



5 **IHE Pathology and Laboratory Medicine (PaLM)**
White Paper

10 **Digital Pathology Aid for Telemedicine**

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Foreword

This is a white paper of the IHE Pathology and Laboratory Medicine domain.

30 This white paper is published on November 18, 2022. Comments are invited and can be submitted at https://www.ihe.net/PaLM_Public_Comments.

General information about IHE can be found at [IHE.net](https://www.ihe.net).

35 Information about the IHE Pathology and Laboratory Medicine domain can be found at [IHE Domains](#).

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at [Profiles](#) and [IHE Process](#).

40 The current version of the IHE Pathology and Laboratory Medicine Technical Framework can be found at [PaLM Technical Framework](#).

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1 Introduction

This document, the IHE PaLM Digital Pathology Aid for Telemedicine White Paper, describes the process of sharing digital pathology slides in the context of telemedicine.

1.1 Purpose of the Digital Pathology Aid for Telemedicine White Paper

The demand for exchange of digital pathology images is increasing in several key settings. Due to the high specialization required for specific types of tissue evaluation, general anatomic pathologists are challenged to evaluate and report on specific types of biopsies (e.g., medical kidney, muscle, transplant, etc.). This leads to increased morbidity and mortality for a number of complex diagnoses that may be missed or delayed. Due to the high costs for health organizations and public administrations, access to highly specialized pathologists is limited in certain geographic regions. Currently digital pathology is not deployed in all LHAs (Local Health Authorities) and HTs (Hospital Trusts) as well as the image access and sharing among them in this field. The lifecycle management of these kinds of images begins in the scanner and often ends in the local hard disk of the scanner itself or in some non-standard external storage that is carried to a consultant or forwarded with legacy format or internet links. The image management should move across department or enterprise boundaries also according to a Vendor Neutral Archive approach and an accurate sharing of information and to privacy and security regulations.

This white paper is intended to address the image exchange of digital pathology slides in a telemedicine scenario by summarizing and exploring the different IHE profiles in the imaging area extending their application to the digital pathology specific context.

1.2 Intended Audience

The intended audience of the IHE PaLM Digital Pathology Aid for Telemedicine White Paper is:

- Digital Pathology Information Systems and Scanner vendors
 - IT departments of healthcare institutions
 - Experts involved in digital pathology and standards development
- Open and Closed Issues

2 Sharing Digital Slides

In order to make available digital pathology images in a telemedicine scenario it is necessary to:

1. acquire and store digital slides

155 2. share those slides within a community, making them available to be retrieved

The following sections will provide an overview of the profiles needed to make available digital pathology slides and how those profiles should be combined in order to reach interoperability.

2.1 Profiles

2.1.1 Digital Pathology Workflow - Image Acquisition (DPIA)

160 The main digital asset acquisition from a physical asset is defined in the Digital Pathology Workflow - Image Acquisition (DPIA). The actors involved in the process are the Acquisition Modality, the Acquisition Manager, the Image Manager/Image Archive and the Image Display. The process embraces the concept of a service defined IWOS (Imaging Work Order Step) that establishes details for the image acquisition and it is the mechanism by which the Acquisition
165 Manager mainly triggers the acquisition to the Acquisition Modality and receives the notifications of the status of the requests. The acquisition phase and the digital pathology specific aspects are crucial for the entire process that follows and this profile will therefore be included in the present white paper.

2.1.2 Cross-Enterprise Document Sharing for Imaging (XDS-I.b)

170 The Cross-Enterprise Document Sharing for Imaging (XDS-I.b) by extending the XDS Profile represents an effective solution for the imaging documents sharing across health enterprises in a community. This interoperability profile states that an Imaging Document Source provides the DICOM KOS, a document containing the references to the images (see DICOM Supplement 59 for more information about Key Object Selection Document SOP Class), to a Document
175 Repository in order to be notified as metadata to a Document Registry according to an Affinity Domain convention. This allows a substantial facilitation in the imaging retrieve phase required by an Imaging Document Consumer that needs to consult an image study in a broader context.

2.1.3 Web-based Image Access (WIA)

180 Web-based Image Access (WIA) provides methods for image sharing and interactive viewing of imaging studies using RESTful services regardless of the backend image management infrastructure. This profile defines that an Imaging Document Consumer (e.g., mobile tablet, medical camera, etc.) that queries or retrieve imaging objects, an Imaging Document Source (e.g., PACS, VNA, proxy) that responses to consumer imaging objects retrieval requests and an Imaging Document Responder (e.g., PACS, VNA, proxy) that responses to consumer imaging
185 objects query requests.

2.2 Conventions

This white paper considers different models that one could use for sharing and retrieving digital slides, supposing that the community supports an XDS-I.b infrastructure or prefers to use RESTful services.

This white paper will not address the definition of processes needed for acquiring digital slides but it will assume that once that a digital slide has been acquired and stored it could be shared within a community. Anyway, DPIA seems to be the profile to be followed to achieve this goal. Thus, DPIA actors can be combined with XDS-I.b actors or WIA actors or both, in order to permit the sharing and retrieving of digital slides in the community. Also, using the DPIA Profile permits to simplify the retrieval part of the infrastructure in some models that are shown in the following section.

For some further information about the usage of DICOM SOP Instances regarding the storing and retrieving digital slides in a Pathology context, refer to the DICOM Supplement 122.

This white paper also agrees that there must be an arrangement within the community about the patient identification, in order to uniquely identify the patient. There could also be an agreement within the community to have a local identification of the patient and a central system that manages the cross-referenced identities between systems. In this case, see Section 4.1 about the IT Infrastructure (ITI) PIX Profile.

2.3 Data Models

This section will provide an overview about how Images Sharing actors defined in DPIA, XDS-I.b and WIA Profiles could be combined together in order to share within a community digital pathology slides acquired by a digital camera or whole slide imaging scanner. More than one model could be possible and they are described in the following sections.

The Acquisition Manager in the following pictures is shaded because it is out of scope how the digital camera or image scanner will be triggered to initialize the acquisition of a digital slide.

2.3.1 XDS-I.b Sharing and Retrieving Model

This model assumes that an Imaging Document Source, defined in XDS-I.b Profile, could be grouped with an Image Manager/Image Archive, as defined in DPIA Profile, in order to enable sharing of digital slides, acquired by the Acquisition Modality and stored in an Image Archive/Image Manager, within a community. So, thanks to an XDS infrastructure, an Imaging Document Consumer, defined in XDS-I.b Profile, can search and retrieve the digital slides.

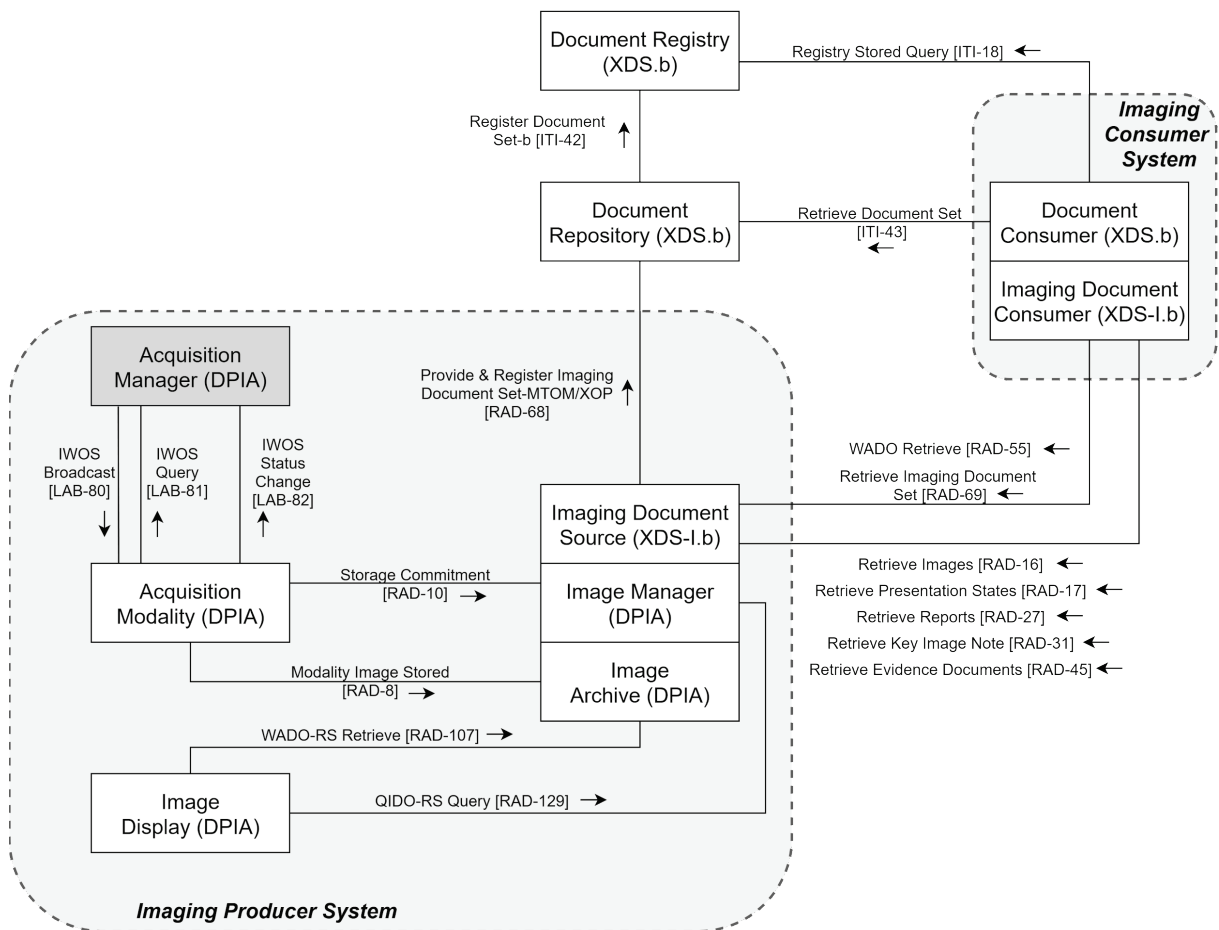


Figure 2.3.1-1: XDS-I.b sharing and retrieving model Diagram

The Image Display may be used by the pathologist operating on site in the imaging creation facility. The Imaging Document Consumer is used by the clinician called to provide the consultation. It is likewise possible for the on-site pathologist to use the Imaging Document Consumer as well.

2.3.1.1 Model Considerations

To enable digital slides sharing, according data model in Figure 2.3.1-1, the sharing infrastructure SHALL be provided with:

- XDS Document Registry (see Table 2.3.1.1-1 for constraints regarding transactions that shall be supported)
- at least one XDS Document Repository (see Table 2.3.1.1-1 for constraints regarding transactions that shall be supported)
- an Imaging Consumer System (see Section 2.3.1.1.1 Imaging Consumer System for constraints regarding transaction and functionalities that shall be supported)

- 235
- an Imaging Producer System (see Section 2.3.1.1.2 Imaging Producer System for constraints regarding transaction and functionalities that shall be supported)

Table 2.3.1.1-1: XDS-I.b sharing and retrieving model - Registry and Repository transactions

Actors	Transactions	Optionality	TF Reference
XDS Document Registry	Register Document Set-b [ITI-42]	R	ITI TF-2: 3.42
	Registry Stored Query [ITI-18]	R	ITI TF-2: 3.18
XDS Document Repository	Provide & Register Imaging Document Set [RAD-68]	R	RAD TF-2: 4.68
	Retrieve Document Set [ITI-43]	R	ITI TF-2: 3.43
	Register Document Set-b [ITI-42]	R	ITI TF-2: 3.42

240 **2.3.1.1.1 Imaging Consumer System**

An Imaging Consumer System needs to support the functionalities of an Imaging Document Consumer and an XDS Document Consumer (see Table 2.3.1.1.1-1 for constraints regarding transactions that shall be supported). There should be some agreement in the community regarding what transaction shall be implemented, based on what is the better application in the use cases and according to the technology implementation in the community.

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Table 2.3.1.1.1-1: XDS-I.b sharing and retrieving model - Actors and Transactions for an Imaging Consumer System

Actors	Transactions	Optionality	TF Reference
Imaging Document Consumer	Retrieve Images [RAD-16]	O (Note 1)	RAD TF-2: 4.16
	Retrieve Presentation States [RAD-17]	O	RAD TF-2: 4.17
	Retrieve Reports [RAD-27]	O (Note 1)	RAD TF-2: 4.27
	Retrieve Key Image Note [RAD-31]	O	RAD TF-2: 4.31
	Retrieve Evidence Documents [RAD-45]	O (Note 1)	RAD TF-2: 4.45
	WADO Retrieve [RAD-55]	O (Note 1)	RAD TF-2: 4.55
	Retrieve Imaging Document Set [RAD-69]	O (Note 1)	RAD TF-2: 4.69
XDS Document Consumer	Retrieve Document Set [ITI-43]	R	ITI TF-2: 3.43
	Registry Stored Query [ITI-18]	R	ITI TF-2: 3.18

Note 1: At least one of the optional retrieve transactions is required to be supported. Refer to Section 18.4 of RAD TF-2 for additional requirements on the Imaging Document Consumer.

250

Based on Note 1, at least one of the optional retrieve transactions is required to be supported by the Imaging Document Consumer to retrieve the digital slides in DPAT.

2.3.1.1.2 Imaging Producer System

An Imaging Producer System needs to support the following functionalities:

1. producing the digital slides
2. producing and storing the KOS document in the XDS Document Repository
3. managing the retrieving request of the digital slides images

In order to fulfill point 1 the Imaging Producer System should (Note 3) support the functionalities described in DPIA Profile (see Table 2.3.1.1.2-1 for constraints regarding transactions that shall be supported).

In order to fulfill points 2 and 3 the Imaging Producer System shall support the functionalities of an Imaging Document Source (see Table 2.3.1.1.2-1 for constraints regarding transactions that shall be supported).

Table 2.3.1.1.2-1: XDS-I.b Sharing and Retrieving Model - Actors and Transactions for an Imaging Producer System

Actors	Transactions	Optionality	TF Reference
Imaging Document Source	Provide and Register Imaging Document Set – MTOM/XOP [RAD-68]	R (Note 1)	RAD TF-2: 4.68
	Retrieve Images [RAD-16]	R (Note 2)	RAD TF-2: 4.16
	Retrieve Presentation States [RAD-17]	R (Note 2)	RAD TF-2: 4.17
	Retrieve Reports [RAD-27]	R (Note 2)	RAD TF-2: 4.27
	Retrieve Key Image Note [RAD-31],	R (Note 2)	RAD TF-2: 4.31
	Retrieve Evidence Documents [RAD-45]	R (Note 2)	RAD TF-2: 4.45
	WADO Retrieve [RAD-55]	R (Note 2)	RAD TF-2: 4.55
	Retrieve Imaging Document Set [RAD-69]	R (Note 2)	RAD TF-2: 4.69
Acquisition Manager (Note 3)	Imaging Work Order Step Broadcast [LAB-80]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Query [LAB-81]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Status Change [LAB-82]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF

Actors	Transactions	Optionality	TF Reference
Acquisition Modality (Note 3)	Imaging Work Order Step Broadcast [LAB-80]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Query [LAB-81]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Status Change [LAB-82]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Modality Image Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager / Image Archive (Note 3)	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF
	Modality Image Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Display (Note 3)	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF

Note 1: Support of at least one of the four document types described by the options in Section 18.2 of RAD TF-2 is required.

Note 2: These transactions are only required if the Imaging Document Source supports the ‘Set of DICOM Instances’

Note 3: This model does not require an Imaging Producer System to support actors and transactions of DPIA Profile as long as the Imaging Producer System is able to produce the digital slides and make it available for future retrieval issued by the Imaging Consumer System.

2.3.1.2 Model Overview

The XDS-I.b sharing and retrieving model may suffer from a slow retrieval of the images due to their size, but this model leads to a solid sharing infrastructure in which the references to the images are maintained in the KOS document shared within the community. This permits that these references are available for every system that intends to retrieve the images, once the KOS

document has been retrieved. Also, this model permits the sharing of reports with possible clickable hyperlinks to the images, as WADO-URI.

280 In this model, as well as the definition of the Affinity Domain that is the core of an XDS infrastructure, the security and policy considerations play a central role, considering that the communications can be done in an open communication network within the community. In order to permit a system to access the documents or to retrieve the images, some policies shall be defined in the community; these policies shall be used within the security layer to grant the access to the systems, after authorization evaluation, and track the operations. For further
285 consideration about security and privacy see Section 5.

2.3.1.3 Use Cases

In the following paragraphs are presented the use cases about the sharing and retrieving of some digital slides, focal points to reach the main purposes of DPAT. The use cases that are shown below consider the application of the XDS-I.b sharing and retrieving model.

290 2.3.1.3.1 Use case #1: Sharing Digital Slides

This use case describes a scenario in which a system that has acquired some digital slides will share them to the broad community in order to allow their consultation.

2.3.1.3.1.1 Sharing Digital Slides Use Case Description

295 The Imaging Producer System operator, after the creation of the digital slides, needs to share them with the community, which is based on a XDS-I.b infrastructure. Thus, operating from the Imaging Producer System, the operator shares, within the community, the digital slides, providing their references in a KOS.

2.3.1.3.1.2 Sharing Digital Slides Process Flow

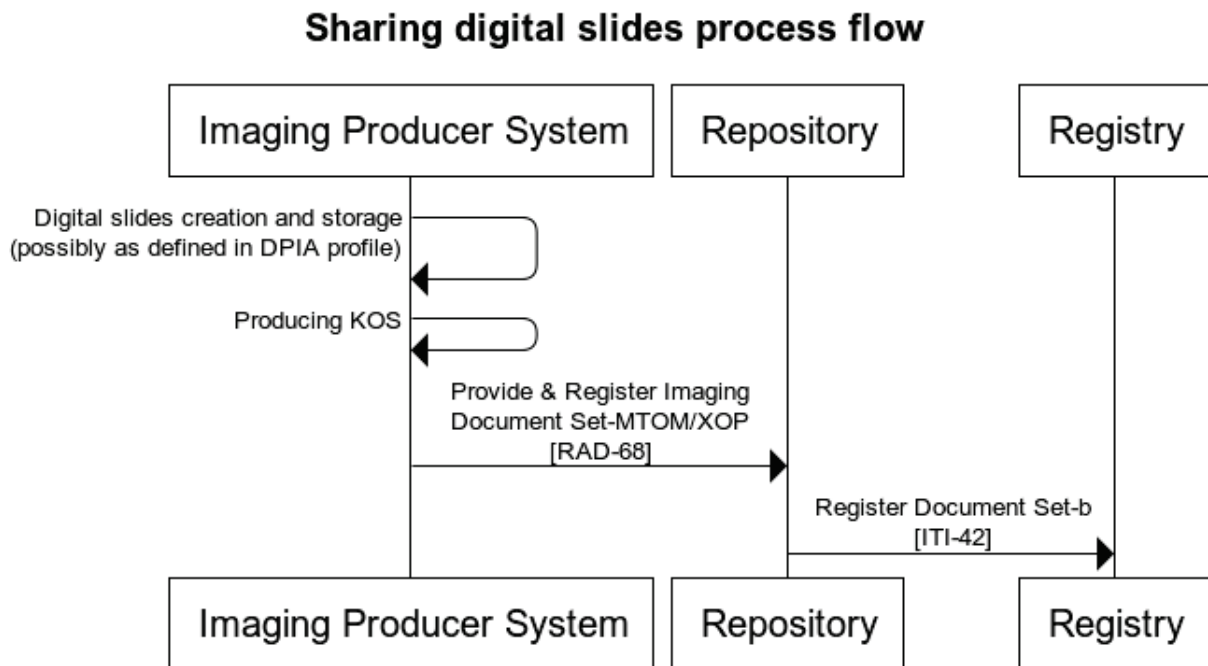


Figure 2.3.1.3.1.2-1: Sharing Digital Slides Process Flow

Imaging Producer System possibly creates the digital slides according to what is defined in the DPIA Profile.

In order to share the digital slides within the XDS-I.b community, Imaging Producer System performs a Provide & Register Imaging Document Set-MTOM/XOP [RAD-68] transaction to the Repository. The [RAD-68] Request Message contains the KOS document that contains the digital slides references and the metadata of that document.

After receiving the [RAD-68] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the KOS document.

2.3.1.3.2 Use case #2: Retrieving Digital Slides

This use case describes a scenario in which a system wants to retrieve and consult the digital slides shared from another system.

2.3.1.3.2.1 Retrieving Digital Slides Use Case Description

Doctor Smith intends to retrieve some digital slides previously produced and shared from an Imaging Producer System within the community. Thus, using his Imaging Consumer System, Doctor Smith can search for the KOS document in which there are the references to the digital slides he needs to study. Once retrieved the document with the references Doctor Smith can access the digital slides from his Imaging Consumer System.

2.3.1.3.2Retrieving Digital Slides Process Flow

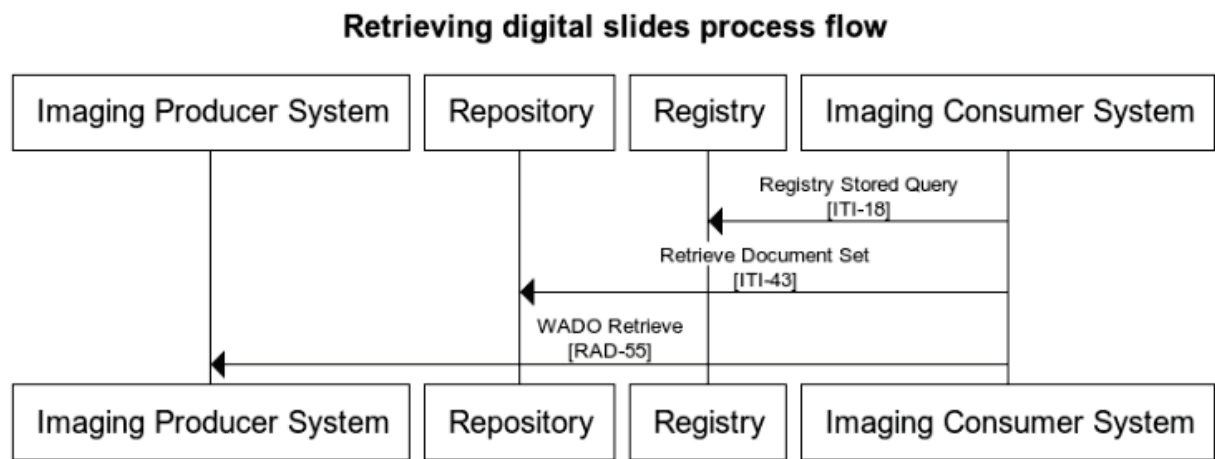


Figure 2.3.1.3.2.2-1: Retrieving Digital Slides Process Flow

The Imaging Consumer System searches for the KOS document performing a Registry Stored Query [ITI-18] transaction to the XDS Document Registry.

Once found the references to the KOS document, the Imaging Consumer System performs a Retrieve Document Set [ITI-43] transaction to the XDS Document Repository, in order to retrieve the KOS document with the digital slides references.

Having the digital slides references, the Imaging Consumer System can access them performing a WADO Retrieve [RAD-55] transaction to Imaging Producer System, according to the agreement about which retrieve transactions are supported in the community.

2.3.2 WIA Sharing and Retrieving Model

This model assumes that an Imaging Document Consumer, defined in WIA Profile, searches and retrieves for digital slides directly to an Image Manager/Image Archive, defined in DPIA Profile, after that the images were acquired and stored according to the DPIA Profile.

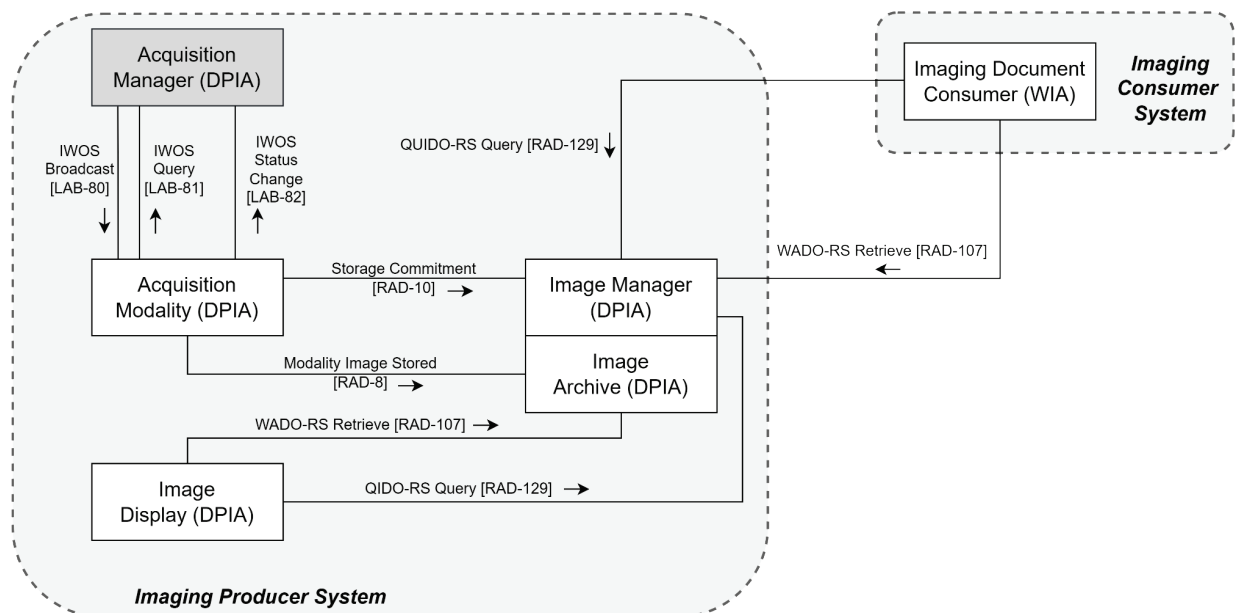


Figure 2.3.2-1: WIA Sharing and Retrieving Model Diagram

335 The Image Display may be used by the pathologist operating on site in the imaging creation facility. The Imaging Document Consumer is used by the clinician called to provide the consultation. It is likewise possible for the on-site pathologist to use the Imaging Document Consumer as well.

2.3.2.1 Model Considerations

340 To enable digital slides sharing, according data model in Figure 2.3.2-1, the sharing infrastructure SHALL be provided with:

- an Imaging Consumer System (see Section 2.3.2.1.1 Imaging Consumer System for constraints regarding transaction and functionalities that shall be supported)
- an Imaging Producer System (see Section 2.3.2.1.2 Imaging Producer System for constraints regarding transaction and functionalities that shall be supported)

345

2.3.2.1.1 Imaging Consumer System

An Imaging Consumer System needs to support the functionalities of an Imaging Document Consumer of the WIA Profile (see Table 2.3.2.1.1-1 for constraints regarding transactions that shall be supported).

350

Table 2.3.2.1.1-1: WIA Sharing and Retrieving Model - Actors and Transactions for an Imaging Consumer System

Actors	Transactions	Optionality	TF Reference
Imaging Document Consumer (WIA)	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF

2.3.2.1.2 Imaging Producer System

An Imaging Producer System needs to support the following functionalities:

355

1. producing the digital slides
2. managing the searching request of the digital slides images
3. managing the retrieving request of the digital slides images

In order to fulfill all the three points, the Imaging Producer System shall (Note 1) support the functionalities described in DPIA Profile (see Table 2.3.2.1.2-1 for constraints regarding transactions that shall be supported).

360

Table 2.3.2.1.2-1: WIA Sharing and Retrieving model - Actors and Transactions for an Imaging Producer System

Actors	Transactions	Optionality	TF Reference
Acquisition Manager	Imaging Work Order Step Broadcast [LAB-80]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Query [LAB-81]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Status Change [LAB-82]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
Acquisition Modality	Imaging Work Order Step Broadcast [LAB-80]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Query [LAB-81]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF

Actors	Transactions	Optionality	TF Reference
	Imaging Work Order Step Status Change [LAB-82]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Modality Image Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager / Image Archive	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF
	Modality Image Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Display	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF

Note 1: In this model, the requirement of DPIA implementation permits the Imaging Producer System to manage the search and retrieve of the images without the needs of implementation of the Imaging Document Responder and the Imaging Document Source Actors of WIA Profile.

2.3.2.2 Model Overview

The WIA sharing and retrieving model permits a faster and easier navigation of the images, enabling an on demand viewing mode, and will fit more for mobile implementations. On the other hand, this model is mostly usable in a closed infrastructure, as a peer to peer network, in which there are no references to images outside the Imaging Producer System and this requires many interoperability activities for future applications outside the specific context.

The possibility of a closed communication network permits a simpler security and policies layer to grant the access to the images and all the rules can be implemented by the Images Producer System itself. For further consideration about security and privacy, see Section 5.

2.3.2.3 Use Cases

In the following paragraphs are presented the use cases about the sharing and retrieving of some digital slides, focal points to reach the main purposes of DPAT. The use cases that are shown below consider the application of the WIA sharing and retrieving model.

2.3.2.3.1 Use case #1: Searching and Retrieving Digital Slides

This use case describes a scenario in which a system wants to retrieve and consult the digital slides acquired from another system.

2.3.2.3.1.1 Searching and Retrieving Digital Slides Use Case Description

Doctor Smith intends to consult some digital slides previously acquired from an Imaging Producer System. Thus, using his Imaging Consumer System, Doctor Smith can search for the references to the digital slides he needs to study. Once retrieved the references, Doctor Smith can retrieve and access the digital slides from his Imaging Consumer System.

2.3.2.3.1.2 Searching and Retrieving Digital Slides Process Flow

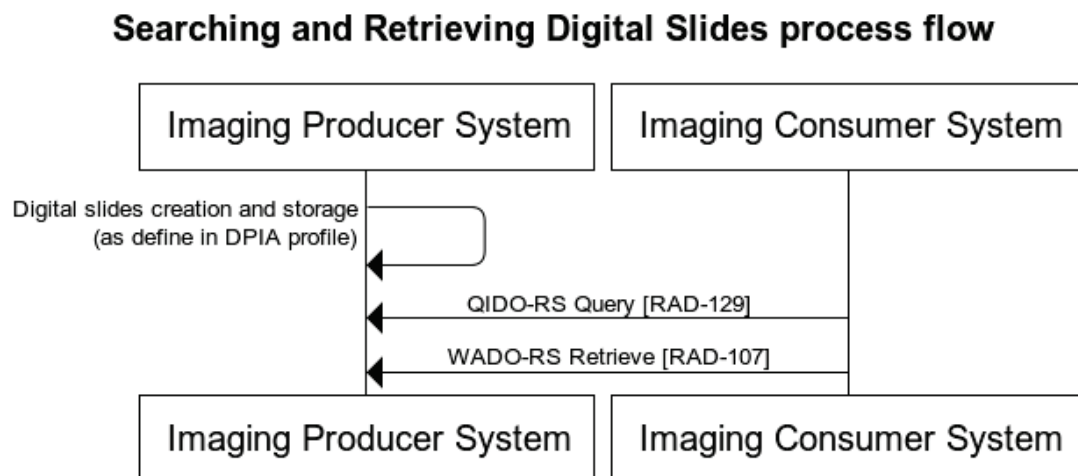


Figure 2.3.2.3.1.2-1: Searching and Retrieving Digital Slides Process Flow

The Imaging Producer System acquires and stores digital slides as defined in DPIA Profile.

The Imaging Consumer System searches the references to the images to a Imaging Producer System performing a QIDO-RS Query [RAD-129] transaction.

Once found the references to the images, the Imaging Consumer System performs a WADO-RS Retrieve [RAD-107] transaction to the Imaging Consumer System, in order to retrieve the images.

2.3.3 XDS-I.b sharing and WIA Retrieving Model

This model assumes that an Imaging Document Source, defined in XDS-I.b Profile, shall be grouped with an Image Manager/Image Archive, as defined in DPIA Profile in order to enable sharing of digital slides, acquired by the Acquisition Modality and stored in an Image Archive/Image Manager, within a community. So, thanks to the XDS-I Backend Option of the WIA Profile, an Imaging Document Consumer, defined in WIA Profile, searches in the XDS infrastructure the references to the images and then retrieves the digital slides.

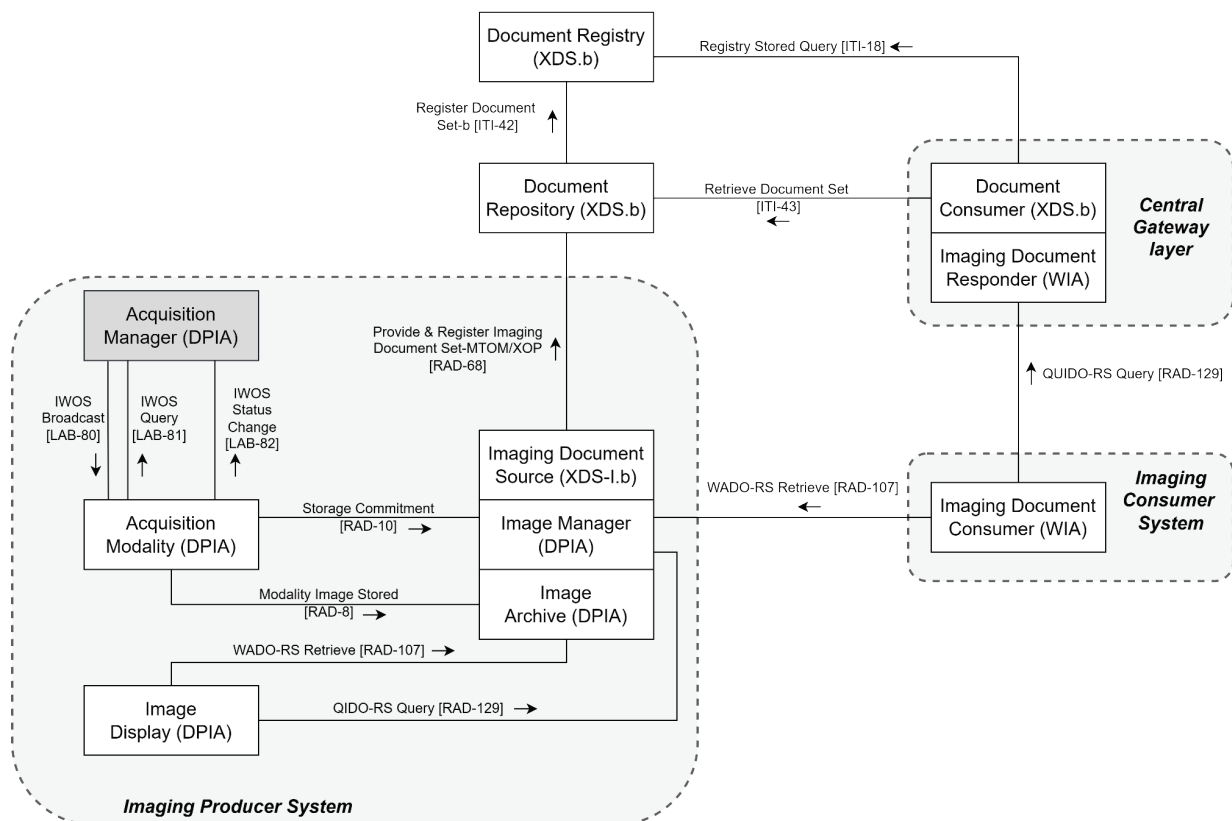


Figure 2.3.3-1: XDS-I.b Sharing and WIA Retrieving Model Diagram

The Image Display may be used by the pathologist operating on site in the imaging creation facility. The Imaging Document Consumer is used by the clinician called to provide the consultation. It is likewise possible for the on-site pathologist to use the Imaging Document Consumer as well.

2.3.3.1 Model Considerations

To enable digital slides sharing, according data model in Figure 2.3.3-1, the sharing infrastructure SHALL be provided with:

- XDS Document Registry (see Table 2.3.3.1-1 for constraints regarding transactions that shall be supported)
- at least one XDS Document Repository (see Table 2.3.3.1-1 for constraints regarding transactions that shall be supported)
- a Central Gateway layer (see Section 2.3.3.1.1 Central Gateway layer for constraints regarding transaction and functionalities that shall be supported)

- an Imaging Consumer System (see Section 2.3.3.1.2 Imaging Consumer System for constraints regarding transaction and functionalities that shall be supported)
- an Imaging Producer System (see Section 2.3.3.1.3 Imaging Producer System for constraints regarding transaction and functionalities that shall be supported)

Table 2.3.3.1-1: XDS-I.b Sharing and WIA Retrieving model - Registry and Repository Transactions

Actors	Transactions	Optionality	TF Reference
XDS Document Registry	Register Document Set-b [ITI-42]	R	ITI TF-2: 3.42
	Registry Stored Query [ITI-18]	R	ITI TF-2: 3.18
XDS Document Repository	Provide & Register Imaging Document Set [RAD-68]	R	RAD TF-2: 4.68
	Retrieve Document Set [ITI-43]	R	ITI TF-2: 3.43
	Register Document Set-b [ITI-42]	R	ITI TF-2: 3.42

2.3.3.1.1 Central Gateway Layer

A Central Gateway layer needs to support the functionalities of a WIA Imaging Document Responder grouped with an XDS Document Consumer (see Table 2.3.3.1.1-1 for constraints regarding transactions that shall be supported).

Table 2.3.3.1.1-1: XDS-I.b Sharing and WIA Retrieving Model - Actors and Transactions for an Imaging Consumer System

Actors	Transactions	Optionality	TF Reference
Imaging Document Responder (WIA)	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
XDS Document Consumer	Retrieve Document Set [ITI-43]	R	ITI TF-2: 3.43
	Registry Stored Query [ITI-18]	R	ITI TF-2: 3.18

2.3.3.1.2 Imaging Consumer System

An Imaging Consumer System needs to support the functionalities of an Imaging Document Consumer of the WIA Profile (see Table 2.3.3.1.2-1 for constraints regarding transactions that shall be supported).

Table 2.3.3.1.2-1: XDS-I.b Sharing and WIA Retrieving Model - Actors and Transactions for an Imaging Consumer System

Actors	Transactions	Optionality	TF Reference
Imaging Document Consumer (WIA)	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF

440

2.3.3.1.3 Imaging Producer System

An Imaging Producer System needs to support the following functionalities:

1. producing the digital slides
2. producing and storing the KOS document in the XDS Document Repository
3. managing the retrieving request of the digital slides images

445

In order to fulfill points 1 and 3 the Imaging Producer System shall (Note 1) support the functionalities described in DPIA Profile (see Table 2.3.3.1.3-1 for constraints regarding transactions that shall be supported).

450

In order to fulfill point 2 the Imaging Producer System shall support the functionalities of an Imaging Document Source (see Table 2.3.3.1.3-1 for constraints regarding transactions that shall be supported).

Table 2.3.3.1.3-1: XDS-I.b Sharing and WIA Retrieving Model - Actors and Transactions for an Imaging Producer System

Actors	Transactions	Optionality	TF Reference
Imaging Document Source	Provide and Register Imaging Document Set – MTOM/XOP [RAD-68]	R (Note 2)	RAD TF-2: 4.68
	Retrieve Images [RAD-16]	R (Note 3)	RAD TF-2: 4.16
	Retrieve Presentation States [RAD-17]	R (Note 3)	RAD TF-2: 4.17
	Retrieve Reports [RAD-27]	R (Note 3)	RAD TF-2: 4.27
	Retrieve Key Image Note [RAD-31],	R (Note 3)	RAD TF-2: 4.31
	Retrieve Evidence Documents [RAD-45]	R (Note 3)	RAD TF-2: 4.45
	WADO Retrieve [RAD-55]	R (Note 3)	RAD TF-2: 4.55
	Retrieve Imaging Document Set [RAD-69]	R (Note 3)	RAD TF-2: 4.69

Actors	Transactions	Optionality	TF Reference
Acquisition Manager	Imaging Work Order Step Broadcast [LAB-80]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Query [LAB-81]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Status Change [LAB-82]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
Acquisition Modality	Imaging Work Order Step Broadcast [LAB-80]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Query [LAB-81]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Imaging Work Order Step Status Change [LAB-82]	R	Digital Pathology Workflow – Image Acquisition (DPIA) supplement to PaLM TF
	Modality Image Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager / Image Archive	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF
	Modality Image Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Display	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF

Note 1: In this model, the requirement of DPIA implementation permits the Imaging Producer System to manage the search and retrieve of the images without the implementation of the Imaging Document Responder and the Imaging Document Source Actors of WIA Profile.

Note 2: Support of at least one of the four document types described by the options in Section 18.2 of RAD TF-2 is required.

Note 3: These transactions are only required if the Imaging Document Source supports the ‘Set of DICOM Instances’

2.3.3.2 Model Overview

460 The XDS-I.b sharing and WIA retrieving model try to combine the advantages of the previous
two models, the faster and easier navigation of the images and a solid sharing infrastructure in
which references to the images are maintained in the KOS document shared within the XDS
Community. But this model needs a complex layer in which a Document Consumer shall be
465 grouped with Imaging Document Responder and the Imaging Producer System shall support
both the XDS-I.b and WIA Profile together.

The security and policy consideration follow the same consideration as per the XDS-I.b sharing
and retrieving model.

2.3.3.3 Use Cases

470 In the following paragraphs are presented the use cases about the sharing and retrieving of some
digital slides, focal points to reach the main purposes of DPAT. The use cases that are shown
below consider the application of the XDS-I.b sharing and WIA retrieving model.

2.3.3.3.1 Use Case #1: Sharing Digital Slides

This use case describes a scenario in which a system that has acquired some digital slides will
share them to the broad community in order to allow their consultation.

475 2.3.3.3.1.1 Sharing Digital Slides Use Case Description

The Imaging Producer System operator, after the creation of the digital slides, needs to share
them with the community, which is based on a XDS-I.b infrastructure. Thus, operating from the
Imaging Producer System, the operator shares, within the community, the digital slides,
providing their references in a KOS.

2.3.3.3.1.2 Sharing Digital Slides Process Flow

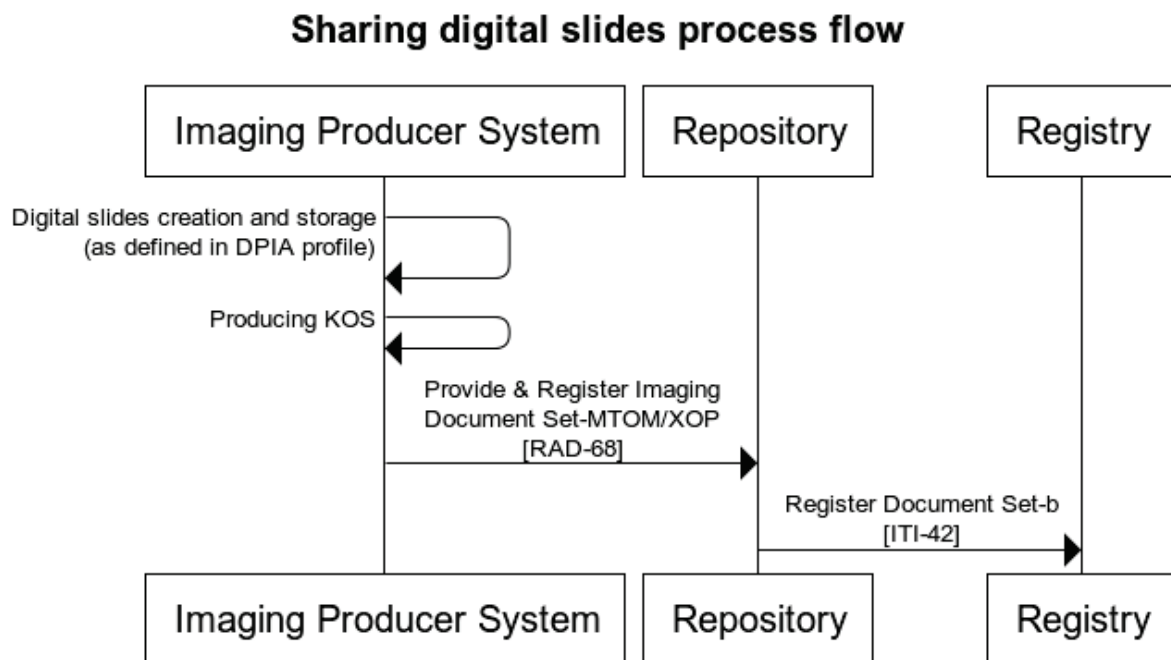


Figure 2.3.3.3.1.2-1: Sharing Digital Slides Process Flow

Imaging Producer System creates the digital slides according to what is defined in the DPIA Profile.

In order to share the digital slides within the XDS-I.b community, Imaging Producer System performs a Provide & Register Imaging Document Set-MTOM/XOP [RAD-68] transaction to the Repository. The [RAD-68] Request Message contains the KOS document that contains the digital slides references and the metadata of that document.

After receiving the [RAD-68] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the KOS document.

2.3.3.3.2 Use Case #2: Retrieving Digital Slides

This use case describes a scenario in which a system wants to retrieve and consults the digital slides shared from another system.

2.3.3.3.2.1 Retrieving Digital Slides Use Case Description

Doctor Smith intends to consult some digital slides previously acquired from an Imaging Producer System. Thus, using his Imaging Consumer System, Doctor Smith can search for the references to the digital slides he needs to study. Once retrieved the references, Doctor Smith can retrieve and access the digital slides from his Imaging Consumer System.

2.3.3.3.2 Retrieving Digital Slides Process Flow

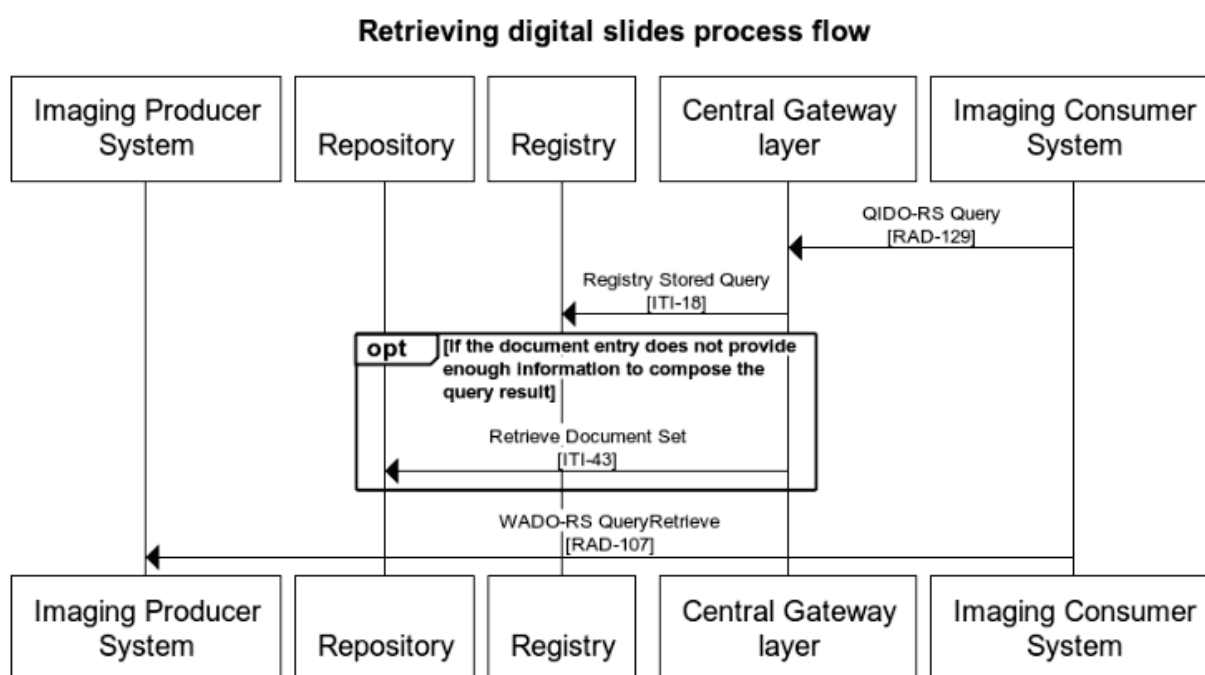


Figure 2.3.3.3.2-1: Retrieving Digital Slides Process Flow

The Imaging Consumer System searches the references to the images to a Central Gateway layer performing a QIDO-RS Query [RAD-129] transaction.

The Central Gateway layer searches for the KOS document performing a Registry Stored Query [ITI-18] transaction to the XDS Document Registry, in order to compose the query result based on document entries.

If the document entry does not provide enough information to compose the query result, the Central Gateway layer performs a Retrieve Document Set [ITI-43] transaction to the XDS Document Repository, in order to retrieve the KOS document with the images references.

Having the digital slides references, the Imaging Consumer System can access them performing a WADO-RS Retrieve [RAD-107] transaction to Imaging Producer System.

3 Digital Pathology Aid for Telemedicine Workflow

The actual systems are very rarely integrated to share and allow teleconsultation requests, for example to perform an analysis or a second reading. The main areas to be addressed are: the generation and acceptance of the request, the reporting (signed structured report where possible), the availability of the report for the requester also in an EHR perspective, the optional dialogue system between physicians and the administrative closing of the procedure.

Other specific issues about digital pathology are:

- how to represent partial cases, with a selection of slide, sent for evaluation;
- how to represent multiple cases sent together for evaluation (e.g., needle core, excision, biomarkers);
- how to manage multiple consultations requested to many performers on the same set of slides.

3.1 Profiles

3.1.1 Cross Enterprise Document Workflow (XDW)

This section describes the Cross Enterprise Document Workflow Profile approach which aims to manage and track the tasks associated with workflows as well as the input and output document references, according to coordinated activities with applications, health professionals and patients in an interoperability infrastructure. The profile is based on three actors: Content Creator, Content Updater and Content Consumer which are grouped with other IHE actors that perform the actual sharing or exchange of information according to context.

The XDW Document structure is organized in Tasks and Task Events. Each single Task describes one or a group of activities that should be performed or have been performed and has the following attributes: type, owner, current status, input/output references, history of past TaskEvents for this specific task. The Task Event represents a record of a change of a task and the Task Event history is the list of Task Events for a specific task.

3.1.2 Document Metadata Subscription (DSUB)

This profile describes the use of subscription and notification mechanisms for use within an XDS Affinity Domain and across communities. The subscription allows for the matching of metadata during the publication of a new document for a given patient, and results in the delivery of a notification. This notification is also sent after every succeeding publication of the document (update), so it allows the tracking of the status for a certain process that is focused on that document.

According to this profile, the subscription for a document with the [ITI-52] Document Metadata Subscribe transaction is “search-based” therefore the subscription parameters are the same used to search the document directly through transaction [ITI-18] Registry Stored Query defined in XDS Profile. Thus, it is possible to create a subscription for a specific process through the use of

the referenceIdList XDS metadata, if known the identifier of the document, or for certain document types, as a teleconsultation request, through the use of the eventCodeList XDS metadata that identify the clinical act, following what is defined in the Affinity Domain of the community.

The DSUB Profile and its extensions provide two notification methods, also in this case the use of one method over the other is functional to the process in place. The two modes are:

- **push:** for which a notification is sent through transaction [ITI-53] Document Metadata Notify whenever the document for which a subscription has been made is updated;
- **pull:** for which all the document update notifications for which a subscription has been made are queued and sent only upon specific request via query (Transaction [ITI-70] Pull Notification) of the subscriber to a pre-created Pull Point (Transaction [ITI-69] Create Destroy Pull Point).

At the end of the process the previously created subscription could be canceled through the transaction [ITI-52] Document Metadata Subscribe as defined by the DSUB Profile.

3.1.3 Anatomic Pathology Structured Report (APSR)

The Anatomic Pathology Structured Report is an IHE PaLM content profile and defines a structured report document template produced by the Laboratory Information System (LIS), enabling the sharing and exchange for anatomic pathology reports. The sharing is performed through ITI domain profiles. The template is composed of a header conveying the contextual metadata (i.e., patient, context, participants) and a structured body with its sections (i.e., Clinical Information Section, Intraoperative Observation Section, Microscopic Observation Section, Diagnostic Conclusion Section). Each section extends two kinds of content: human readable narrative content and entries for applications that consume the data included in the report.

3.1.4 Cross-Enterprise Remote Reporting for Imaging Workflow Definition (XRR-WD)

Since the DPAT White Paper aims to specify how the digital pathology and cross-sharing profiles should be successfully combined in the context of the digital pathology remote reporting, the Cross-Enterprise Remote Reporting for Imaging Workflow Definition (XRR-WD) comes full circle. The XRR-WD closes the process of the workflow where cross-institutional access to clinical images is needed to perform a teleconsultation or remote request, providing the report as output of the chain. The profile focuses specifically on the managing of remote image reading requests with the use of the Workflow Document from Cross-Enterprise Document Workflow (XDW) Profile to track and support the process in its tasks with a reliable notifications mechanism according to the Document Metadata Subscription (DSUB) Profile.

The main purpose of the XRR-WD Profile is to achieve the practice of having medical images interpreted (Read) by a reading specialist who is not present at the site where the image study was acquired with the use of Remote Reading Workflow Document. The Task Requester that demands a Read request is responsible for initiating the workflow by creating the Remote

Reading Workflow Document that is received from the Task Manager. Then, this actor assigns the Read request to a Task Performer in accordance with Collaboration Group policies. There is also the case that the Task Performer claims the Read request itself. The Task Performer is responsible for the execution of the Read and shall be capable of producing and sharing documents produced during the execution of the Read (Final Report or Final APSR Report, Preliminary Report, etc.). The Watcher Actor tracks/monitors the evolution of the workflow.

3.1.5 Multi-Patient Query (MPQ)

The Multi-Patient Query is a Profile that describes a mechanism in order to enable aggregated query for a Document Registry from a Document Consumer. The structure of the query is based on specific criteria that meet different settings related to data analysis (i.e., quality, population health monitoring). Since the multiple patients query is not viable in one operation with the XDS transactions, this profile is able to detect all the documents that meet the desired parameters (i.e., a certain eventCodeList XDS metadata). There might be two different kinds of outputs: semi-anonymized identifiers referring each to a single document (ObjectRefs in XDS) or complete clear data entries with full metadata (LeafClass).

In order to enable an actor to discover information about a document in the event it did not receive expected DSUB notification for that document or when it hasn't been subscribed for it, that actor could be grouped with an MPQ Document Consumer.

3.2 Conventions

This white paper assumes that the XDS-I.b sharing and retrieving model described in Section 2.3.1 shall be combined with the XRR-WD Profile actors in order to share and allow teleconsultation requests performed on shared digital slides within an open community.

Thus, the XRR-WD Task Requester shall be grouped with an Imaging Producer System, described in Section 2.3.1.1.2, and the XRR-WD Task Performer shall be grouped with an Imaging Consumer System, described in Section 2.3.1.1.1.

The first grouping enables combining the ability of requesting a digital pathology teleconsultation with the ability of sharing the digital slides on which the teleconsultation shall be performed.

The second grouping enables combining the ability to claim and perform a teleconsultation request on digital slides with the ability of retrieving those digital slides.

Because of this, this white paper assumes that the community supports an XDS infrastructure and its infrastructure shall support the XDS Environment Option of XRR-WD Profile (see Section 41.2.1 of the [Radiology XRR-WD supplement](#)).

For some further information about the usage of DICOM SOP Instances regarding the storing and retrieving digital slides in a Pathology context, refer to the DICOM Supplement 122.

This white paper also agrees that there must be an arrangement within the community about the patient identification, in order to uniquely identify the patient. There could also be an agreement within the community to have a local identification of the patient and a central system that

manages the cross-referenced identities between systems. In this case, see Section 4.1 about the ITI PIX Profile.

3.3 XRR-WD with XDS-I.b Sharing and Retrieving Model

This section will provide an overview of the combination of the XRR-WD with the systems previously described in the data model in the sharing digital slides paragraph, according to the conventions described in Section 3.2.

The dashed lines around the XRR-WD actors in Figure 3.3-1 means that these actors can support all the transactions thanks to the grouping requirements defined in XRR-WD Profile according with the XDS Environment Option but, for simplicity, in the figure are reported only the principal actors. For more details, see Section 41.3 of the Radiology XRR-WD supplement for Grouping Requirements.

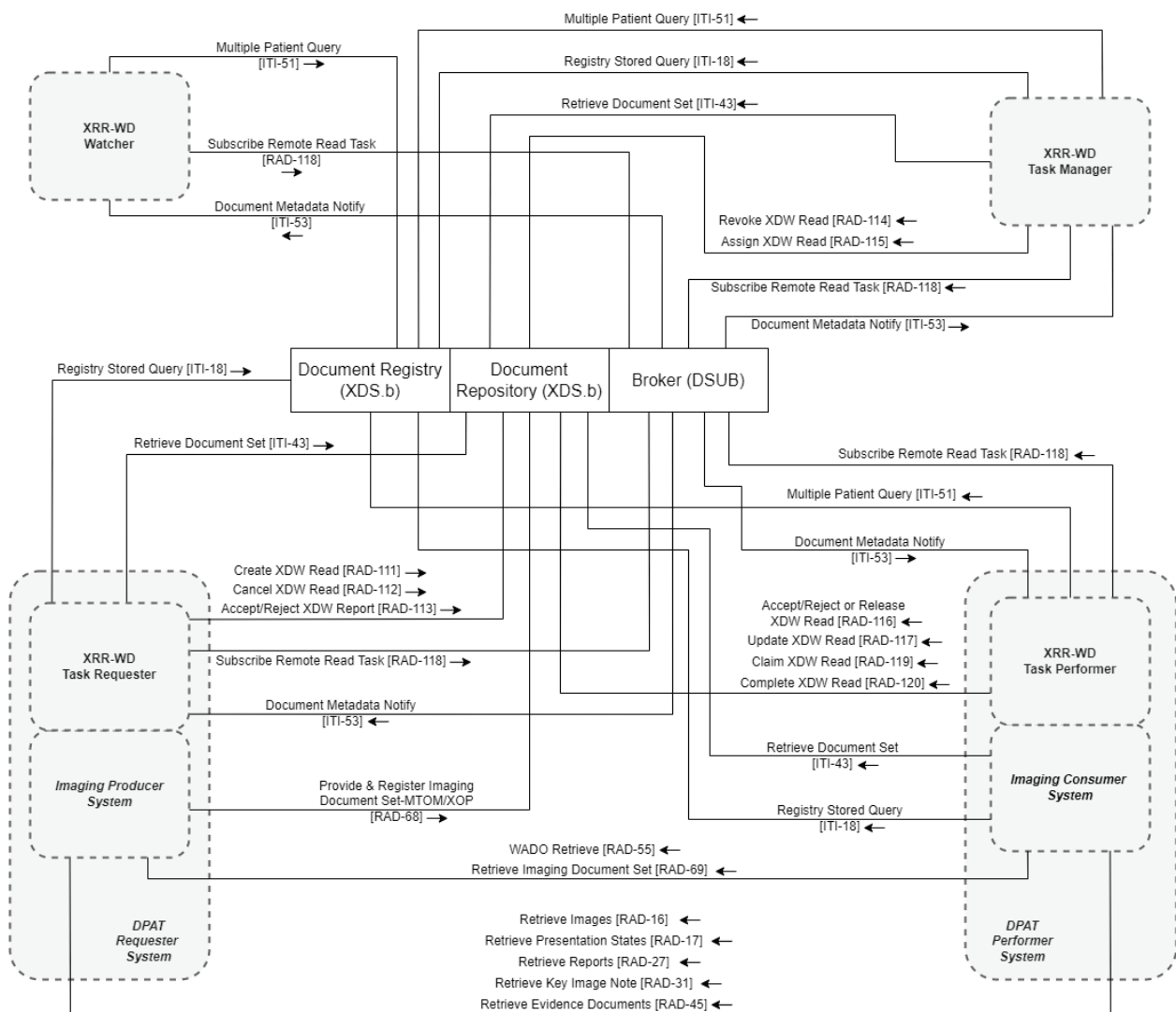


Figure 3.3-1: Digital Pathology Aid for Telemedicine Workflow Diagram

3.3.1 Model Considerations

To enable Digital Pathology Aid for Telemedicine Workflow, according to data model in Figure 3.3-1, the DPAT infrastructure SHALL be provided with:

- XDS Document Registry (see Table 3.3.1-1 for constraints regarding transactions that shall be supported)
- At least one XDS Document Repository (see Table 3.3.1-1 for constraints regarding transactions that shall be supported)
- DSUB Document Metadata Notification Broker (see Table 3.3.1-2 for constraints regarding transactions that shall be supported)
- XRR-WD Watcher (see Table 3.3.1-3 for constraints regarding transactions that shall be supported)
- XRR-WD Task Manager (see Table 3.3.1-4 for constraints regarding transactions that shall be supported)
- a DPAT Requester System (see Section 3.3.1.1 DPAT Requester System for constraints regarding transaction and functionalities that shall be supported)
- a DPAT Performer System (see Section 3.3.1.2 DPAT Performer System for constraints regarding transaction and functionalities that shall be supported)

Table 3.3.1-1: Digital Pathology Aid for Telemedicine Workflow - Registry and Repository Transactions

Actors	Transactions	Optionality	TF Reference
XDS Document Registry	Register Document Set-b [ITI-42]	R	ITI TF-2: 3.42
	Registry Stored Query [ITI-18]	R	ITI TF-2: 3.18
	Multiple Patient Query [ITI-51]	R	ITI TF-2: 3.51
XDS Document Repository	Provide & Register Imaging Document Set [RAD-68]	R	RAD TF-2: 4.68
	Retrieve Document Set [ITI-43]	R	ITI TF-2: 3.43
	Register Document Set-b [ITI-42]	R	ITI TF-2: 3.42
	Create XDW Read [RAD-111]	R	RAD TF-2: 4.111
	Cancel XDW Read [RAD-112]	R	RAD TF-2: 4.112
	Accept/Reject XDW Report [RAD-113]	R	RAD TF-2: 4.113
	Revoke XDW Assignment [RAD-114]	R	RAD TF-2: 4.114
	Assign XDW Read [RAD-115]	R	RAD TF-2: 4.115
	Accept/Reject or Release XDW Read [RAD-116]	R	RAD TF-2: 4.116

Actors	Transactions	Optionality	TF Reference
	Update XDW Read [RAD-117]	R	RAD TF-2: 4.117
	Claim XDW Read [RAD-119]	R	RAD TF-2: 4.119
	Complete XDW Read [RAD-120]	R	RAD TF-2: 4.120

Table 3.3.1-2: Digital Pathology Aid for Telemedicine Workflow - Broker Transactions

Actors	Transactions	Optionality	TF Reference
DSUB Document Metadata Notification Broker	Subscribe Remote Read Task [RAD-118]	R	RAD TF-2: 4.118
	Document Metadata Notify [ITI-53]	R	ITI TF-2: 3.53

Table 3.3.1-3: Digital Pathology Aid for Telemedicine Workflow - XRR-WD Watcher Transactions

Actors	Transactions	Optionality	TF Reference
XRR-WD Watcher	Subscribe Remote Read Task [RAD-118]	R	RAD TF-2: 4.118
	Multiple Patient Query [ITI-51]	R (Note 1)	ITI TF-2: 3.51
	Document Metadata Notify [ITI-53]	R (Note 1)	ITI TF-2: 3.53

Note 1: Supported because of the Grouping Requirements of XDS Environment Option.

Table 3.3.1-4: Digital Pathology Aid for Telemedicine Workflow - XRR-WD Task Manager Transactions

Actors	Transactions	Optionality	TF Reference
XRR-WD Task Manager	Revoke XDW Assignment [RAD-114]	R	RAD TF-2: 4.114
	Assign XDW Read [RAD-115]	R	RAD TF-2: 4.115
	Subscribe Remote Read Task [RAD-118]	R	RAD TF-2: 4.118
	Registry Stored Query [ITI-18]	R (Note 1)	ITI TF-2: 3.18
	Retrieve Document Set [ITI-43]	R (Note 1)	ITI TF-2: 3.43
	Multiple Patient Query [ITI-51]	R (Note 1)	ITI TF-2: 3.51
	Document Metadata Notify [ITI-53]	R (Note 1)	ITI TF-2: 3.53

Note 1: Supported because of the Grouping Requirements of XDS Environment Option.

3.3.1.1 DPAT Requester System

A DPAT Requester System needs to support the functionalities of an Imaging Producer System (see Section 2.3.1.1.2 Imaging Producer System) and an XRR-WD Task Requester (see Table 3.3.1.1-1 for constraints regarding transactions that shall be supported).

Table 3.3.1.1-1: Digital Pathology Aid for Telemedicine Workflow - XRR-WD Task Requester Transactions

Actors	Transactions	Optionality	TF Reference
XRR-WD Task Requester	Create XDW Read [RAD-111]	R	RAD TF-2: 4.111
	Cancel XDW Read [RAD-112]	R	RAD TF-2: 4.112
	Accept/Reject XDW Report [RAD-113]	R	RAD TF-2: 4.113
	Subscribe Remote Read Task [RAD-118]	R	RAD TF-2: 4.118
	Registry Stored Query [ITI-18]	R (Note 1)	ITI TF-2: 3.18
	Retrieve Document Set [ITI-43]	R (Note 1)	ITI TF-2: 3.43
	Document Metadata Notify [ITI-53]	R (Note 1)	ITI TF-2: 3.53

Note 1: Supported thanks to the Grouping Requirements of XDS Environment Option.

675 3.3.1.2 DPAT Performer System

A DPAT Performer System needs to support the functionalities of an Imaging Consumer System (see Section 2.3.1.1.1 Imaging Consumer System) and an XRR-WD Task Performer (see Table 3.3.1.2-2 for constraints regarding transactions that shall be supported).

Table 3.3.1.2-1: Digital Pathology Aid for Telemedicine Workflow - Actors and Transactions for a DPAT Performer System

Actors	Transactions	Optionality	TF Reference
XRR-WD Task Performer	Accept/Reject or Release XDW Read [RAD-116]	R	RAD TF-2: 4.116
	Update XDW Read [RAD-117]	R	RAD TF-2: 4.117
	Subscribe Remote Read Task [RAD-118]	R	RAD TF-2: 4.118
	Claim XDW Read [RAD-119]	R	RAD TF-2: 4.119
	Complete XDW Read [RAD-120]	R	RAD TF-2: 4.120
	Multiple Patient Query [ITI-51]	R (Note 1)	ITI TF-2: 3.51
	Document Metadata Notify [ITI-53]	R (Note 1)	ITI TF-2: 3.53

Note 1: Supported thanks to the Grouping Requirements of XDS Environment Option.

3.3.2 Model Overview

Because of the XRR-WD and XDS-I.b Profiles are both based on XDS, the XRR-WD with XDS-I.b sharing and retrieving model permits to build an open community based on an XDS

685 infrastructure, without adding any complexity layer, with all the consideration about sharing and
retrieving the digital slides described for XDS-I.b sharing and retrieving model in Section
2.3.1.2.

Furthermore, because the XRR-WD is based also on DSUB and MPQ Profiles, the consultation
request can be sent to the performer directly with a notification or can be searched by the
690 performer itself; searching for available consultation to be performed will prevent missing of the
notifications related to the DSUB Profile and will also enable an asynchronous consultation
mode (see Section 3.3.3.2).

Moreover, in a consultation scenario the suffering from a slow retrieval of the images using
XDS-I.b can be overtaken by the DPAT Performer System retrieving the images already at the
695 moment of the notification, in order to have all the digital slides required to perform the request.

3.3.2.1 Managing Different Types of Consultation

The XRR-WD can be used to manage different types of consultation requests using the
appropriate method of referencing.

In the case in which the teleconsultation request is sent for only a portion of the images, in the
700 XRR-WD can be referenced a KOS that contains only the references to that selection of slides,
on which the consultation has to be done. On the opposite, if a teleconsultation request is sent for
two or more sets of acquisition, in the XRR-WD can be referenced all the KOS about the
multiple cases on which the consultation has to be done.

If multiple consultations have to be done on the same set of slides, multiple WRR-WD could be
705 created, each of these regarding a single consultation that has to be done by a single consultant,
and cross-referenced each other with the XDW references mechanisms.

3.3.3 Use Cases

The use cases presented below are described assuming the following environment that illustrates
a typical purpose of the DPAT.

710 The creation of a pathology network would enable the pooling of expertise and competence as
well as the collaboration between different hospital trusts and local health authorities with
different levels of specialization.

In this way one can use a higher level of expertise and competence, whether they are related to
professionals or physical resources and it will also improve patient quality of life moving toward
715 a collaborative working environment.

3.3.3.1 Use Case #1: Assigning Teleconsultation Request

This use case describes the scenario in which Dr. Brown, who operates from a DPAT Requester
System, decides to ask for a teleconsultation request ready to be assigned to a performer.

In this section are reported below the use case description, the process flow and the related
720 workflow steps.

3.3.3.1.1 Assigning Teleconsultation Request Use Case Description

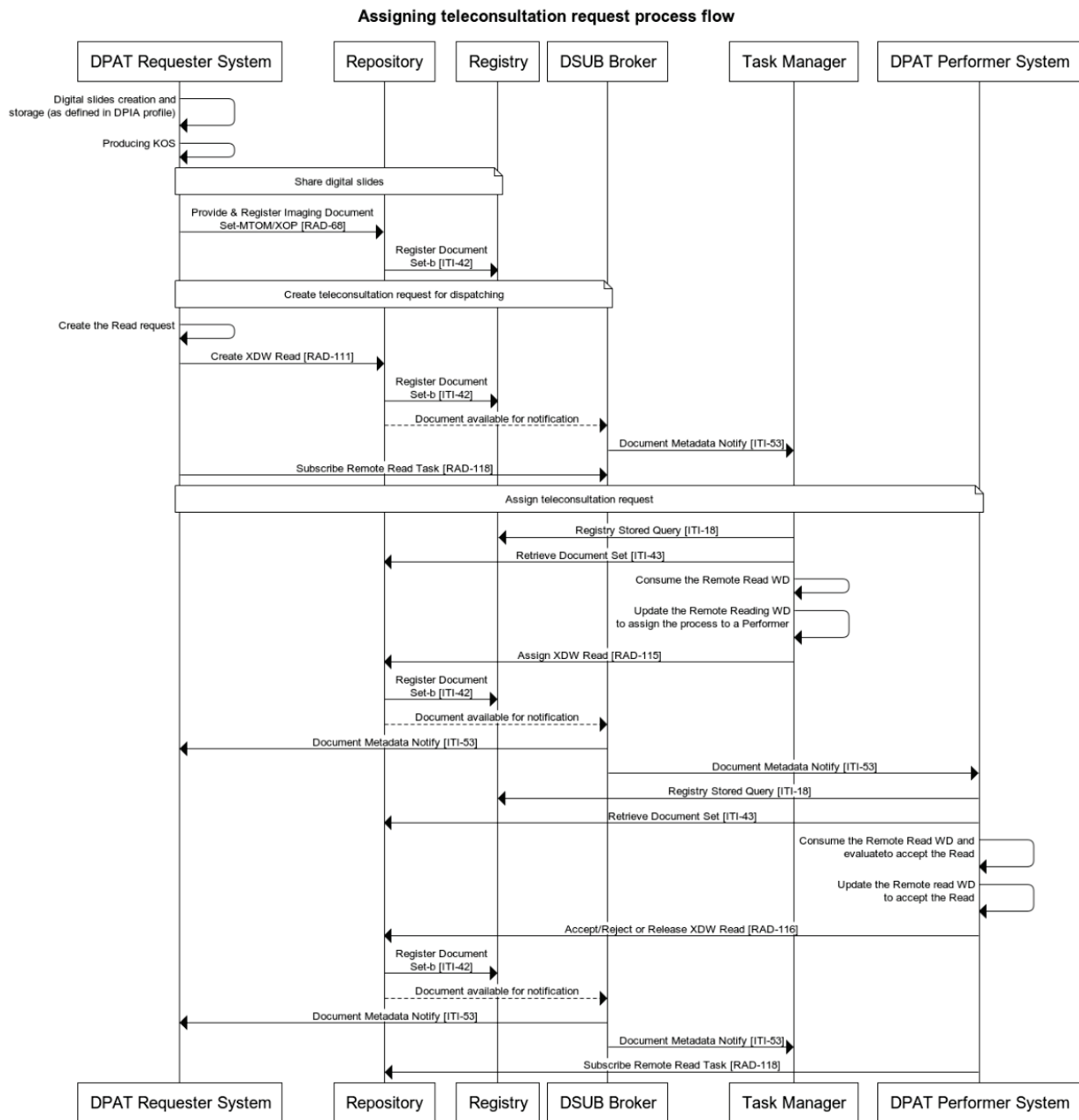
Dr. Brown, a Goodcare Hospital's anatomic pathologist, during the execution of an examination notices something that needs to be further investigated on a kidney biopsy slide. He decides to ask for a consultation. According to the digital imaging policies of the Goodcare Hospital, he asks for the digital slide creation of the study to be associated with the case.

Therefore using his workstation, Dr. Brown sends a consultation request. Dr. Brown fills the missing data on a request form which is already partially completed by the LIS and can choose to assign the request to a performer in two ways:

- asking directly to Dr. Smith, a Sacred Heart Hospital's kidney specialist pathologist, reporting all the information needed in the request;
- letting the Task Manager assign the request to a performer, based on the Collaboration Group policies of the community, which could be Dr. Smith or another performer.

The performer considers whether to accept the request and once he agrees to the request, Dr. Brown is notified about its acceptance.

735

3.3.3.1.2 Assigning Teleconsultation Request Process Flow**Figure 3.3.3.1.2-1: Assigning Teleconsultation Request Process Flow**

The DPAT Requester System creates the digital slides according to what is defined in the DPIA Profile.

740

In order to share the digital slides within the XDS-I.b community, DPAT Requester System performs a Provide & Register Imaging Document Set-MTOM/XOP [RAD-68] transaction to

the Repository. The [RAD-68] Request Message contains the KOS document that contains the digital slides references and the metadata of that document.

745 After receiving the [RAD-68] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the KOS document.

The DPAT Requester System creates the Read request of the teleconsultation and performs a Create XDW Read [RAD-111] transaction, to create the XRR-WD containing the Request Remote Read XDWTASK in status COMPLETED with the references to the Read request, to the KOS and to other Relevant Clinical Documents or Images, and containing the Dispatch Remote
750 Read XDWTASK, in status READY, in which in the <notificationRecipients> tag there could be the references to a performer directly identified by the DPAT Requester System.

After receiving the [RAD-111] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the XRR-WD.

755 Because of the availability of the workflow document, the DSUB Broker performs a Document Metadata Notify [ITI-53] transaction to notify the Task Manager.

The DPAT Requester System performs a Subscribe Remote Read Task [RAD-118] transaction to the DSUB Broker to subscribe for Workflow Instance Id of the XRR-WD.

The Task Manager, after receiving the notification, searches the XRR-WD performing a Registry Stored Query [ITI-18] to the Registry.

760 Obtaining the references to the XRR-WD in the [ITI-18] Response Message, the Task Manager performs a Retrieve Document Set [ITI-43] transaction to retrieve the XRR-WD.

The Task Manager consumes and updates the XRR-WD to assign the process to a performer, then performs an Assign XDW Read [RAD-115] transaction to the Registry to update the XRR-WD, setting the Dispatch Remote Read XDWTASK in status COMPLETED and adding the
765 Perform Remote Read XDWTASK in status READY, in which in the <notificationRecipients> tag there shall be the references to the performer.

After receiving the [RAD-115] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the XRR-WD.

770 Based on the active subscription and the new version of the XRR-WD, the DSUB Broker performs a Document Metadata Notify [ITI-53] transaction to notify the DPAT Requester System and the DPAT Performer System.

The DPAT Performer System, after receiving the notification, searches the XRR-WD performing a Registry Stored Query [ITI-18] to the Registry.

775 Obtaining the references to the XRR-WD in the [ITI-18] Response Message, the DPAT Performer System performs a Retrieve Document Set [ITI-43] transaction to retrieve the XRR-WD.

The DPAT Performer System consumes and updates the XRR-WD to accept the task, then performs an Accept/Reject or Release XDW Read [RAD-116] transaction to the Registry to update the XRR-WD, setting the Perform Remote Read XDWTASK in status IN_PROGRESS.

- 780 After receiving the [RAD-116] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the XRR-WD. Based on the active subscription and the new version of the XRR-WD, the DSUB Broker performs a Document Metadata Notify [ITI-53] transaction to notify the DPAT Requester System and the Task Manager.
- 785 The DPAT Performer System performs a Subscribe Remote Read Task [RAD-118] transaction to the DSUB Broker to subscribe for Workflow Instance Id of the XRR-WD.

3.3.3.1.3 Assigning Teleconsultation Request Workflow Steps

In Figure 3.3.3.1.3-1 is shown the XRR-WD evolution according to the process flow steps and the XRR-WD transactions performed by the actors.

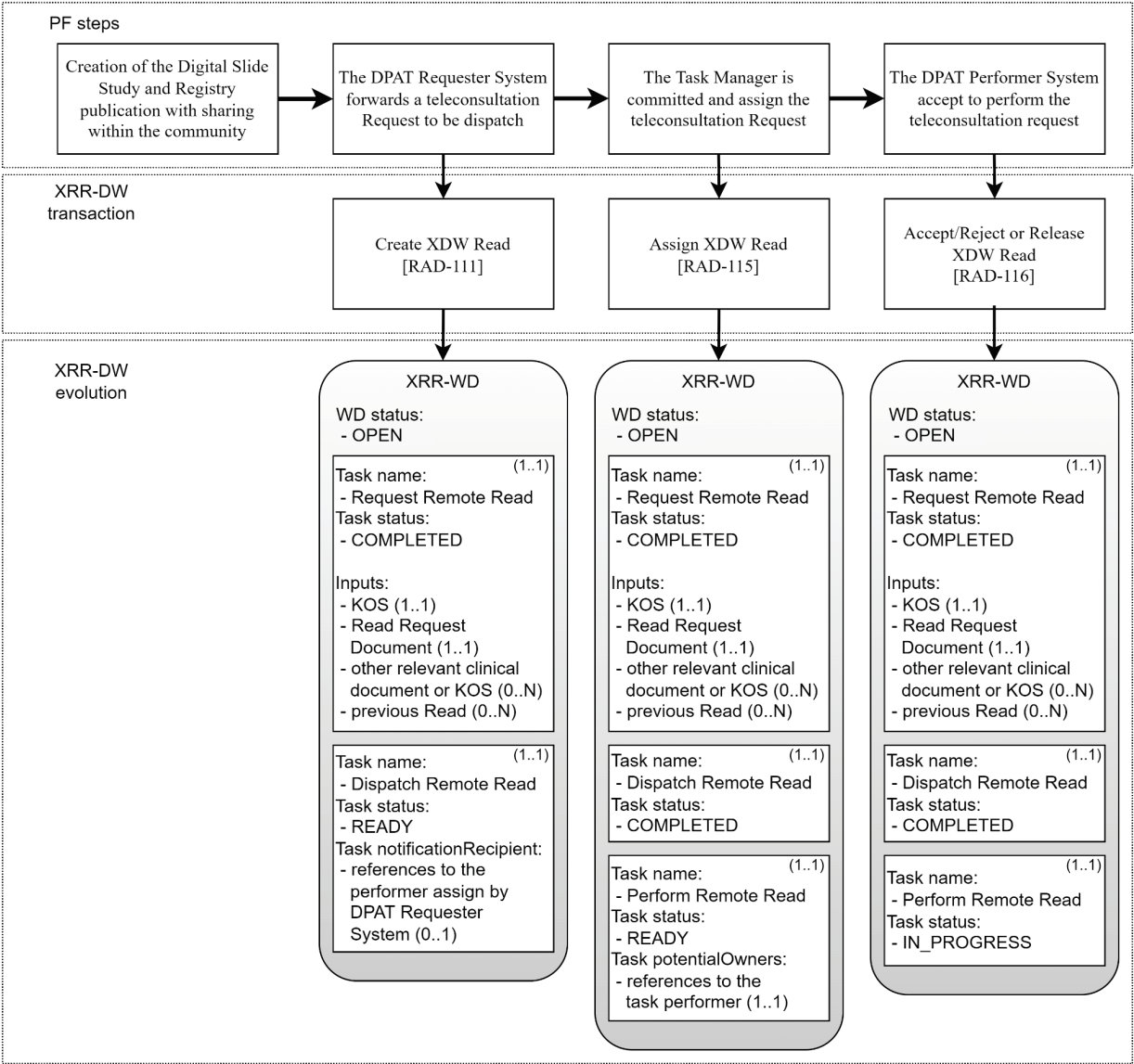


Figure 3.3.3.1.3-1: Assigning Teleconsultation Request Workflow Steps

3.3.3.2 Use Case #2: Claiming Teleconsultation Request

This use case describes the scenario in which Dr. Brown, who operates from a DPAT Requester System, decides to ask for a teleconsultation request with the community, waiting for a performer that will claim the request.

In this section are reported below the use case description, the process flow and the related workflow steps.

3.3.3.2.1 Claiming Teleconsultation Request Use Case Description

- 800 Dr. Brown, a Goodcare Hospital's anatomic pathologist, during the execution of an examination notices something that needs to be further investigated on a kidney biopsy slide. He decides to ask for a consultation with the community. According to the digital imaging policies of the Goodcare Hospital, he asks for the digital slide creation of the study to be associated with the case.
- 805 Therefore using his workstation, Dr. Brown sends a consultation request. Dr. Brown fills the missing data on a request form which is already partially completed by the LIS and sends the request to the community.
- 810 Dr. Smith, a Sacred Heart Hospital's kidney specialist pathologist, identifies the request and evaluates that she can perform the request, so using his workstation, Dr. Smith claims the request and Dr. Brown is notified about its acceptance.

3.3.3.2.2 Claiming Teleconsultation Request Process Flow

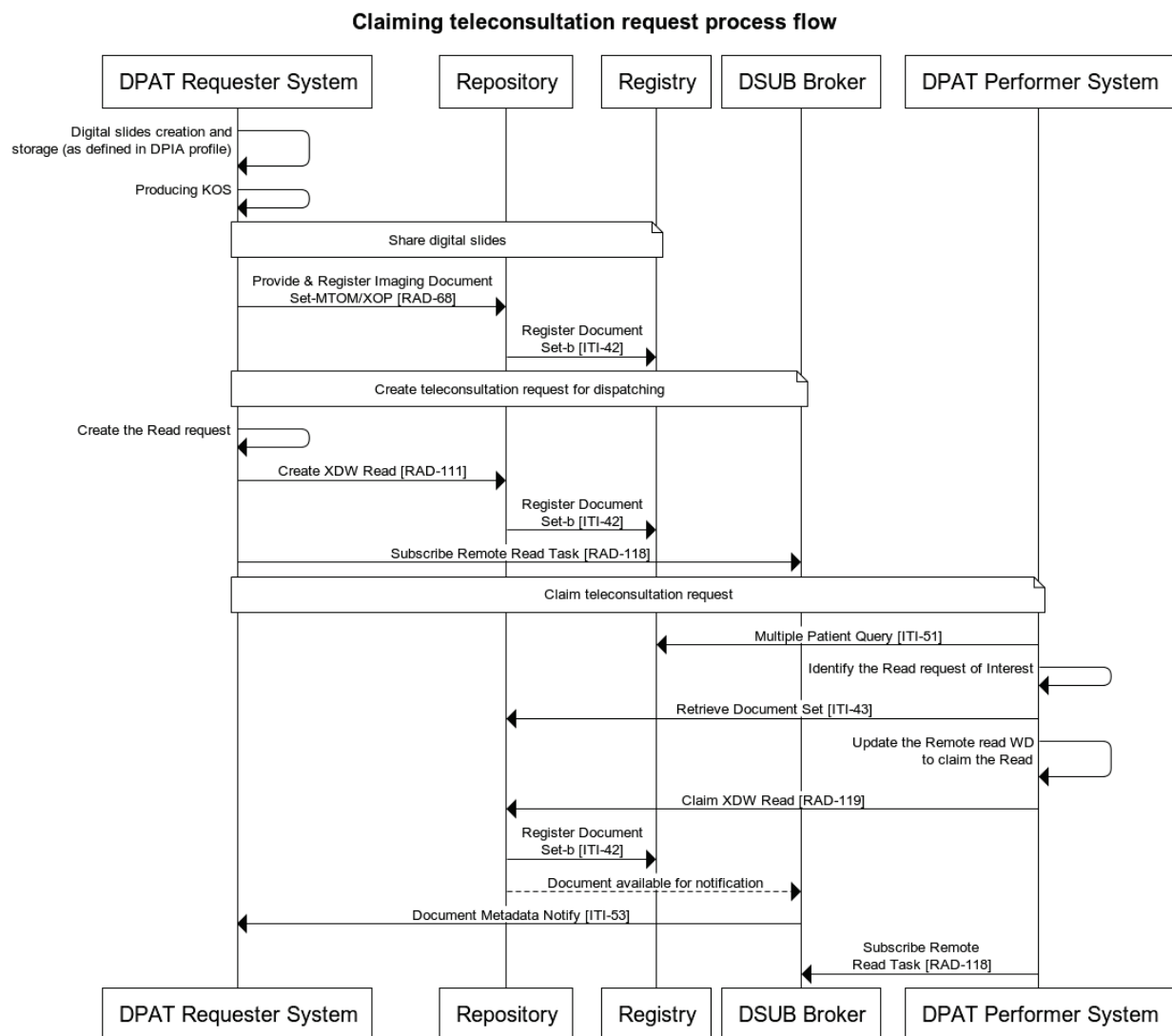


Figure 3.3.3.2.2-1: Claiming Teleconsultation Request Process Flow

815 The DPAT Requester System creates the digital slides according to what is defined in the DPIA Profile.

In order to share the digital slides within the XDS-I.b community, DPAT Requester System performs a Provide & Register Imaging Document Set-MTOM/XOP [RAD-68] transaction to the Repository. The [RAD-68] Request Message contains the KOS document that contains the digital slides references and the metadata of that document.

820 After receiving the [RAD-68] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the KOS document.

- 825 The DPAT Requester System creates the Read request of the teleconsultation and performs a Create XDW Read [RAD-111] transaction, to create the XRR-WD containing the Request Remote Read XDWTask in status COMPLETED with the references to the Read request, to the KOS and to other Relevant Clinical Documents or Images.
- After receiving the [RAD-111] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry in order to register the metadata of the XRR-WD.
- The DPAT Requester System performs a Subscribe Remote Read Task [RAD-118] transaction to the DSUB Broker to subscribe for Workflow Instance Id of the XRR-WD.
- 830 A DPAT Performer System performs a Multiple Patient Query [ITI-51] transaction to the Registry to obtain the information about what Read requests were created to identify the Read request of interest.
- Identifying the Read request of interest, the DPAT Performer System performs a Retrieve Document Set [ITI-43] transaction to retrieve the XRR-WD.
- 835 The DPAT Performer System consumes and updates the XRR-WD to claim the request, then performs a Claim XDW Read [RAD-119] transaction to the Registry to update the XRR-WD, adding the Perform Remote Read XDWTask in status IN_PROGRESS.
- After receiving the [RAD-119] Request Message, the Repository performs a Register Document Set-b [ITI-42] transaction to the Registry, in order to register the metadata of the XRR-WD.
- 840 Based on the active subscription and the new version of the XRR-WD, the DSUB Broker performs a Document Metadata Notify [ITI-53] transaction to notify the DPAT Requester System.
- The DPAT Performer System performs a Subscribe Remote Read Task [RAD-118] transaction to the DSUB Broker to subscribe for Workflow Instance Id of the XRR-WD.
- 845 **3.3.3.2.3 Claiming Teleconsultation Request Workflow Steps**
- In Figure 3.3.3.2.3-1 is shown the XRR-WD evolution according to the process flow steps and the XRR-WD transactions performed by the actors.

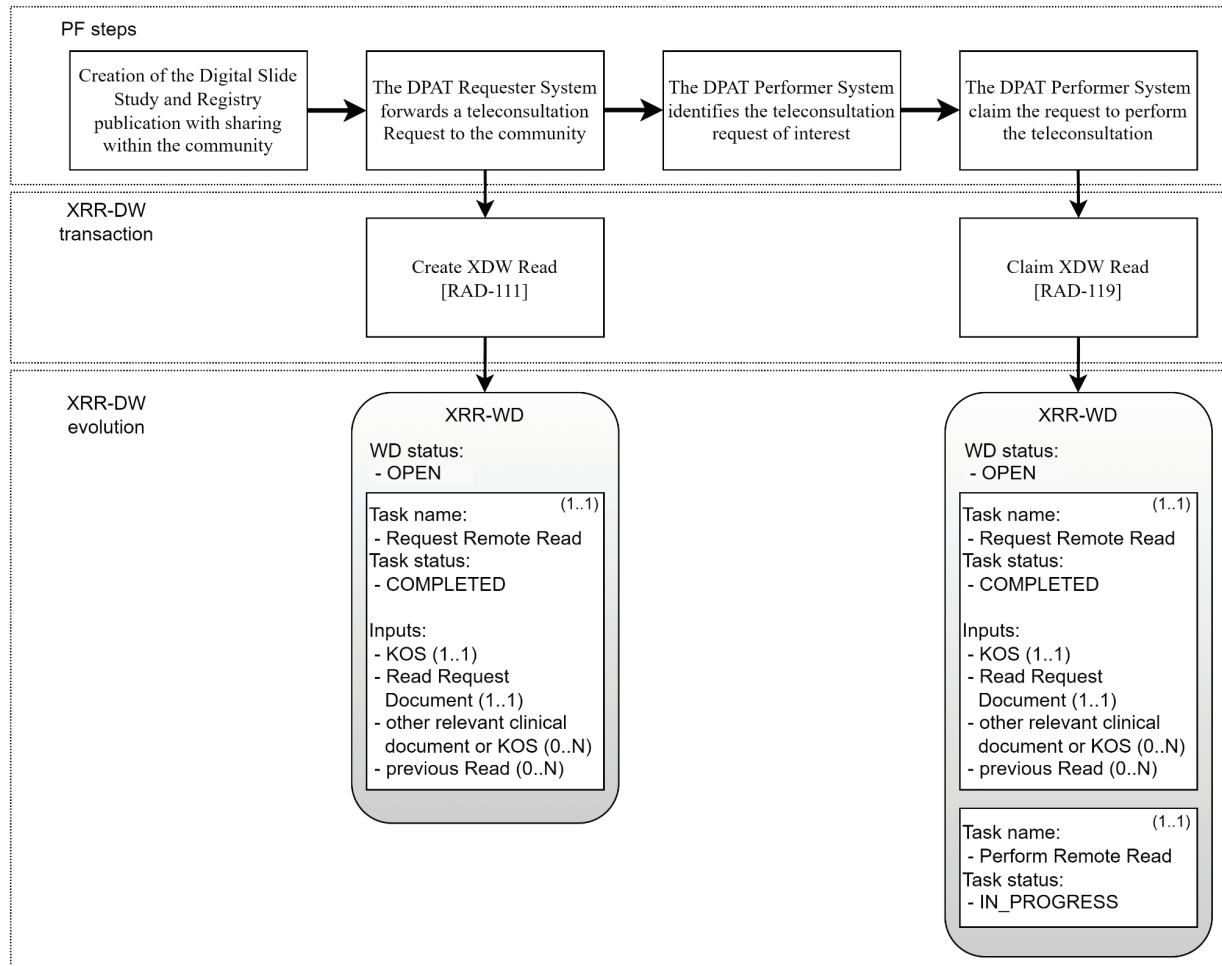


Figure 3.3.3.2.3-1: Claiming Teleconsultation Request Workflow Steps

850 3.3.3.3 Use Case #3: Performing Teleconsultation Request

This use case describes the scenario in which Dr. Smith, who operates from a DPAT Performer System, after she has accepted or claimed the teleconsultation request, performs the consultation and produces a final report. The requester is notified about the execution of the teleconsultation request, therefore he can evaluate the final report and close the request.

855 In this section are reported below the use case description, the process flow and the related workflow steps.

3.3.3.3.1 Performing Teleconsultation Request Use Case Description

A teleconsultation request has been accepted or claimed by Dr. Smith.

860 The request also includes the references to the digital slide study data for the retrieval of the images, therefore once Dr. Smith has accepted or claimed the request, she retrieves the related images and starts the reporting with the LIS at her disposal.

Once Dr. Smith has finished the reporting, she produces a report and completes the request. Then, Dr. Brown is notified about the completion of the request so he can retrieve the report done by Dr. Smith.

865 The report results are analyzed by Dr. Brown, who can decide which therapy or other actions are best for the patient and who also can close the request.

3.3.3.3.2 Performing Teleconsultation Request Process Flow

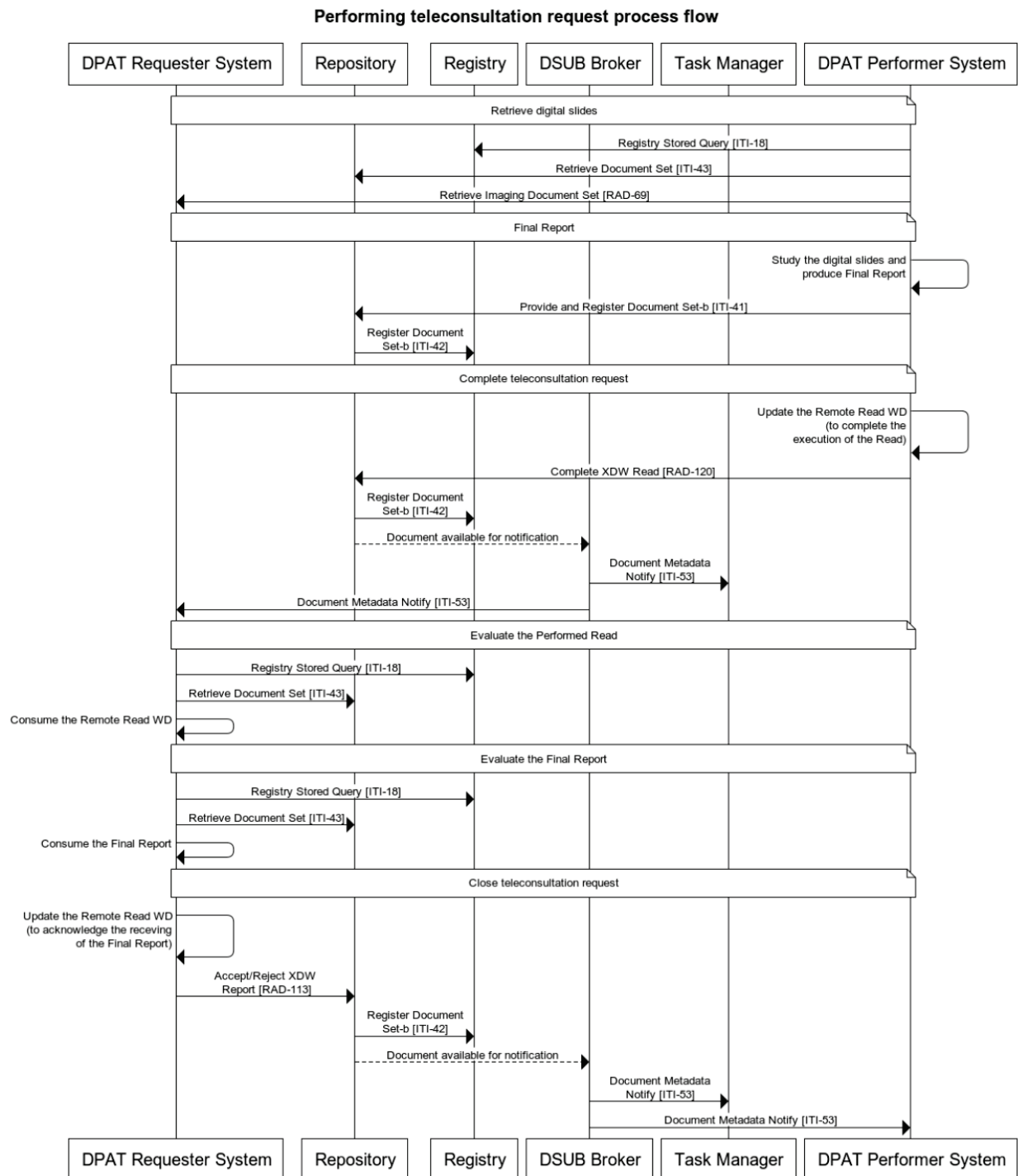


Figure 3.3.3.3.2-1: Performing Teleconsultation Request Process Flow

870 The DPAT Performer System sea

rchers for the KOS document performing a Registry Stored Query [ITI-18] transaction to the XDS Document Registry.

875 Once found the references to the KOS document, the DPAT Performer System performs a Retrieve Document Set [ITI-43] transaction to the XDS Document Repository, in order to retrieve the KOS document with the digital slides references.

Having the digital slides references, the DPAT Performer System can access them performing a Retrieve Imaging Document Set [RAD-69] transaction to DPAT Requester System, according to the agreement about which retrieve transactions are supported in the community.

880 After studying the digital slides and producing the final report, the DPAT Performer System performs a Provide & Register Document Set-b [ITI-41] transaction to the XDS Document Registry in order to share the final report with the XDS community.

After receiving the [ITI-41] Request Message, the XDS Document Repository performs a Register Document Set-b [ITI-42] transaction to the XDS Document Registry, in order to register the metadata of the final report document.

885 The DPAT Performer System updates the XRR-WD to complete the execution of the request, then performs a Complete XDW Read [RAD-120] transaction to the XDS Document Registry to update the XRR-WD, setting the Perform Remote Read XDWTASK in status COMPLETED and with the references to the final report in it.

890 After receiving the [RAD-120] Request Message, the XDS Document Repository performs a Register Document Set-b [ITI-42] transaction to the XDS Document Registry, in order to register the metadata of the XRR-WD.

Based on the active subscription and the new version of the XRR-WD, the DSUB Broker performs a Document Metadata Notify [ITI-53] transaction to notify the DPAT Requester System and the Task Manager.

895 The DPAT Performer System performs a Subscribe Remote Read Task [RAD-118] transaction to the DSUB Broker to subscribe for Workflow Instance Id of the XRR-WD.

The DPAT Requester System, after receiving the notification, searches the XRR-WD performing a Registry Stored Query [ITI-18] to the XDS Document Registry.

900 Obtained the references to the XRR-WD in the [ITI-18] Response Message, the DPAT Requester System performs a Retrieve Document Set [ITI-43] transaction to the XDS Document Repository to retrieve the XRR-WD and consume it.

The DPAT Requester System, in order to evaluate the final report, searches for the document performing a Registry Stored Query [ITI-18] to the XDS Document Registry.

905 Obtained the references to the XRR-WD in the [ITI-18] Response Message, the DPAT Requester System performs a Retrieve Document Set [ITI-43] transaction to the XDS Document Repository to retrieve the final report document and consume it.

The DPAT Requester System updates the XRR-WD to acknowledge the receiving of the final report and accept it, then performs an Accept/Reject XDW Report [RAD-113] transaction to the

910 XDS Document Registry to update the XRR-WD, adding the Complete Remote Read XDWTask in status COMPLETED.

After receiving the [RAD-113] Request Message, the XDS Document Repository performs a Register Document Set-b [ITI-42] transaction to the XDS Document Registry, in order to register the metadata of the XRR-WD.

915 Based on the active subscription and the new version of the XRR-WD, the DSUB Broker performs a Document Metadata Notify [ITI-53] transaction to notify the DPAT Performer System and the Task Manager.

3.3.3.3.3 Performing Teleconsultation Request Workflow Steps

In Figure 3.3.3.3.3-1 is shown the XRR-WD evolution according to the process flow steps and the XRR-WD transactions performed by the actors.

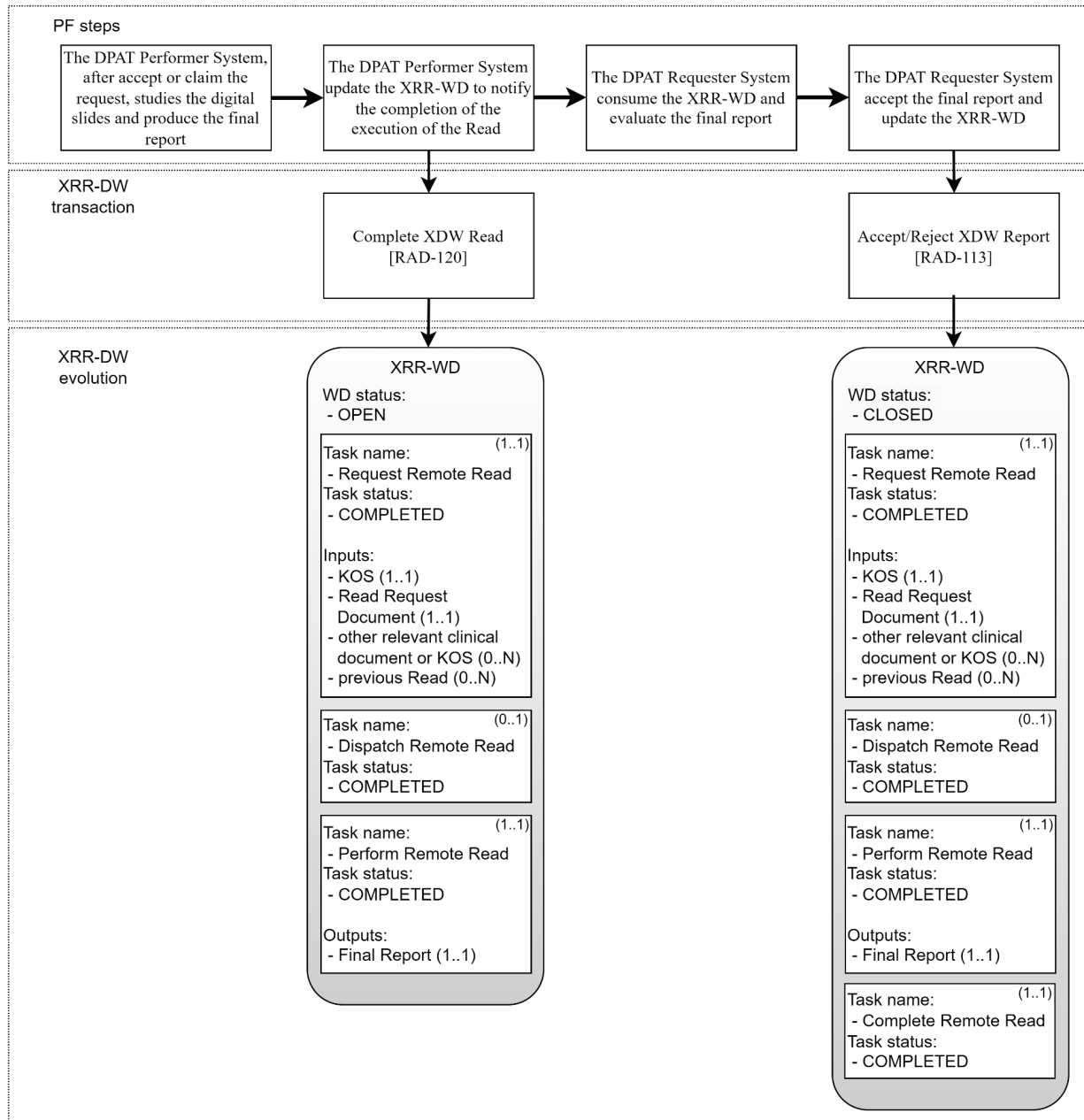


Figure 3.3.3.3-1: Performing Teleconsultation Request Workflow Steps

4 Patient Identification

The Digital Slides Sharing and Document Sharing defined in this white paper are patient centric, meaning that a patient is associated with each slide and document shared, also the Remote Reading Workflow Document carrying the teleconsultation request and the report drawn up by the performer of the request. When data related to an individual patient is exchanged among healthcare information systems it is critical to ensure that the participating systems are referring to the same patient. This requirement can be accomplished in several different ways.

This is an introduction to the Profiles used within a DPAT. These profiles include other use-case support, and other optional functions. Please reference the Profiles for details in PIX and PDQ.

Some contents above are taken from the Health Information Exchange (HIE) White Paper.

4.1 Patient Identity Cross-Reference (PIX)

The Patient Identity Cross-Reference PIX Profile supports the access to a central registry of cross-referenced identities, and the feed of identity updates from distributed identity domains.

Most health information systems assign to each patient an identifier (usually a string of letters and/or numbers) that is unique to the patient within only that information system. Thus, when this information system retrieves documents shared by other information systems, it has to match their patient identifiers with its own patient identifier.

IHE utilizes the concept of Patient Identifier Domains which defines a domain of patient identifiers, like identifiers assigned within a local Hospital, assigned by a single authority and an identifier for each assigning authority. For example, the local Hospital identifier is unique within the assigning authority for the local Hospital. If the local Hospital's system wants to communicate with the specialist's system for a teleconsultation about Gary Collins's digital slides, both systems must be able to know that 98T72A assigned by the local Hospital is equivalent to A129A assigned by the specialist's office, and that neither of those identifiers is equivalent to Garry Collin with an ID of 9870 at a Primary Care Physician. This is known as a cross-reference that links the two patient identifiers for Gary Collins.

The PIX Profile is IHE's answer to the difficulty of managing an individual patient's multiple Identifiers. A PIX Manager system receives feeds from multiple patient identity domains, such as the local Hospital and specialist offices, and uses the demographics in those feeds to create a cross-referencing table which associates identities with matching demographics and does not associate identities found not to match. The PIX Profile does not specify how patient matching occurs. Each deployment is welcome to use their own matching algorithms to determine which IDs should be cross-referenced.

A consumer system may query the PIX Manager to receive a list of identifiers which are cross-referenced with the identifier specified in the query. In this way the local Hospital office can discover the identifier used by the specialist's system and thus can communicate with that system using a known patient identifier.

4.2 Patient Demographics Query (PDQ)

960 The Patient Demographics Query (PDQ) Profile allows application systems to discover full
identity information and/or visit data on a patient given some set of demographics information
the application knows. The premise of this profile is that the PDQ service will be made available
by systems with more comprehensive and more accurate demographic information about patients
than other systems. The query might be based on: partial or complete patient name, patient ID,
965 partial ID entry or scan, date of birth or age range, bed ID.

PDQ Profile allows a Patient Demographics Supplier to receive a Patient Demographics Query
or Patient Demographics and Visit Query request from the Patient Demographics Consumer, and
returns demographics (and, where appropriate, visit) information.

970 When the Patient Demographics Supplier is grouped with actors in other IHE profiles that
perform patient information reconciliation activities (e.g., Radiology PIR), the PDQ Supplier
Actor may use the updated information to respond to PDQ Queries. In addition, the Patient
Demographics Query Profile may play an integral workflow role in conjunction with other IHE
Profiles.

975 A typical use of PDQ is to discover the patient's XDS Affinity Domain Patient ID. Imagine that
John Paul heads to the local public health department for a vaccination. The public health
department's clinical system does not assign local patient identifiers and thus cannot use the PIX
Profile to discover John's XDS Affinity Domain Patient ID. The public health department can
use PDQ to find matches for John and will receive John's XDS Affinity Domain Patient ID as
part of the demographics returned. With the knowledge of John's XDS Affinity Domain Patient
980 ID, the public health department can now publish his vaccination record to the community via
the XDS Profile.

5 Security and Privacy

This section will discuss how a community that leverages IHE Profiles for document sharing can protect patient privacy and information security; some contents are taken from the Health Information Exchange (HIE) White Paper.

IHE solves Interoperability problems via the implementation of technology standards. It does not define Privacy or Security Policies, Risk Management, Healthcare Application Functionality, Operating System Functionality, Physical Controls, or even general Network Controls. But, while community Policies and Risk Management are outside its scope, IHE does recognize that these elements are a necessary piece of a system implementation.

5.1 Policies and Risk Management

It is especially important for the reader to understand that the scope of an IHE profile is only the technical details necessary to ensure interoperability. It is up to any organization building a community to understand and carefully implement the policies of that community and to perform the appropriate risk analysis.

The policy landscape that the community is built on needs to be defined well before the community is built.

The Policy Environment is made up of many layers of policies. These policies work together in an interlocking hierarchy. At the highest layer are international policies, like the International Data Protection Principles. Countries or regions will have specific policies. There are horizontal policies that are common among a specific industry, such as those from medical professional societies. Then within the enterprise will be specific information technology policies.

Implementers need to be aware of different kinds of policies that need to be harmonized with those policies of the local health enterprises connected to the community. The following is a list of sample policy fragments to stimulate discussion. These policies are not a flat set, but often interlock and at other times cascade:

- Policies for who has access to what type of documents in the community
- Policies for who is allowed to publish documents into the community
- Policies on the acceptable types of documents that can be published into the community
- Policies that indicate acceptable levels of risk within community
- Policies that indicate what sanctions will be imposed on individuals that violate the community policies
- Policies on training and awareness
- Policies on user provisioning and de-provisioning within the community and local operation
- Policies on emergency mode operations

- Policies on acceptable network use (browser, decency, external-email access, etc.)
- Policies on user authentication methods that are acceptable
- Policies on backup and recovery planning
- 1020 • Policies on acceptable third-party access
- Policies on secondary use of the information in the community
- Policies on the availability of the community systems (are the community systems considered life critical, normal, or low priority)
- Policies for maintenance downtime
- 1025 • Policies for length of time that information will be maintained in the community

An important set of policies are those around emergency modes. There are wide definitions of cases that are referred to as emergency mode that are to be evaluate under risk management, like:

- Natural or manmade catastrophic disasters (e.g., hurricane, earthquake) – often times additional workforce migrates into the area from other places to help out. These individuals need to quickly be screened and provisioned with appropriate access.
- 1030 • Utility failure (e.g., electric failure) – this situation is common and easily handled through uninterruptible power supplies and backup generation
- IT infrastructure failure (e.g., hard drive crash) – this situation is also common and handled through common infrastructural redundancy
- 1035 Furthermore, it has to be considered that policy development often is frustrated by apparent conflicts in the goal or effect of multiple layers of policies. These conflicts are often only on the surface and can be addressed upfront once the details of the policy are understood.

5.2 Technical Security and Privacy Controls

- 1040 Based on the experience of the IHE participants in implementing community environments there is a common set of Security and Privacy controls that have been identified. These controls are informed by a combination of the Organization for Economic Cooperation and Development (OECD) data protection principles, experience with explicit policies at community implementations, and Security Risk Management.

These security and privacy controls are:

- 1045 1. Audit Log Controls – The controls that can prove the system is protecting the resources in accordance to the policies. This set of controls includes security audit logging, reporting, alerting and alarming.
- 1050 2. Identification and Authentication Controls – The controls that prove that a system or person is who they say that they are. For example: personal interactions, Digital Certificates, security assertions, OpenID-Connect, OAuth, Kerberos, and LDAP.

- 1055 3. Data Access Controls – The controls that limit access by an authenticated entity to the information and functions that they are authorized to have access to. These controls are often implemented using Role Based Access Controls (RBAC), or Attribute Based Access Control (ABAC).
- 1060 4. Secrecy Controls– As sensitive information is created, stored, communicated, and modified; this control protects the information from being exposed. For example: encryption or access controls.
- 1060 5. Data Integrity Controls – The controls that prove that the data has not changed in an unauthorized way. For example: digital signatures, secure hash algorithms, CRC, and checksum.
- 1065 6. Non-Repudiation Controls – The controls that ensure that an entity cannot later refute that they participated in an act. For example, author of a document, order of a test, prescribe of medications.
- 1065 7. Patient Privacy Controls – The controls that enforce patient specific handling instructions.
8. Availability Controls – The controls that ensure that information is available when needed. For example: backup, replication, fault tolerance, RAID, trusted recovery, uninterruptible power supplies, etc. (not an area where Interoperability applies)

5.3 Applying Security and Privacy to Document Sharing

- 1070 IHE does not set policies but is policy sensitive. Therefore, we now discuss the policy enabling technologies but not the policies themselves.

This section shows how the existing security controls in the local health IT system are leveraged and extended when they become interconnected through document sharing.

5.3.1 Basic Security

- 1075 IHE recognizes that in healthcare, with patient lives at stake, audit control is the primary method of accountability enforcement. The profile that provides this basic security principle is Audit Trail and Node Authentication (ATNA).

- 1080 ATNA is an integration profile from the IHE ITI Domain that provides patient information confidentiality, data integrity and user accountability addressing the issues of security measures according to Security Policies and Procedures. The process is marked by the user authentication, connection authentication and audit trails that limit the access between and to each node of the network. This profile requires three things of each system:

- User authentication and Access Controls are enforced accordingly
- Security Audit Logs are recorded
- 1085 • Strong network authentication and encryption for all communications of sensitive patient data.

1090 The Security Audit Logging includes a set of security relevant events that must be audited. When one of these events happens the record of the event must be described in a specific way. The systems are expected to support the recording of all of the security relevant events that might happen in the system. The ATNA Profile offloads the recording, filtering, alerting, and reporting to an audit service. The more centralized this audit log analysis can be, the easier it is to prove accountability across the whole Document Sharing exchange.

1095 Once it is known that the system will enforce Access Controls and Audit Controls then it can be connected to other systems that have also been assessed positively. In this way these systems only talk to other systems that also agree to enforce the common policies. This creates a basis for a chain of trust through accountability among all of the systems participating in the Document Sharing exchange. The communications between these trusted systems are also encrypted.

For more information see the ITI [ATNA](#) Profile.

5.3.2 Protecting Different Types of Documents

1100 The IHE Document Sharing profiles allow for many different types of documents to be shared. These documents are likely to have different levels of confidential information in them. For instance, one document might contain the very basic health information that the patient considers widely distributable. Another document might be made up totally of information necessary for proper billing such as insurance carrier and billing address. Yet another document might carry the results of a very private procedure that the patient wishes to be available only to direct care providers.

1110 These documents can be labeled with one or more codes, known as confidentialityCode. In the same way that the Document Sharing metadata ‘doctype’ defines what the document is in terms of the clinical/administrative content, the confidentialityCode defines what the document is in terms of privacy/security content, sometimes referred to as sensitivity. The confidentialityCodes should be looked at as a relatively static assessment of the document content privacy/security characteristics. Some documents are so sensitive in nature that they simply should not be shared or published.

1115 The access to these documents can be verified through a Role Based Access Control (RBAC). In this way, an user can access a document only if it has a role that, based on the Community policies, permits the access to that document with a specific confidentialityCode.

1120 These roles would be conveyed from the requesting organization through the use of the Internet User Authorization (IUA) Profile, or Cross-Enterprise User Assertion (XUA) Profile. These profiles define how a user and the security/privacy context of the request is defined. Additional information can be carried such as the PurposeOfUse or what the user intends to use the data for.

For more information see the ITI [XUA](#) Profile with the ITI [IUA](#) Profile and the ITI [Access Control White Paper](#).

5.3.3 Patient Privacy Consent to Participate in Document Sharing

1125 In a Community about managing shared documents, there are agreements between organizations (usually covered in a material transfer agreement or business associate agreement or both) and there are agreements between a patient and an organization (consent).

1130 The topic of Patient Privacy Consent (Authorization) to collect, use, and disclose is a complex topic. This complexity does not always need to be exposed in full detail across a Document Sharing exchange. That is, a request for information does need to consider the current status of any Patient Privacy Consent that the patient has given, but most of the time explaining the detail of this Privacy Consent to the requesting system/individual adds no value. Most often the requesting system/individual is either fully empowered to receive and use the content, or not authorized at all. In these cases, the use of user identity context, as discussed above around the ITI [IUA](#) or ITI [XUA](#) Profiles, is sufficient to make the Access Control decision. The trust
1135 relationship of the Document Sharing exchange includes background governance on appropriate use, as discussed above around the ITI [ATNA](#) Profile.

Privacy Consents may need to be expressed in a way that all parties in a Document Exchange can understand. The ITI domain has published the Basic Patient Privacy Consents ([BPPC](#)) Profile that can be used to enable basic privacy consent controls, and the Advanced Patient
1140 Privacy Consents ([APPC](#)) Profile that can encode more complex rules specific to a patient consent.

If authorizations are tracked electronically and managed to grant or deny the access to a document, then dynamic connections are possible using a further layer of policies in the community.

1145 For more information, see the ITI [BPPC Profile](#) with the ITI [APPC Profile](#).