployment architectures may be considered for the Source Server-side viewing**:

- ***SSV1*- A Server-Side Viewer hosted on an Imaging Studies Storage**: In this deployment, the Imaging Study Viewers are hosted at the source PACS or VNA storage systems and locally access imaging studies for display in a web browser of the requester. Such viewers are called by URL links within the imaging reports



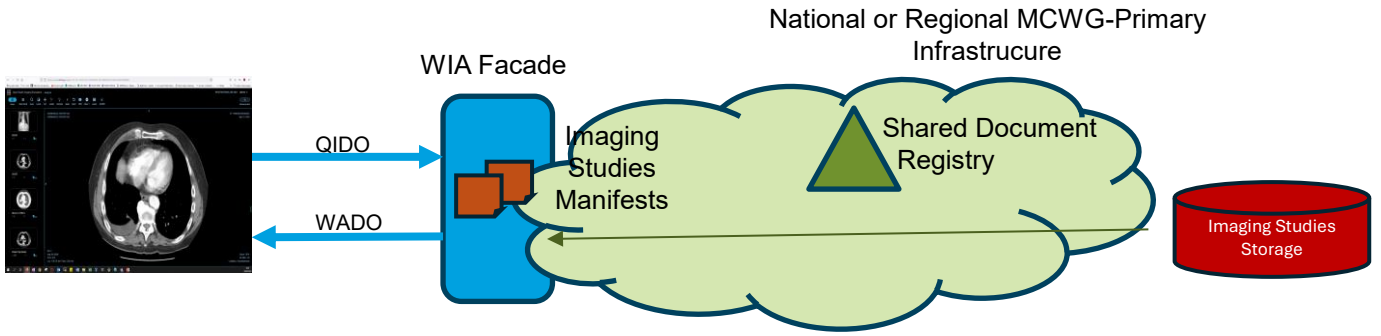
- ***SSV2*- A Centrally Hosted Server-Side Viewer**: In this deployment, the Imaging Study Viewer is centrally hosted and leverages any of the three deployment architectures to access Manifests and imaging studies for display in a web browser of the requester. Such viewers are called by a constructed URL made of a base URL assigned to the central viewer, plus IHE IID attributes extracted from the metadata of the imaging report.



- Both cases rely on the fact that the user needs to be authenticated (e.g., use of OAuth) and authorized to access the KOS Manifest. Access to the Manifest implies access to images referenced by the Manifest.

Optional Web Imaging Access Facade as front-end to the primary imaging sharing infrastructure

- **WIA facade option to access the MCWG recommended primary imaging sharing infrastructure.** This WIA Facade option allows access to the content of KOS Manifests of imaging studies as described in the *IHE Profile WIA Use Case 4*.



- The intended use is only to support a local DICOM image viewer with a WIA compliant interface to access the primary imaging sharing infrastructure.
  This type of access can be positioned as a third alternative between:
  - the simpler web browser based (IHE IID URL) to the source server-side viewer (Great for GPs and patients),
  - and the richer access to images via KOS Manifest as well as other documents such as the imaging report.

NOTE: The WIA QIDO query/return key mappings to the content of the KOS Manifests is aligned with the MCWG recommendations on XDS metadata and Imaging Manifest contents with one intended exception:

- DICOM Procedure Code Sequence mapping in WIA is to the XDS-I metadata typeCode whilst MCWG recommends a mapping to the eventCodeList using the nested procedure code display name as an eventCodeList value.

Management of various Patient Demographics

Patient demographic data (including identifiers) is included in an imaging report and imaging study manifest. On registering these document types into a document sharing system (XDS or MHD Registry/Repositories), the Document Source includes demographic details (PatientId and optional SourcePatientInfo), as part of the shared metadata, corresponding to the document's demographic data.

XDS [or MHD] Registry Metadata:
- patientId
- sourcePatientId
- sourcePatientInfo
  - Name
  - Dob
  - Sex

- Updates to the above demographics details can be made after document registration due to scenarios as outlined in IHE_RAD_TF_Vol1x - Appendix G: Patient Information Reconciliation for XDS-I.b (INFORMATIVE)

- The result of any such updates can lead to there being a difference between the document's original demographic data and the optional Registry source patient info metadata, as said in IHE RAD TF Vol1x Appendix G: *"The Registry maintains supporting patient information such as Name, Sex, DoB, etc. but is NOT obligated to ensure the referential integrity of this data."*

- The Registry patientId will be reliable and should always be used as the primary registry search key by the Document Consumer. The Document Consumer must be able to receive documents whose contained demographic data does not necessarily match the Registry metadata for the same patientId.

Patient demographics contained in the Imaging Report and in the Manifest:
- IDs
- Name
- Dob
- Sex

Recommendation: The Document Consumer should use the Registry patientId to reconcile with its local patient demographic data and not assume the retrieved "document" demographic data to be consistent.

Deployment Challenges and Solutions for these Recommendations

1. **Product Interoperability alignment:** The present recommendations assume that three types of products need to conform to the standard transactions recommended while clinical users and patients operate in a way as integrated as possible within their common working environment :

   a) **PACS** (XDS-I Doc Source or MHDS Doc Source, WADO-RS Server)

   b) **RIS** (CDA or FHIR based report source-HL7 2 ORU/MDM)

   c) **Document Sharing Infrastructure**: Registry/Repository (XDS and/or MHD/FHIR receiver/responder).

   Most Products would need some minor or major extensions. The present recommendations are designed to support these standards/Profiles either in a "native way" or through a "proxy implementation". A proxy interfaces with the PACS only with existing DICOM QUERY/MOVE/STORE services and with RIS with HL7 ORU/MDM report sending interfaces).

2. **Technical Completeness:** The present three sets of recommendations cover about 95% of the goals of an interoperable specifications. The remaining ~5% require the development of :

   a) the Imaging Report content. A CDA with PDF content specification exists (IHE XDS-SD) that needs to be refined with the addition of imaging metadata in the CDA Header for which **an MCWG recommendation is under development**. The profiles for a FHIR based report with PDF content imaging report specification is not currently available. Likewise, a profile for a FHIR based structured imaging report is not currently available.

   b) a series of small but necessary details, that are often country-specific. Professional and patient Identification, the reuse/adaptation of authentication and security measures (provisioning of healthcare delivery structures).

Open Issues (May 2024)

1. **One Open issue, at the time of publication:**
   a) Address fully the imaging report content beyond the selection of CDA+PDF or FHIR+PDF for unstructured report and FHIR Document for structured Report (see slide 12).

2. **The reader is encouraged to consider the two companion recommendations to the present set of recommendations :**
   a) Recommendations on Metadata and Linkages.
   b) Recommendations on the Imaging Study Manifest.

   Additional Recommendations are considered (such as on Product alignment for deployment).

3. **MCWG Members and IHE welcome the participation of additional countries.**

Questions, Comments and Suggestions are welcome and should be sent to the IHE-Europe Secretariat:
secretariat@ihe-Europe.net