Kanta

Technical Specification of the Imaging Data Repository

Version 3.0 RC1

Kela, Kanta Services
27.11.2024

Change history

Version	Change	Author	Date
2.3.4	No technical changes. Specified XUA instructions in chapter 7.2 when Private service provider's Joint connection is used. The following SAML AttributeValues have been specified: - Service provider's organisation ID - Custodian	Kela, Kanta Services	20.12.2018
2.3.5	Changes based on Finnish version of the document: Ch. 4.6 & 4.6.1: Study copies shall not to be saved to Kvarkki Ch.12.1.3: Chapter removed, because of regional reform was not enforced 2020. Ch.14.13.1: Addition of Local copies are still not be removed. Ch. 9.1 splitted 9.1.1 & 9.1.2: Removed unsupported document options. Added 9.12 ECG.	Kela, Kanta Services	
2.4	Accessibility changes Changes of consent management based on asiakastietolaki (784/2021) Changes based on Finnish version of the document: Ch 4.3, 4.5 & 9 updated Ch 9.1.3 added Ch 4.12 (Data collection on radiation exposure) & Ch. 18 (Needs for change in other specifications) removed	Kela, Kanta Services	31.8.2023
2.4.1	Ch 4.6 addition: notes made to a study copy can be archived Ch 4.8 recommendations for RAD-69 added Ch 4.9.3 metadata change removed, changes to the study are made according ch 4.9.2 and 4.9.8 Ch 4.9.3 invalidation of imaging studies added Ch 4.12 changes to retention period based on asiakastietolaki (703/2023) Ch 5.1 Format requirements of Study Instance UID added Ch 6 divided on sub-chapters 6.1 and 6.2 Ch 6.2 merging of patient data applies only to data of the same patient Ch 7 Addition to use of the Kanta consent based on asiakastietolaki (703/2023) Ch 9.1 focused the studies to be implemented Ch 9.1.1 archiving video studies is prohibited Ch 9.1.4 added Ch 10 supported tranfer syntax table removed	Kela, Kanta Services	30.1.2024
3.0	Changes to names in the Kanta Services e.g. The Archive of Imaging Data -> Imaging Data Repository. The changes caused by the technical reform of the Imaging Data Repository, the most important of which are presented in the introduction chapter.	Kela, Kanta Services	27.11.2024

Version	Change	Author	Date
	The structure of the document has been revised somewhat, e.g. by merging overlapping partitions.		

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1 Introduction

This specification document describes the functionality of the Kanta Imaging Data Repository and its connections to other solutions and specifications in the national healthcare systems. The technical implementation is described with respect to the interfaces and data formats as fully as possible including the functional principles for the storage of imaging objects and consent and access management.

The specification refers to the content definitions of the Patient Data Repository and other functional and technical specifications of Kanta. It is not possible to build interoperability with the Patient Data Repository and the Imaging Data Repository by reading this specification only.

In version 3.0 of the specification document there are taken into account the name changes of Kanta services (from archives to repositories) and changes to the implementation and the terminology used with the technical reform of the Imaging Data Repository. The structure of the technical specification document has also been somewhat renewed compared to the previous version.

In the technical reform of the Imaging Data Repository, the effects on external interfaces have been limited to as little as possible, and there are no mandatory new technical requirements for the systems already joined to the Imaging Data Repository.The main changes in the technical reform are:

- limited query types available in the XDS interface (ITI-18/ITI-38) metadata query (chapter 4.7),
- added consent management checks for XDS interface (RAD-69/RAD-75) imaging study query (chapters 4.1.2 and 4.7),
- an option (not currently in use) has been added to the Imaging Data Repository to limit the number of search results for metadata and imaging study queries (chapter 4.7.5),
- submissionSet removed from the metadata model (chapter 8) and
- updates to the XDS interface error codes (Appendix 4).

1.1 Overview of the Kanta architecture

This specification document describes the implementation of the Imaging Data Repository and its imaging data sharing infrastructure. Document is translated and condensed from the

official version written in Finnish with this additional introduction part for the readers not familiar with the Finnish healthcare system and the Kanta architecture. The following figure depicts the overall Kanta architecture where the Imaging Data Repository (Imaging Infrastructure) is presented as a part of the Patient Data Repository.

Kanta architecture is mostly based on HL7 V3, CDA R2 and FHIR interfaces and the Imaging Data Repository extends the architecture with IHE XDS and DICOM interfaces and DICOM studies. At first the XDS interfaces were used only for searhing imaging related data (radiology referrals, study documents, reports and DICOM studies) but since 2021 it has been allowed to store also the ECG data and since 2024 dental and eye healthcare studies to the Imaging Data Repository.

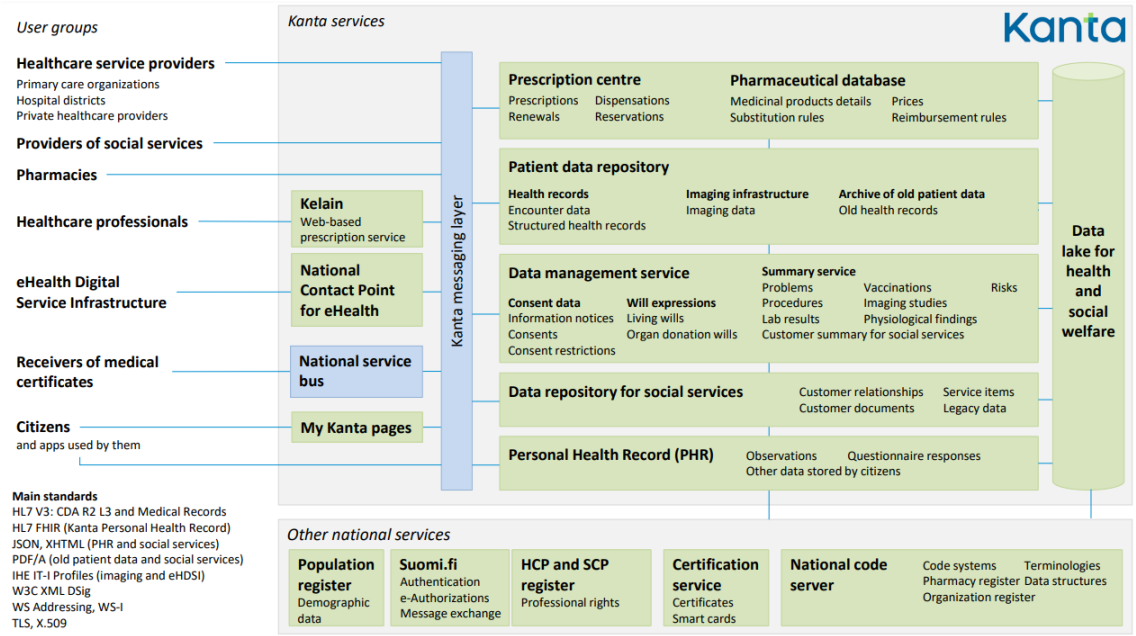

Figure 1. Kanta overall architecture

1.2 Architecture of the Imaging Data Repository

There are described the architecture and interfaces of the Imaging Data Repository with the following **Virhe. Viitteen lähdettä ei löytynyt.**. Imaging studies in DICOM format and their metadata are stored and managed in the Imaging Data Repository. For CDA R2 patient records (including the imaging referrals, study documents and reports) the “original document” is always stored in the Patient Data Repository of the Kanta.

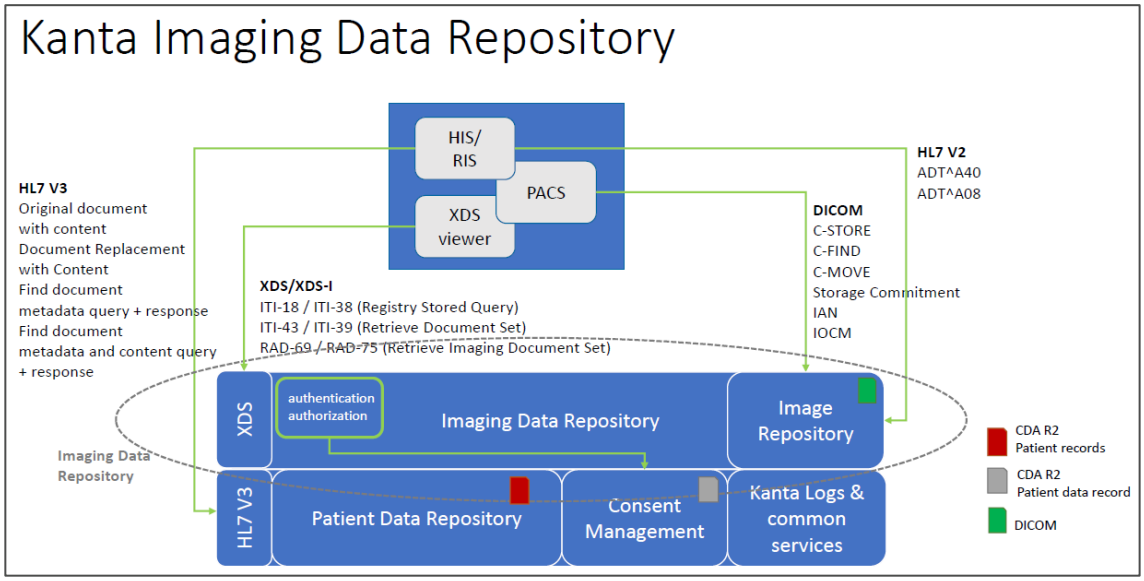

Figure 2. Architecture model of the Imaging Data Repository and co-existence with other Kanta services

This specification describes the Imaging Data Repository functionalities and the integration to other national Kanta services. Technical implementation provides blueprint for employing the interfaces and information entities (XDS and DICOM interfaces as used in Finnish architecture) as comprehensively as currently possible in order to be able to implement the required services. Additional requirements include e.g. managing the retention periods and consent management policies. This specification provides only the Imaging Data Repository interfaces and national requirements.

The specification is based on the Patient Data Repository content profiles, nationally defined use cases for HIS systems and other functional and technical specifications. This specification is not comprehensive enough in itself for building a total radiology imaging solution (including HIS, RIS and PACS systems) that operates with Patient Data Repository. Some of the less relevant or self-evident (e.g. in glossary) parts of the Finnish text have not been translated but are erased or condensed for this English version.

2 Glossary

Term	Description	Reference
Accession number	Referral ID, typically from RIS. Synonym AC number.	https://www.ihe-europe.net/glossary-of-terms
Affinity Domain	An area covering one XDS registry. Also known as the Home Community. May serve several repositories. Communication between affinity domains is managed with XCA and XCA-I profiles in the IHE XDS model.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
Assigning Authority	An organisation responsible for giving identifiers for citizens. In practice, in Finland this is the Digital and Population Data Services Agency (1.2.246.21) with respect to personal identity codes. The national code of conduct for temporary personal identity codes has still to be agreed on. An Affinity Domain normally defines the available assigning authorities.	https://www.kanta.fi/jarjestelmakehittajat/affinity-domain-opas
ATNA	Audit Trail and Node Authentication. An IHE profile.	See term IHE ATNA
Audit trail	In information systems: a log that verifies events and their times and performers.	See term IHE ATNA
CDA R2	A healthcare (Clinical documents R2) document format in XML, defined by the international HL7 community.	https://www.kanta.fi/jarjestelmakehittajat/potilastiedon-arkisto
C-MOVE	DICOM transfer command	https://dicom.nema.org/medical/dicom/current/
C-STORE	DICOM store command	https://dicom.nema.org/dicom/
C-FIND	DICOM query/retrieve command	https://dicom.nema.org/medical/dicom/current

Term	Description	Reference
DICOM	Digital Imaging and Communications in Medicine transfer protocol,file format and transactions for managing and transferring imaging examinations in standard format.	https://www.dicomstandard.org/current
DICOM data element	A unit of information as defined by a single entry in the data dictionary. An encoded Information Object Definition (IOD) Attribute that is composed of, at a minimum, three fields: a Data Element Tag, a Value Length, and a Value Field. For some specific Transfer Syntaxes, a Data Element also contains a VR Field where the Value Representation of that Data Element is specified explicitly. See also PS 3.5, Section 7.	https://dicom.nema.org/medical/dicom/current/
DICOM repository	Synonym Image Repository.	See term Image Repository
DICOM study	Synonym Imaging study.	See term Imaging study
DICOM tag	Tag is often used as shorthand terminology for 'DICOM data element'. A DICOM data element contains a piece of metadata, and the term tag actually refers to an ordered pair of numbers which identify the data element. The Tag is composed of a group number and an element number. For example (0010,0020) corresponds to 'Patient ID'. Refer to Glossary in DICOM PS3.5 for precise definition 'Data Element Tag'	https://dicom.nema.org/medical/dicom/current/
Document consumer	An actor according to the IHE XDS.b profile that queries and retrieves metadata and documents from data repositories.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
DVV	Digi- ja väestötietovirasto (in Finnish). The Digital and Population Data Services Agency. In terms of the Imaging Data Repository, responsible for the official personal identity code and the digital certificates used in healthcare services.	https://dvv.fi/en/organisations

Term	Description	Reference
Encounter	An outpatient visit related to the treatment of an illness or another reason or an inpatient episode in a healthcare organisation. Palvelutapahtuma in Finnish.	https://sotesanastot.thl.fi/
Gateway	Gateway complying with XCA or XCA-I in each XDS domain. Operates in both initiating and responding roles.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
HIS	Hospital information system. An information system used in the imaging workflow to manage patient information and record imaging study referrals.	https://wiki.ihe.net/index.php/Scheduled_Workflow
HL7 V3	Service interface technology defined by the international HL7 community. Based on Web service.	https://www.hl7.org/
HL7 interface	In this specification: concrete HL7 v3 compliant services in the Kanta system.	Chapter 3.1 Data entities in architectures of the Kanta and the Imaging Data Repository
IAN	Instance Availability Notification. Notification for informing status info about SOP instances.	https://www.dicomstandard.org/current
IHE ATNA	Audit Trail and Node Authentication. ATNA profile, obliges to log all functions on a device and use IHE CT and sets requirements for data enticationsecurity solutions.	https://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication
IHE CT	Consistent Time. In practice, utilisation of NTP time	https://wiki.ihe.net/index.php/Consistent_Time

Term	Description	Reference
IHE IOCM	Imaging Object Change Management describes the transactions for imaging objects in change management. Mainly instructions for applying DICOM-based interfaces. IOCM "specifies how one actor communicates local changes applied on existing imaging objects to other actors that manage copies of the modified imaging objects in their own local systems."	https://wiki.ihe.net/index.php/Imaging_Object_Change_Management
IHE PIX	Patient Identity Cross Referencing. Provides tools for patient identification possibly with different identifiers. Not as relevant in Finland in a certain sense as individual and national personal identity codes are in use. On the other hand, one identifier is not enough in the case of temporary and old (at least in cases of gender reassignment) identifiers.	https://wiki.ihe.net/index.php/Patient_Identifier_Cross-Referencing
IHE XCA	Cross Community Access. Expands the use of XDS.b transactions between Affinity Domains or within one Affinity Domain (if multiple repositories are abstracted to be accessible via one interface).	https://wiki.ihe.net/index.php/Cross-Community_Access
IHE XCA-I	Cross Community Access for Imaging. Expands the use of XDS-I.b transactions between Affinity Domains or within one Affinity Domain (if multiple repositories are abstracted to be accessible via one interface).	https://wiki.ihe.net/index.php/Cross-Community_Access_for_Imaging
IHE XDS.b	Cross Enterprise Document Sharing. Specification for the IHE IT Infrastructure domain, containing basic transactions for searching document description data and actual documents and for their registration and recording in the repository. In this description, XDS.b is a synonym of XDS, in practice XDS.b is a new generation of the XDS definition, which includes, e.g. web services interfaces .	https://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing

Term	Description	Reference
IHE XDS-I.b	Cross Enterprise Document Sharing for Imaging. Corresponds to XDS.b, but specialised for imaging objects, i.e. expands XDS.b. In practice, offers Retrieve Imaging Document Set (RAD-69) transactions based on DICOM WADO (RAD-55) and web services.	https://wiki.ihe.net/index.php/Cross-enterprise_Document_Sharing_for_Imaging
IHE XUA	Cross Enterprise User Assertion. Enables transfer of user data and query situation data from Document Consumer to Registry or Repository (to Document Source). In the draft version the extendable profile was called XUA++.	https://wiki.ihe.net/index.php/Cross-Enterprise_User_Assertion_(XUA)
Image Manager	An actor according to the IHE XDS.b profile that provides necessary operations for processing imaging objects (selecting key objects, etc.). In practice, implemented with PACS solution or may be integrated in Imaging Document Source.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
Image Repository	A subsystem of the Imaging Data Repository for storing imaging studies in DICOM format. The Image repository is an actor according to the XDS-I Imaging Document Source. Synonym DICOM Repository.	Chapter 3.1 Data entities in architectures of the Kanta and the Imaging Data Repository
Imaging Data Repository	Imaging Data Repository is a subsystem of the Kanta. In Finnish Kuva-aineistojen tietovaranto (aka Kvarkki). Imaging Infrastructure of the Kanta architecture.	Chapter 1 Introduction
Imaging Document Consumer	Imaging Document Consumer is an actor according to the IHE XDS-I that retrieves imaging studies from Imaging Document Source so that they can be viewed by professionals.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]

Term	Description	Reference
Imaging Document Source	Imaging Document Source is an XDS-I-compliant IHE actor that provides the necessary interfaces for storing and sharing imaging studies. The Image repository of the Imaging Data Repository is Imaging Document Source.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
Imaging study	A study in DICOM format, which is stored in the Image repository of the Imaging Data Repository. An imaging study contains one or more sets, and each set contains one or more images or other DICOM objects. Identified with the Study Instance UID. Synonym DICOM study.	Chapter 3.1 Data entities in architectures of the Kanta and the Imaging Data Repository
Imaging workflow	Controlled process for providing imaging study and report. Scheduled Workflow (SWF) domain.	https://wiki.ihe.net/index.php/Scheduled_Workflow
ITI-18	Registry Stored Query transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
ITI-38	Cross Gateway Query transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
ITI-39	Cross Gateway Retrieve transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
ITI-40	Provide X-User Assertion transaction. Implemented as SAML elements in other transaction messages.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]

Term	Description	Reference
ITI-43	Retrieve Document Set transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
ITI-8	Patient Identity Feed transaction. HL7 v 2.x ADT message. HL7 v3 counterpart is ITI-44.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
KOS, KOS file, Key Object Selection	A term used in XDS-I and DICOM that refers to the manifest. The KOS file is stored in the Imaging Data Repository, and it contains pointers back to the Imaging Document Source which contains the individual images and objects of the imaging study.	https://dicom.nema.org/medical/dicom/current/output/chtml/part03/sect_C.17.6.html
Modality	An imaging device producing imaging studies in DICOM format, e.g. X-ray angiography (XA), ultrasound (US), mammography (MG), endoscopy (ES).	https://dicom.nema.org/medical/dicom/current/output/chtml/part16/sect_CID_29.html
PACS	Picture Archiving and Communication System. Meant for storing and distribution that support the use of imaging studies. In practice, PACS implementations also have properties that support longer-term storage, but in accordance with modern architecture models mainly operative use is used for medium-term storing.	https://wiki.ihe.net/index.php/Scheduled_Workflow
Patient Data Repository	The Patient Data Repository is a subsystem of the Kanta and a national healthcare service data system in active use. It is used with the patient records systems like HIS and RIS. It allows centralised electronic storing of patient records (CDA R2) and long-term storage of the data. Potilastietovaranto in Finnish.	Chapter 1.1 Overview of the Kanta architecture
PAP	Policy Administration Point	see term XACML
PDP	Policy Decision Point	see term XACML

Term	Description	Reference
PEP	Policy Enforcement Point	see term XACML
PIP	Policy Information Point	see term XACML
PRP	Policy Retrieval Point	see term XACML
RAD-10	Storage Commitment transaction. Ensures DICOM storage of the study.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
RAD-16	Retrieve Images transaction. C-MOVE command in DICOM standard, utilised by XDS-I as RAD-16 transaction.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
RAD-66	Rejection Notes Stored transaction. IOCM transaction used for storing change object for imaging study.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
RAD-69	Retrieve Imaging Document Set transaction. Transaction defined by XDS-I for retrieving imaging study object.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
RAD-75	Cross Gateway Retrieve Imaging Document Set transaction. Transaction for XCAI-compliant gateway to transmit retrieval request for imaging study to another domain.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]
RAD-8	Modality Images Stored transaction. Defined and described in SWF profile, but functionally corresponds with storing of imaging study in the DICOM repository.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]

Term	Description	Reference
Register of social welfare and healthcare organisations	Information about healthcare organisations that is required from all healthcare units and from the service units of the healthcare units related to Kanta architecture (‘offices’, ‘place of supply of services’) is gathered in the register of social welfare and healthcare organisations. Organisation units with a business ID have also been identified in the register. In Finnish SOTE-organisaatiorekisteri.	http://koodistopalvelu.kanta.fi/codeserver/pages/classification-view-page.xhtml?classificationKey=421
Retention class	Class determined by Finnish act on processing of social and health care customer data (łaki sosiaali- ja terveydenhuollon asiakastietojen käsittelystä) a.k.a. asiakastietolaki (703/2024). Codesystem: eArkisto – Säilytysaikaluokka (OID:1.2.246.537.5.40158).	https://www.finlex.fi/fi/laki/ajantasa/2023/20230703
RIS	Radiology Information System	https://wiki.ihe.net/index.php/Scheduled_Workflow
SAML	Security Assertion Markup Language. OASIS standard for distributing user identification and authorisation data in the information network.	https://www.oasis-open.org/standard/saml/
SCU role	Service Class User role in DICOM traffic	https://www.dicomstandard.org/current/
SCP role	Service Class Provider role in DICOM traffic	https://www.dicomstandard.org/current/
SOAP	Simple Object Access Protocol. Web service protocol standardised by W3C.	https://www.w3.org/TR/soap/
Study instance UID	Unique identification code for the imaging study	https://dicom.nema.org/medical/dicom/current/output/chtml/part03/sect_C.7.2.html

Term	Description	Reference
Tag	An attribuutti of DICOM-object. Each attribute or data unit has unique id defined in DICOM. Tag contains two pairs of numbers (group number and data unit number).	https://dicom.nema.org/medical/dicom/current/output/html/part05.html#glossentry_DataElementTag
TLS	Transport Layer Security (TLS), previously known as Secure Sockets Layer (SSL), is an encryption protocol for protecting internet applications across IP networks.	https://datatracker.ietf.org/doc/html/rfc8446
Transfer syntax	Content format of the DICOM-formatted imaging study in transfer.	https://dcm4chee-arc-cs.readthedocs.io/
Trial implementation	Name of the definition status in the production process of IHE definitions. Draft version before approval.	http://ihe.net/Technical_Frameworks/
Web service	Interface technology for network services defined in W3C.	https://www.w3.org/TR/ws-arch/
Web service transaction	Individual service implemented with web service technology. IHE XDS and XDS-I services are implemented with the web service technology, and IHE calls them ‘transaction’.	https://wiki.ihe.net/index.php/IHE_ITI_Web_Services_Glossy
XACML	eXtensible Access Control Markup Language. OASIS specification.	https://www.oasis-open.org/committees/download.php/2713/Brief_Introduction_to_XACML.html
XCA gateway	Gateway complying with XCA in each XDS domain. Operates in both initiating and responding roles. Transmits XDS search and retrieval messages.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles [1]
XCA-I gateway	Gateway complying with XCA-I in each XDS domain. Operates in both initiating and responding roles. Transmits imaging study retrieval messages.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles [2]

Term	Description	Reference
XDS domain	Synonym for IHE Affinity domain	see term Affinity domain
XDS Viewer	(Usually) browser-based application for using materials retrieved over XDS interfaces. May also be used as a viewer in some systems. Solutions from different suppliers support different IHE profiles to a varying degree. IHE term Document Consumer and Imaging Document Consumer.	https://wiki.ihe.net/index.php/Scheduled_Workflow

2.1 Notation used in the sequence diagrams

Notation used in the sequence diagrams in this document:

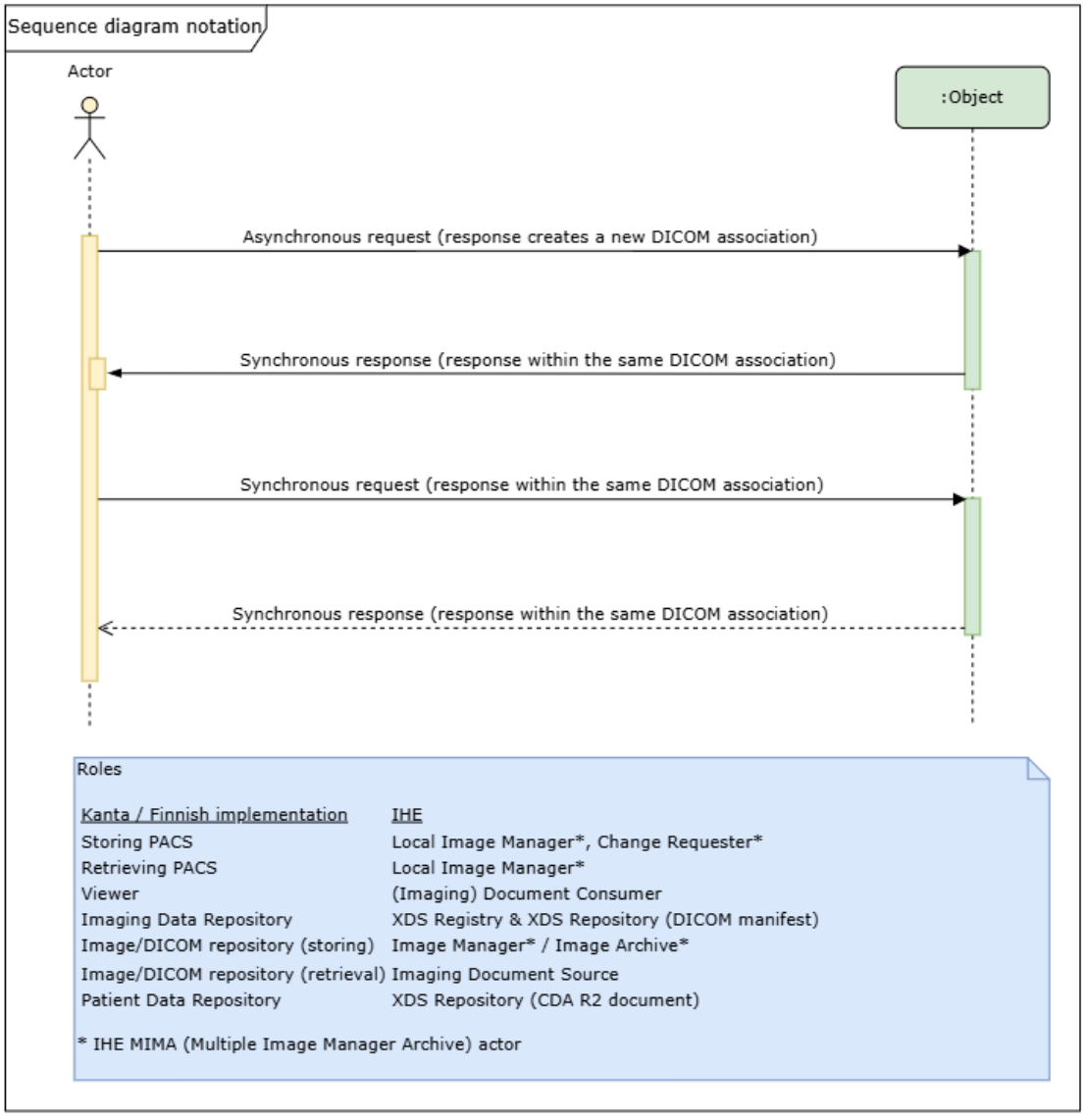

Figure 3. Notation used in sequence diagrams

3 Starting points

The starting point of the architecture of the Imaging Data Repository is to rely on the overall services and principles of the Kanta architecture. This specification document assumes that the functional principles of the Kanta will be implemented in the way they have been described in the Kanta specification. This specification document does not describe these principles again, but it only identifies their interfaces and deals in further detail with cases where these principles are applied in a deviating way in the area of imaging due to, for example, different kinds of materials and technical limitations.

With respect to IHE specifications, after the technical reform the specification of the Imaging Data Repository uses the specification versions for the radiology and the IT framework approved in 2023 [1] [2].

3.1 Data entities in architectures of the Kanta and the Imaging Data Repository

Kanta acts as the national data repository of imaging with respect to encounter data, patient records (also including imaging CDA documents, i.e. imaging referrals, whole sets of imaging study documents, and reports) and documents related to the sharing of patient records (consents, information and denials and sharing notifications). Imaging entries can be located under the “RTG” view, in some cases under the “LAB” view, or under any report text-type view. [3]

The Imaging Data Repository is responsible for the storage and distribution of imaging studies in DICOM format. In addition to this task, retrieval of imaging CDA documents (in CDA R2 format in the Patient Data Repository) with the XDS interface will also be possible, for example, for the needs of XDS viewers.

Imaging-related patient care and treatment documents (requests, study documents and reports) which are stored in CDA R2 format to Patient Data Repository are available for the patient to see in MyKanta Pages. The imaging studies in DICOM format stored in the Imaging Data Repository can only be searched by professionals on the interfaces of the Imaging Data Repository.

Information concepts that are functionally related to architecture of the Imaging Data Repository and the key properties related to them in implementation of the Imaging Data Repository are described in the following table.

Information / document	Format	Location	Role in architecture of the Imaging Data Repository	Storage interface	Retrieve interface
Encounter	CDA R2 document	Patient Data Repository	Establishing patient care context Interrelating the imaging data contents (primary key information). Allocation of consent restrictions.	HL7 V3	HL7 V3
Imaging or laboratory referral document	CDA R2 document	Patient Data Repository	Part of the imaging data content, connected to the encounter. Part of the key medical data in imaging.	HL7 V3	IHE XDS or HL7 V3
Imaging or laboratory study document	CDA R2 document	Patient Data Repository	Part of the imaging data content, connected to the encounter. Includes Study Instance UID reference for imaging study (secondary key information). Part of the key medical data in imaging.	HL7 V3	IHE XDS or HL7 V3
Imaging or laboratory report document	CDA R2 document	Patient Data Repository	Part of the imaging data content, connected to the encounter. Part of the key medical data in imaging.	HL7 V3	IHE XDS or HL7 V3
(Imaging or laboratory) patient care document	CDA R2 document	Patient Data Repository	General name for a CDA document that includes one or several imaging referral, study and report entries.	HL7 V3	IHE XDS or HL7 V3
Imaging study	DICOM study	DICOM repository of the Imaging Data Repository	Part of the imaging data content, connected to the encounter. Study/images Includes a Study Instance UID. Synonym: DICOM study	DICOM	IHE XDS-I

Information / document	Format	Location	Role in architecture of the Imaging Data Repository	Storage interface	Retrieve interface
Metadata of an imaging study		Imaging Data Repository	XDS metadata of an actual imaging study. In XDS-I, stored as metadata of the manifest. Synonym: XDS metadata	XDS store request produced in an automated way in connection with DICOM storing	IHE XDS
Manifest of an imaging study	KOS file	Imaging Data Repository	Localisation of actual imaging study and the objects contained in it. Synonyms: KIN, content description	XDS store request produced in an automated way in connection with DICOM storing	IHE XDS
Imaging study entity			All documents related to an imaging study in the Imaging Data Repository: study entries and DICOM study, as well as the manifest and XDS metadata. Synonym: imaging study entries and DICOM study		
Summary service data (e.g. imaging studies and laboratory results)	CDA R2 document (distributable format)	Kanta Patient Data Summary Service	Part of the patient's key health data, consists of (imaging) referrals, study documents and reports.Connected to patient encounters. Synonym: key health data (in imaging)	HL7 V3	HL7 V3
Informing the patient	CDA R2 document	Kanta Patient Data Management Service	Verifies that the patient has been informed about Kanta services. Synonym: Information about the Kanta Services	HL7 V3	HL7 V3 or simple WS interface

Information / document	Format	Location	Role in architecture of the Imaging Data Repository	Storage interface	Retrieve interface
Consent given by the patient	CDA R2 document	Kanta Patient Data Management Service	Verifies that the patient has given their consent to use the data in a care context and to share it from the national architecture. Synonym: Consent to data sharing	HL7 V3	HL7 V3 or simple WS interface
Consent restrictions given by the patient	CDA R2 document	Kanta Patient Data Management Service	Verifies that the patient has given a sharing restrictions with respect to the data of the service provider, service provider register or encounter. Synonym: Denial of consent	HL7 V3	HL7 V3 or simple WS interface
Outsourcing authorisation	CDA R2 document	Patient Data Repository	Enables storing of data in or retrieval of data from the registry of another service provider. Some old customers of Kanta alternatively, can be managed with a more general arrangement based on Kanta address registry	HL7 V3	HL7 V3 (The DICOM repository automatically verifies in an outsourcing situation) A DICOM study can be stored in the registry of another service provider on the basis of the encounter, i.e. the encounter determines the target registry (the correct logical registry of the custodian) of the study

Information / document	Format	Location	Role in architecture of the Imaging Data Repository	Storage interface	Retrieve interface
(Data) Sharing notification	CDA R2 document	Patient Data Repository	To be produced from patient register data sharing that cross register borders and other shares directly from the information system. With the sharing notification, shares made outside of Kanta services are supplemented as part of the share log of the Patient Data Repository.	HL7 V3	

3.2 Data content in CDA R2 format in the Patient Data Repository and XDS interfaces

When the organization that stores the imaging studies has joined the Imaging Data Repository, the CDA documents stored in the Patient Data Repository and contain imaging data are automatically forwarded to be registered in the Imaging Data Repository in implementation of the Kanta. The metadata of the registered CDA documents is returned in the metadata search of the XDS interface, and the documents themselves can be retrieved using the document retrieval service according to the XDS interface through the Imaging Data Repository.

4 Operating models of the Imaging Data Repository

This chapter describes the Imaging Data Repository from the functional viewpoint. At first, a typical case of using the service is presented in a simplified way. After that, the necessary special operational functions and methods of use deviating from the basic model are described.

The technical solution or method of implementation are described in brief, and the description and plan are not comprehensive. The objective is to present the utilisation of key IHE profiles and the planned national application, adaptation and extension technologies. The rough technical description provides a reader with some knowledge of information technology with references to national and IHE specifications and the standards applied.

4.1 Basic model for storing and utilising studies

In the basic workflow within the same registrar, the documents of the imaging study (referral, study data and report) and the imaging study are stored in Patient Data Repository and Imaging Data Repository of the Kanta as they are completed. The Imaging Data Repository is also used in the workflow to retrieve comparison images. Authorization of the outsourcing service enables the storage of imaging study and documents in Kanta even when users and systems of more than one registrar participate in the workflow, see chapter 4.3.

IHE specifications describe transactions to store and retrieval studies:

- TF Volume 1: Table 10.1-1b: XDS.b - Actors and Transactions. [1]
  - The table includes references to a more detailed description of the transactions.
- RAD Volume 1: Table 18.1-1: Cross-enterprise Document Sharing for Imaging Integration Profile – Actors and Transactions. [2]
  - The table includes references to a more detailed description of the transactions. The RAD table also includes transactions not pertaining to the XDS-I profile.

4.1.1 Storing a study

The following figure (**Virhe. Viitteen lähdettä ei löytynyt.**) presents a general model of storing imaging studies and their documents to Kanta.

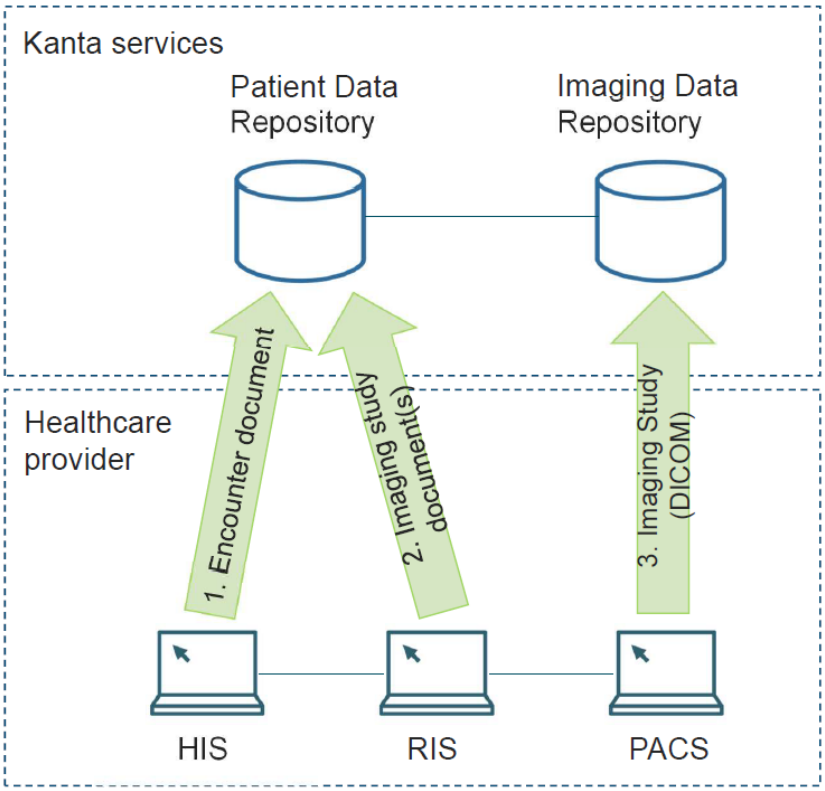

Figure 4. Storing of an imaging study

An encounter is created in the HIS system when booking an appointment or during the visit on a healthcare service provider.The encounter document in CDA R2 format is stored in the Patient Data Repository of Kanta services. Imaging documents created later are attached to this encounter.

A referral is formed to the encounter using a HIS or a RIS system. The system establishes a CDA R2 imaging study document that contains a referral entry and stores it to the Patient Data Repository. The information about performed imaging study is recorded in the RIS system which cretes a CDA R2 format document containing the imaging study entry and stores it to the Patient Data Repostory [3]. Storing a document containing imaging study entries (referral, study details, report) in the Patient Data Repository automatically starts the registration of its metadata in the Imaging Data Repository.

The DICOM study is stored from the PACS to the Image Repository of the Kanta Imaging Data Repostory. The DICOM storage automatically starts the formation of the manifest of the imaging study and storing and registering of it to the Imaging Data Repository. The transactions presented above are described from the perspective of the Imaging Data Repostory as a sequence diagram in the following image (Figure 5):

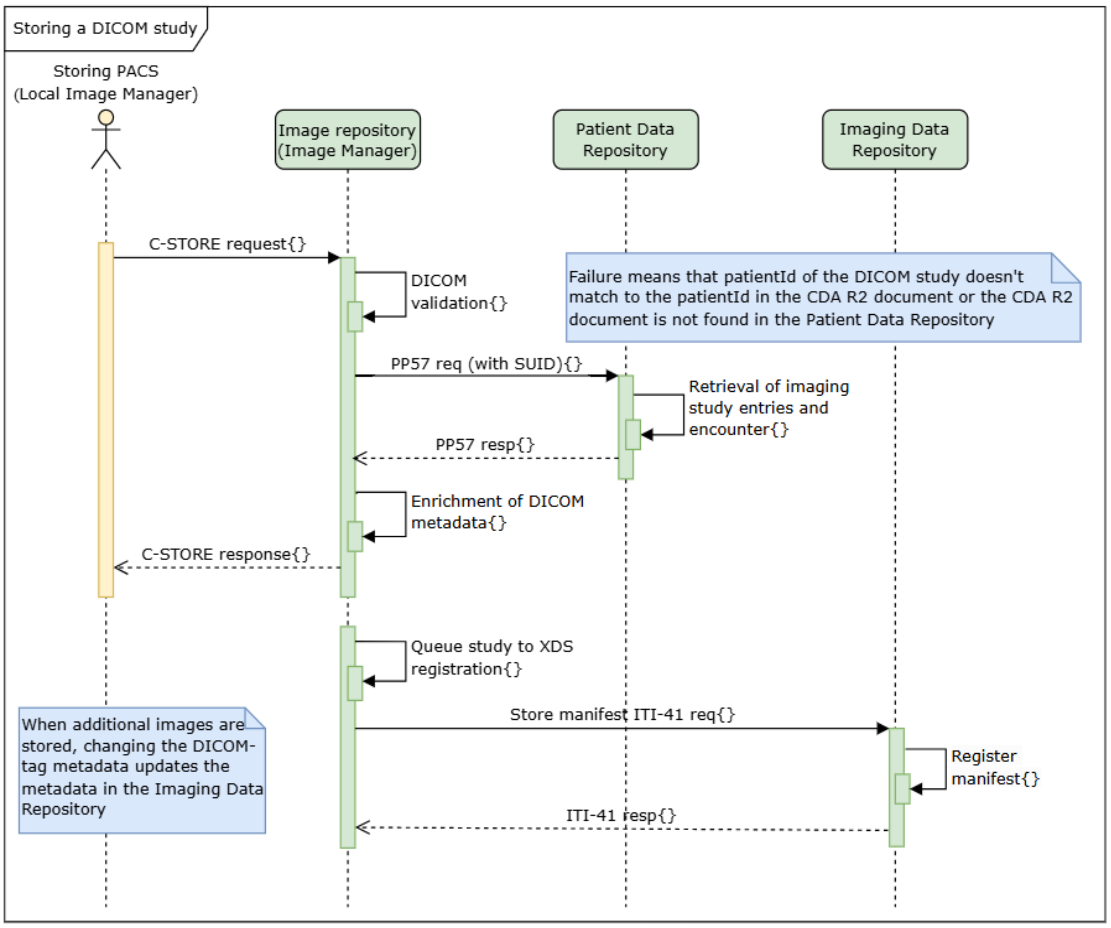

Figure 5. Storing of a DICOM study

The study report or reports are stored in the HIS or the RIS system in the workflow. The system creates report entries for a study document in CDA format and stores the document in the Patient Data Repository as a new version or as a completely new imaging study document. All imaging entries can be versioned to the same CDA R2 document or these entries can be combined into separate documents. Technically it is required that all imaging studies have a CDA R2 document containing the study entry and the Study Instance UID stored in the Patient Data Repository. The Patient Data Repository registers all imaging study documents in the Imaging Data Repository. All changes in the imaging study documents are also updated in the Imaging Data Repository.

4.1.2 Retrieval of a study

The user can search for imaging studies in the database of image materials using a search according to XDS-I. The query must also include identification data on the professional

needed for consent management, which is sent in accordance with XUA, as well as other contextual information related to the query (encounter of the care context, emergency query, etc.), which are described in further detail in the section related to consent management, which are described in more detailed in chapter 7. It is also possible to retrieve own imaging studies with DICOM protocol for example with a reference stored in the PACS.

In the simplest way utilisation of studies from XDS-I system of the Imaging Data Repository with a viewer application takes place with a three-phase retrieval as follows (Figure 6):

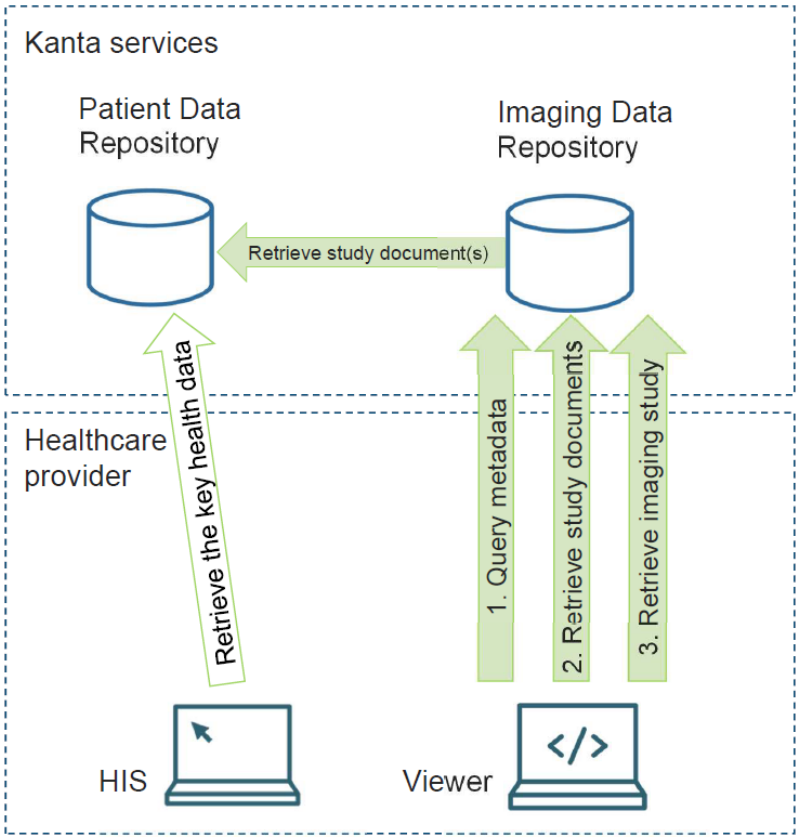

Figure 6. Querying and retrieving documents in the imaging study entity

A XDS metadata query, ITI-18, is carried out with the viewer at first. As a criterion for the query the patient's personal identity code must be provided and in addition e.g. timeframe, study code or a part of it can be provided. Search parameters are described more detailed in chapter 4.7. The query is sent to the Imaging Data Repository. The consent management carries out all possible exclusions on the basis of consent data and consent restrictions based on the documents stored by the patient in the Patient Data Management service. In the result set of the query, the metadata of the imaging studies and CDA R2 documents permitted by the consent management is returned.

The Patient Data Repository has registered the CDA documents in the Imaging Data Repository and their metadata were included in the result set of the metadata search. The documents can be retrieved with the ITI-43 (Retrieve Document Set) transaction or the HL7 V3 interface of the Patient Data Repository.

The metadata query steps are described in the following sequence diagram (Figure 7):

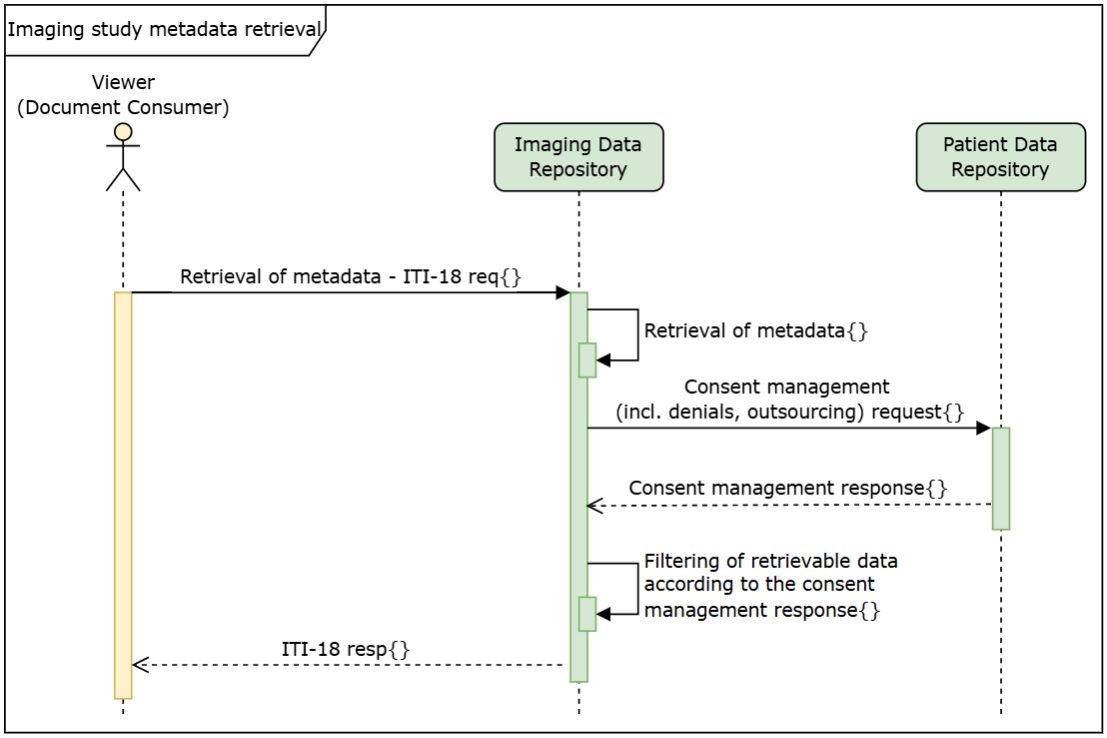

Figure 7. Retrieval of imaging study metadata

After the metadata result set has been returned, a search for the manifest of the imaging study is carried out with Retrieve Document set transaction, ITI-43. Based on the homeCommunityId and the repositoryUniqueId returned from the metadata query, the search is directed to the correct repository of the Imaging Data Repository and the Patient Data Repository. The manifest includes the 'location data' and object references of the study. The manifest also contains other information, such as the patient's identification number. However, metadata related to the patient should always be retrieved from the metadata returned from the Imaging Data Repository for the user's view.

Above steps are described in the sequence diagram below (Figure 8):

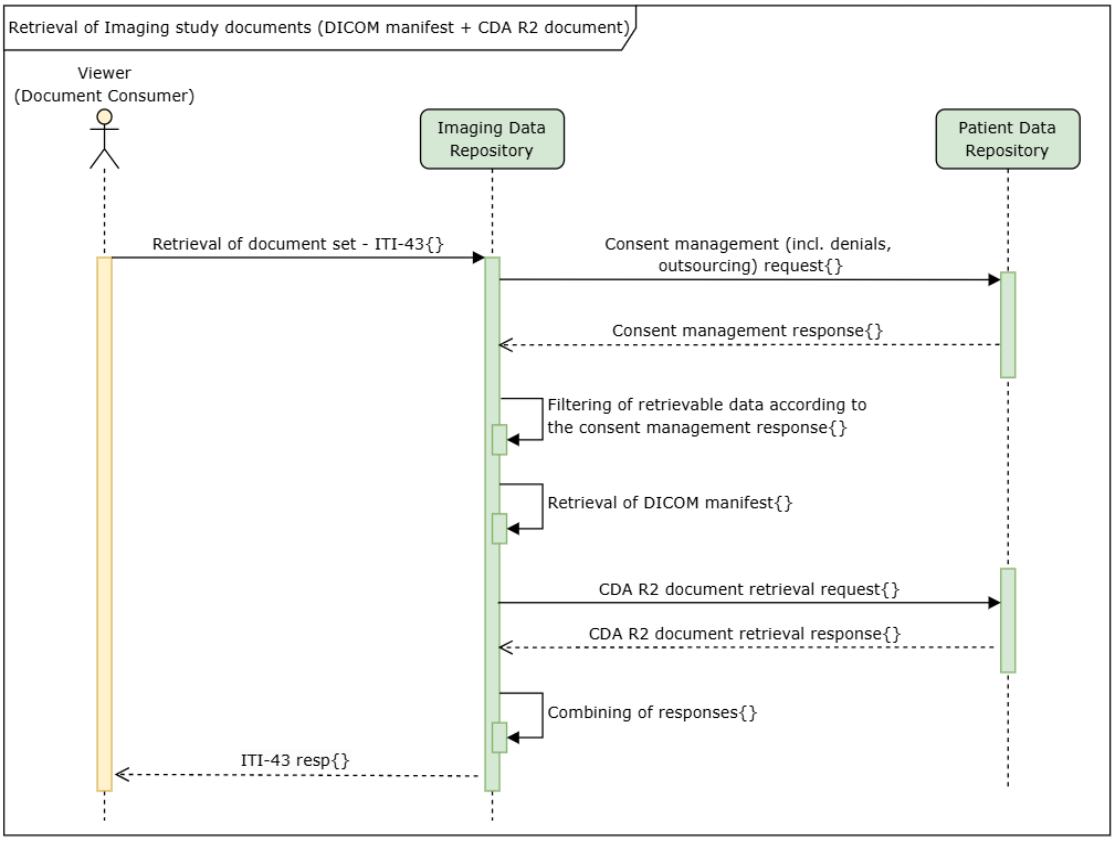

Figure 8. Retrieval of imaging study documents (DICOM manifest + CDA R2 documents)

The actual imaging study or its objects are retrieved to the viewer with the Retrieve Imaging Document Set transaction, RAD-69. The manifest of the imaging study includes the location data and object reference data required in the retrieval. Operation is described in the following sequence diagram (Figure 9):

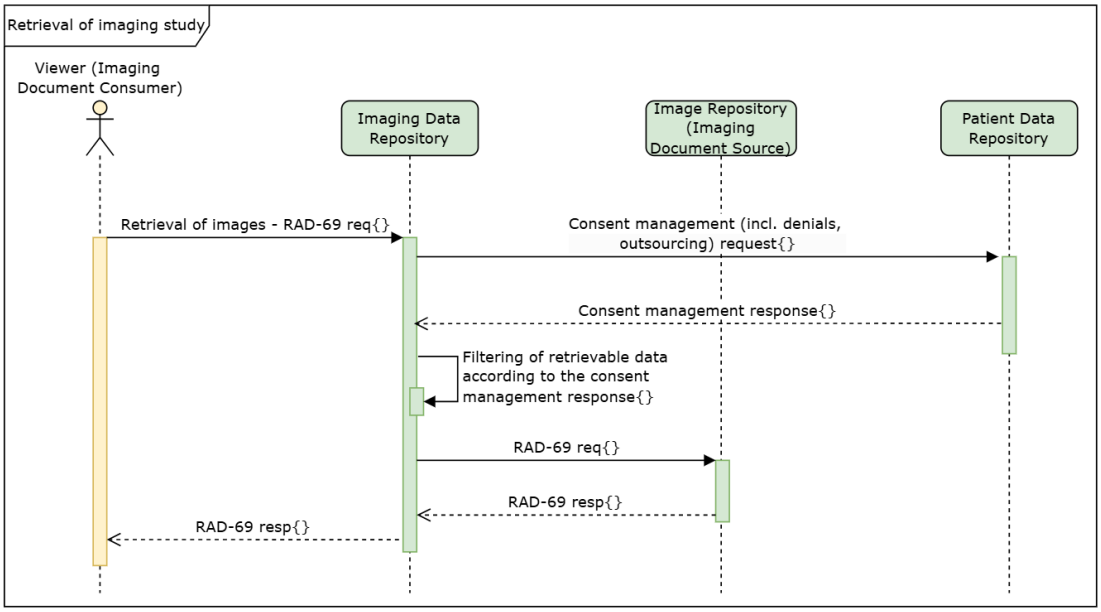

Figure 9. Retrieval of the imaging study (Images & KOS objects)

In addition, the Imaging Data Repository supports the search of own studies with a stored reference (see chapter 4.8). In such a case, it is possible to send a direct RAD-16 (DICOM C-MOVE) request, without using XDS interfaces, to the DICOM repository which sends the study to the PACS system using a DICOM C-STORE command.

The user can utilise imaging studies stored in the Imaging Data Repository also from the key health data of imaging in the Patient Data Summary service or the imaging study documents stored in the Patient Data Repository. The study documents include the metadata (for example, the encounter id, service provider and service unit data, time qualifiers) and the actual contents of the document (for example, SUID identifier, i.e. Study Instance UID, and the imaging study code), which may be used as metadata search results limitation criteria. Opening a specific imaging study in the viewer takes place in the same 3-phase search as described above.

4.1.3 Ensuring the storing of the studies

To ensure whether the study is stored in the Imaging Data Repository there are different options that deviate from one another in terms of transferring the responsibility of storing the study. The DICOM Storage commitment is mandatory since it is the only way to transfer the responsibility of storing the study for Kela.

- DICOM Storage Commitment
    - Storage commitment ensures technically that the study is stored and it can be read back into the client PACS system. The responsibility of storing the study is transfered to Kela with the succesful storage commitment.
    - If the Storage Commitment request returns a successful response, the Imaging Data Repository has approved and stored the study, in which case the study is also compatible with XDS registration. Registration is not ensured.
    - However, if registration fails and the client has received confirmation of storing with Storage Commitment, it is a question of error situation in the Imaging Data Repository and Kela is responsible for clearing the error.
    - Storage commitment has to be sent always after storing the imaging study including IOCM KOS objects.
    - Storage commitment is queued and efforts are made to send it to the client system for 24 hours.
- DICOM Instance Availability Notification – IAN
    - If the Imaging Data Repository sends information about the storing of the study with an IAN notification, the study is also registered successfully.
    - IAN does not ensure technically that the study can be read back into the customer's PACS system so transferring the responsibility of storing is not possible.
    - Imaging Data Repository will send IAN notification to supported systems after registering the DICOM study. The sending of the IAN notification is queued and efforts are made to send it to the client system for 24 hours.
- Utilisation of XDS interfaces when ensuring the storing of studies in the Imaging Data Repository

- Similar to IAN: using XDS interface only does not transfer the responsibility of storing the study for Kela.

The operation of DICOM Storage Commitment is described as sequence diagram in below (Figure 10):

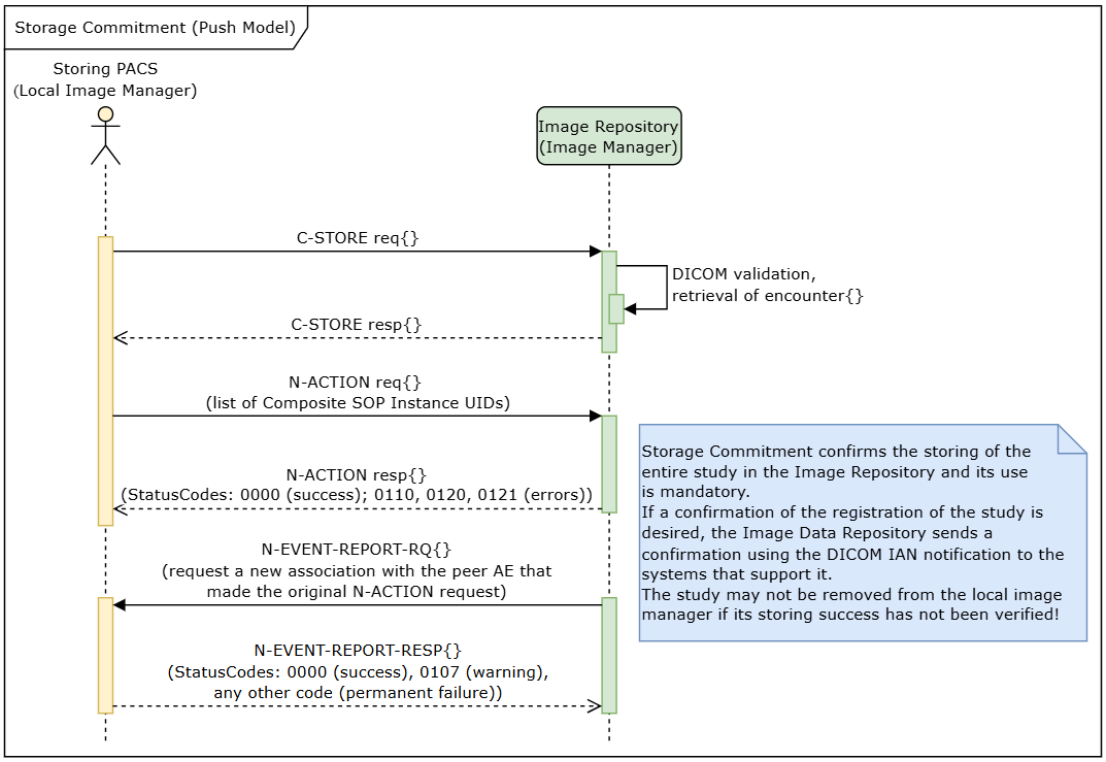

Figure 10. DICOM Storage Commitment usage in the Imaging Data Repository

4.1.4 Time values (UTC) in the Imaging Data Repository

According to the IHE specifications [4] all date time values of XDS metadata in the Imaging Data Repository are stored using Coordinated Universal Time [UTC]: *"UTC" implies that time shall be converted from/to the local time*". This involves the metadata of DICOM and CDA R2 documents that are registered in the Imaging Data Repository. UTC time is also used in XDS transactions and the Document Consumer is responsible for the conversion to the local time when presenting the data to the user.

The Imaging Data Repository supports the DICOM tag Timezone Offset From UTC (0008,0201). If time zone is given in this tag, time values of the manifest will be converted accordingly to the XDS metadata when registering the manifest. If the tag (0008,0201) is not

given or it is empty, the Imaging Data Repository will convert XDS metadata of the manifest according to the Finnish time zone when registering the manifest. Conversion will always take daylight saving time into account.

DICOM studies are always stored to the Imaging Data Repository as is which means that no time value conversions are made to DICOM tags – only to the XDS metadata of the manifest (e.g. serviceStartTime).

Concerning CDA R2 documents, the Patient Data Repository does not currently support time zones. The Imaging Data Repository will however convert time values to UTC when CDA R2 document is registered in the Imaging Data Repository. Conversion will be done according to the Finnish time zone taking daylight saving time into account. The Imaging Data Repository has however support for time zones for future use if the Patient Data Repository start utilizing time zones.

4.1.5 Management of the offline status in the Imaging Data Repository

If the CDA document containing imaging entries is nullified in the Patient Data Repository, the Imaging Data Repository utilizes the DocumentEntry.documentAvailability metadata's offline value with the manifest that was referenced by Study Instance UID from the CDA document. Such cases can be e.g. a wrong encounter id in the CDA. The manifest's documentAvailability metadata is set to offline but availabilityStatus metadata remains 'Approved'. The metadata of the manifest will then not be returned in metadata queries (request MetaDataLevel is '1' by default).

However if the CDA document is corrected and stored again with correct data and the same Study Instance UID, the manifest will be set to 'Online' again and its metadata is updated with correct information e.g. correct encounter id.

4.1.6 Technical solution and implementation

Implementation of the Imaging Data Repository is presented in the following figure (Figure 11), which contains the functional subsystems, as well as the most relevant healthcare organisation systems and Kanta subsystems in terms of the Imaging Data Repository. The most important direct connections between the subsystems are presented in the figure without technical details. The latter chapters of the specification provide a more extensive and detailed description.

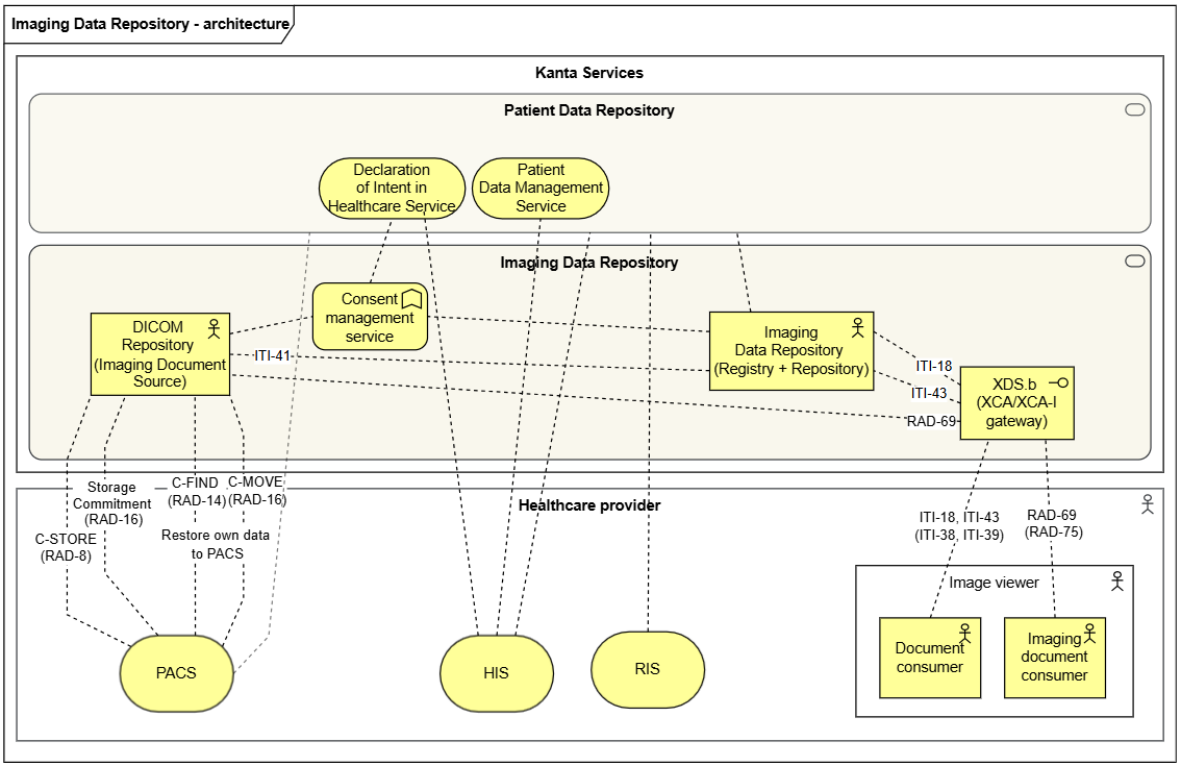

Figure 11. Technical architecture with IHE and Kanta concepts

Subsystems, services and components related to the architecture of the Imaging Data Repository:

- Consent management service
    - Carries out a consent management check when the Imaging Data Repository returns patient data
- Kanta Declaration of Intent in Healthcare Service
    - Source of consent documents (Kanta informing, consent, consent restricitions) for the Imaging Data Repository
- Kanta Patient Data Management Service
    - The aggregator and the source of patient's key health data (including imaging data) for those utilising the imaging study entity.
- Patient Data Repository
    - Source of encounter information for the Imaging Data Repository
    - Repository of imaging study documents
- HIS – a hospital information system, that

  - establishes the encounter required by the Imaging Data Repository
  - retrieves studies from the Patient Data Repository
- RIS – a radiology information system, that
  - plays a key part in the imaging workflow
  - is used to record and store imaging study document entries
- PACS – a picture archiving and communication system, that
  - stores imaging studies to the Image Repository of the Imaging Data Repository
  - a healthcare provider may have one or several PACS systems
- Image Repository (IHE: Imaging Document Source)
  - Repository for imaging studies in DICOM format
- Imaging Data Repository (IHE: Registry, Repository)
  - Repository for the metadata of manifests and CDA R2 documents
  - Repostory for the manifests of imaging studies
- XDS.b interface
  - XDS interface for users of the Imaging Data Repository
  - XCA / XCA-I gateway
- Viewer (IHE: Document consumer)
- Image viewer (IHE: Imaging Document Consumer)

4.2 Management of encounters with the Patient Data Repository

The Imaging Data Repository complies with the Patient Data Repository principle that it is not possible to store patient care documents for an encounter until the encounter document has been stored and the encounter has been established. Therefore, when the imaging study is stored the Imaging Data Repository verifies the existence of the encounter document from the Patient Data Repository.

In normal situations, it is permitted to carry out storing only with respect to the service provider's (=custodian's) own encounter. Outsourcing scenarios are described in chapter 4.3. The encounter identifier is unique for the stored imaging study, i.e. the study can be subject to one encounter only.

4.2.1 Technical solution and implementation

The encounter check is carried out by the DICOM repository of the Imaging Data Repository. It is assumed that the DICOM repository has already carried out the check and the check will not be carried out again when the manifest is stored and registered. The Patient Data Repository performs a encounter check always when storing CDA documents, and a check is not needed in registration of CDA document's metadata.

The Imaging Data Repository searches the information about the existence of a encounter with a Study Instance UID from the Patient Data Repository [5].

The DICOM has no standardised way to notify of storing that has been prevented due to an unknown encounter (an encounter missing from the Patient Data Repository). The mechanism for the failed storing due to an encounter error has been specified to be returned as a custom Cxxx DICOM error code. The PACS handles the error situation on the basis of the return values specified by the Imaging Data Repository. The custom DICOM error codes and recovery guidelines are provided in appendix 1.

4.3 Outsourced services

Outsourced services enable the storing of imaging studies and imaging CDA documents in the imaging study entity also when users and systems of several custodians take part in the workflow. The Imaging Data Repository supports outsourcing in accordance with the principle of the Kanta specifications. In this context, outsourcing refers to the production of encounters, studies or their parts by someone else than the service organizer responsible for the service. The technical implementation of outsourced services can be built in three ways (methods) in the interface of the Kanta and the Imaging Data Repository.

1) Outsourcing authorisation gives the service provider the privileges to search and/or store documents in accordance with the general rules on outsourcing authorisations (patient-specific or registry-specific outsourcing).

2) In permanent outsourcing scenarios (for example, regional imaging or laboratory organisation), documents may be stored in the organizer's register without storing the authorisation of the outsourced service. In such a case, the imaging study is stored directly under the organizer's name and the Kanta addressing service has specified that the service provider is allowed to use the organizer's connection point. In this model, operations are treated as if they were carried out by the organisation itself and the

organisation providing the imaging service is treated as if it were part of the organizer of the service. This option may no longer be used in new solutions for outsourcing situations, old previously agreed permanent solutions for outsourcing are still supported [6]. Permanent outsourcing scenarios can also be implemented according to 1st method.

3) A DICOM study is stored in another party's registry in accordance with the encounter in the Patient Data Repository, the custodian and registry information is not transferred in DICOM messaging. The right to store in the registry of the organizer of the outsourced service has been verified when the encounter and imaging documents are stored in the Patient Data Repository prior to DICOM storing.

Contents are stored into the Imaging Data Repository by different parties (the service organizer, i.e. the subscriber, or the service provider) depending on whether an outsourced service the entire encounter, the study in its entirety or only the report is produced. It is common in these situations that the storing of the encounter is required before the study documents are stored.

When an entire imaging study entity is produced as an outsourced service, the operating model described in the specifications of the Patient Data Repository shall be complied with, where also the encounter is established by the provider in the organizer's registry. After the study has been completed, the outsourced service provider stores the completed imaging study and the related imaging CDA documents for the encounter it has established in the organizer's registry. The organizer may also store the encounter to its own register and pass it on to the outsourced service provider.

When a whole study is produced as an outsourced service, the organizer of the outsourced service stores the CDA document containing the referral in the Patient Data Repository under the encounter it has established. The outsourced service provider retrieves the document or obtains the information on referral from elsewhere, and carries out the imaging study. After the study has been completed, the outsourced service provider stores the completed imaging study and the related imaging CDA documents in the organizer's registry for the encounter established by the organizer.

When the report is produced as an outsourced service, the organizer of the outsourced service shall store the imaging study in the Imaging Data Repository under the encounter it has established and the imaging CDA documents, including the referral and study entries, in the Patient Data Repository. The outsourced service provider retrieves the stored documents

and imaging study with any reference images, and produces the report. The report is stored in the imaging CDA document in accordance with the CDA definitions, and it is stored in the Patient Data Repository under the organizer's encounter and the organizer's registry.

In implementation of the 1st method, the outsourcing authorisation gives the service provider the right to use (store or view) patient information (documents) in organizer's register. With the viewing right of the outsourced service authorization, the service provider can, for example, use information from the organizer's register that is necessary to carry out the study regardless of consents or consent restrictions set by the patient. The right is taken into account in connection with the outsourced service and consent management checks in the Imaging Data Repository. The outsourcing authorisation whose validity has expired can be used in the retrieval situation to verify the treatment relationship, but in this case the result set follows the principles of the consent management and consent and consent restrictions given by the patient are taken into account.

4.3.1 Technical solution and implementation

The outsourcing authorisation document (form CDA R2) stored in the Patient Data Repository is required in outsourced service method 1 in order to deduct the storing right. DICOM studies stored in the Image Repository are allocated to the encounter in accordance with outsourced service 3rd method with the encounter id and study Instance UID.

When using the outsourced service authorisation, the sender of the service request shall not include a reference to the authorisation, but the Patient Data Repository or the Imaging Data Repository subsystem that provides the service will verify the authorisation if the sender of the message otherwise does not have a right to carry out the operation. In the query situation, the organisation data is produced in SAML attributes, which are described in chapter 7.2 of this specification document.

The message frames will include the organizer's information even if the sender is the service provider in the service request messages to the Patient Data Repository when using a permanent addressing connection (method 2). This operating model requires an agreement between the organizer and the provider, and the Imaging Data Repository access control does not interpret the situation as an outsourced service. In an outsourced service of 3rd method, the Study Instance UID obtained from the DICOM traffic will connect the recording to the encounter in the Patient Data Repository, and on the basis of the technical verification of its connection the DICOM study can also be stored as an outsourced service.

4.4 Storing of incomplete documents for reporting or patient transfers

An ‘incomplete’ imaging study can be stored in the Imaging Data Repository as soon as the required encounter document and the study document containing the Study Instance UID reference have been stored in the Patient Data Repository. However, from the viewpoint of the architecture of the Imaging Data Repository, a study is never actually incomplete, but it can be versioned by supplementing the imaging study entity and by implementing change management methods. An imaging study produced by an aborted or failed examination must not be stored.

A PACS must send updates of the imaging study, i.e. added or altered objects, to the DICOM repository whenever they have been stored in the PACS. Storing as quick as possible is important especially to enable patient transfers and outsourced reporting of the study.

Completing an incomplete imaging study is manifested so that the entity of imaging documents includes all entries related to the study, including any reports. This deduction is left to be carried out by the person utilising the imaging study. It is not possible to deduct in a reliable way in all situations because stored documents do not show, for example, a missing requested additional report or a detected remedial need, and no report is supplied on all studies.

An imaging study that has been completed at a later date may have been shared from the DICOM repository as incomplete to another healthcare unit. Those who have retrieved an imaging study on a previous occasion will not be informed of the completion of an imaging study. This operating model corresponds to the Kanta and the Patient Data Repository in general. This kind of sharing of a previous version can be seen, e.g. in the logs, and the contents of the shared study can be found out from the timestamps of DICOM objects in the latest imaging study version. Logs and a more detailed analysis of the study are used only in exceptional cases in separate studies.

4.5 Management of changes in imaging studies

As a rule, an imaging study may only be updated or corrected in the encounter that is responsible for producing it. The correction procedure of a study stored to the Imaging Data Repository requires more effort than a study that has been stored in the PACS only. Therefore the imaging studies produced by the imaging workflow must be checked before they are stored in the Imaging Data Repository to reduce the subsequent need for corrections and changes. In addition, the corrected study will not be automatically shared

with the organisations that have already retrieved the incorrect version of the study, but it requires a separate query.

There may be multiple copies or references of the same imaging studies in different systems (healthcare provider's PACS, the Image repository of the Kanta Imaging Data Repository). When the changes are made to studies, it is important that corrections and changes at a later date are also propagated in the Imaging Data Repository. As a result of the changes to the imaging study, it will be necessary to update also the manifest document (in the form of a KOS element in accordance with the DICOM standard). A new version of the manifest, which replaces the previous version, will be stored and registered in the Imaging Data Repository.

Changes in the study can be divided into the following cases:

- New objects are added to the study
- The study is corrected
- Objects are removed from the study
- Invalidation of the study
- Changes are made to imaging CDA documents
    - Changes made to the imaging CDA documents are handled in the same way as other changes made in the Patient Data Repository by storing a new version of the documents. This is not described in further detail in this document.

4.5.1 New objects are added to the study

In the life cycle of an imaging study, new study objects may be stored in it, and these will be taken into account in accordance with the DICOM specifications when the new objects of the edited study are sent for storing. The Imaging Data Repository forms the new version of the manifest of the imaging study and registers the new version of the metadata of the manifest.

4.5.2 The study is corrected

Changing the metadata of stored imaging studies (DICOM tag) is necessary in connection with corrections. The corrections must be made before storing the study to the Imaging Data Repository.When the study is stored, the original data source is responsible for the fact that

all corrections are always also sent to the Imaging Data Repository. Otherwise the patient data is not consistent between the operative system and the Imaging Data Repository.

The IHE specifications do not take a stand on the need for changing the study metadata (DICOM tag) or the change mechanisms. The Imaging Data Repository requires that changes to metadata are forwarded to the Image Repository of the Imaging Data Repository. The recommended and safe way to forward corrections is to store the IOCM KOS object and restore the corrected imaging study. This method is described in the following chapters. The Imaging Data Repository also enables resending of the corrected study to be stored with the same identification data of the study, when it is a correction to the DICOM tag metadata of the study.

The Image repository takes care of the registration of the study in the Imaging Data Repository by storing the new version of the manifest with the altered metadata values, technically in the same way as when storing additional objects for the imaging study in the Image repository (chapter 4.5.1).

4.5.3 Objects are removed from the study

IHE specifications are based on the principle that all changes made in the study will remain part of the study in both the imaging system (PACS) and the vendor neutral archive (VNA). The changes that should cause the deletion of the objects form their own KOS object (change element) in accordance with the DICOM standard, which the IHE actors interpret and hide/show/share the objects that are not relevant in the current setting, for example, in a viewing situation. Allowed change element types are

- 113001, "Rejected for Quality Reasons",
- 113037, "Rejected for Patient Safety Reasons" and
- 113038, "Incorrect Modality Worklist Entry".

An object is thus added to the study in a change event to signify the invalid parts of the study. The change element is a new object that may be transmitted from the PACS to the DICOM repository in a similar fashion as any addition of a new object would be in the case of an externalised repository in accordance with the DICOM standard. The Imaging Data Repository is responsible for interpreting and taking care of the registration of the change.

4.5.4 Invalidation of the study

Invalidation of the imaging study from the Imaging Data Repository is done by storing change elements to the study (see chapter 4.5.3). The Imaging study is invalidated when all the object of the study are removed with change element objects.

The correct order must be followed in invalidation in order to preserve the integrity between the Imaging Data Repository and the Patient Data Repository:

1. Changes in the imaging study are stored in the Imaging Data Repository and storing is ensured according chapter 4.1.3.
2. CDA documents related to the study are invalidated and
3. possibly the encounter document is invalidated.

4.5.5 Technical solution and implementation

The IOCM profile of IHE describes how to correct various errors in imaging studies, how the corrections are changed and distributed and how the corrections are expressed as DICOM objects in the imaging study [7]. The Imaging Data Repository requires that the corrections and the storing of corrected contents comply with IOCM. The imaging document source of the Imaging Data Repository limits the objects returned in queries in accordance with IOCM. IOCM does not specify the versioning of the corrected study in the XDS-I repository. Versioning takes place according to the normal versioning principles. The Imaging Data Repository does not create new IDs to corrected studies, but it is the responsibility of the client.

Change information is stored as part of the imaging study in KOS elements in accordance with the DICOM standard, and these elements are named and typed according to the change scenario. PACS stores the change object in the DICOM repository in accordance with the RAD-66 transaction with a C-STORE command. The DICOM repository (Imaging document source) creates a new version of the manifest document after the correction objects are stored, and registers its metadata in the Imaging Data Repository. This action is

in accordance with the IOCM profile extension that is in trial implementation stage [7]. The basic principle of change management is described in the sequence diagram below:

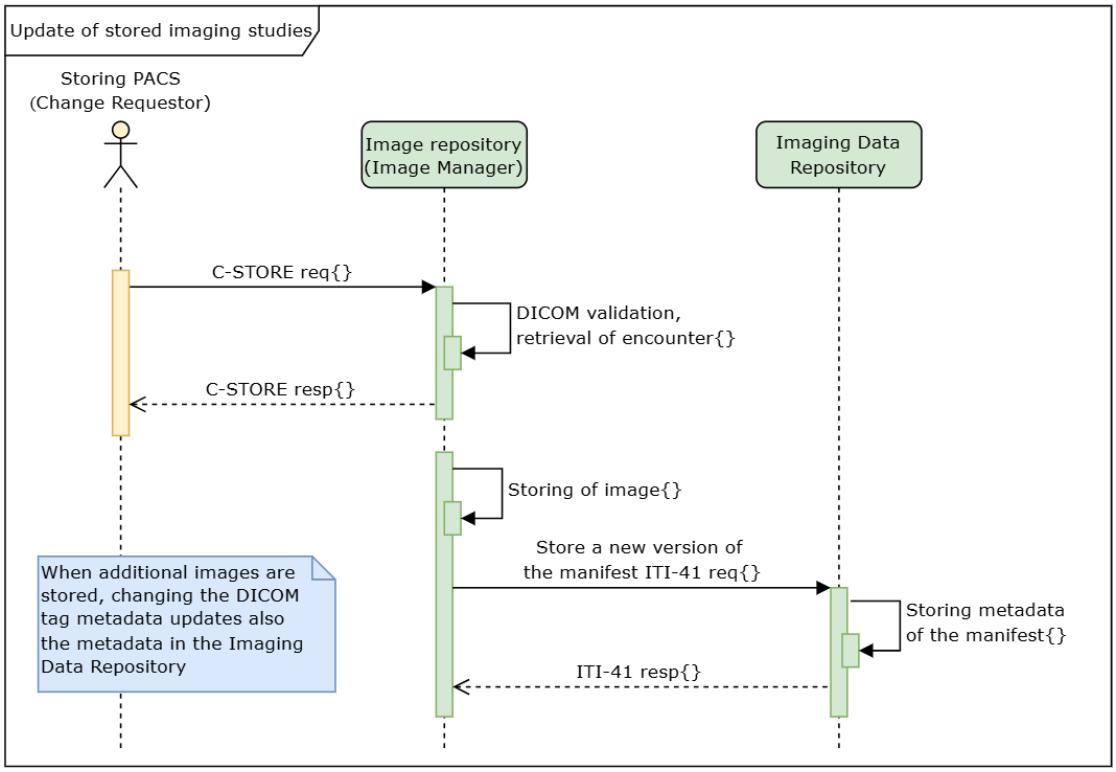

Figure 12. Change management in imaging study

As a result of the IHE specifications, necessary KOS element types have been added to the DICOM specifications: “Rejected for Quality Reasons”, “Rejected for Patient Safety Reasons”, “Incorrect Modality Worklist Entry” and “Data Retention Policy Expired”.

The IHE profile also specifies how the repository must limit the removed objects when the imaging study is returned and how the system that retrieved the study shall show the study.

CDA documents related to the imaging study and stored in the Patient Data Repository are corrected and supplemented in accordance with the specifications of the Patient Data Repository. The Patient Data Repository registers the new version of CDA document in the Imaging Data Repository. As an example, updating the encounter ID is described below:

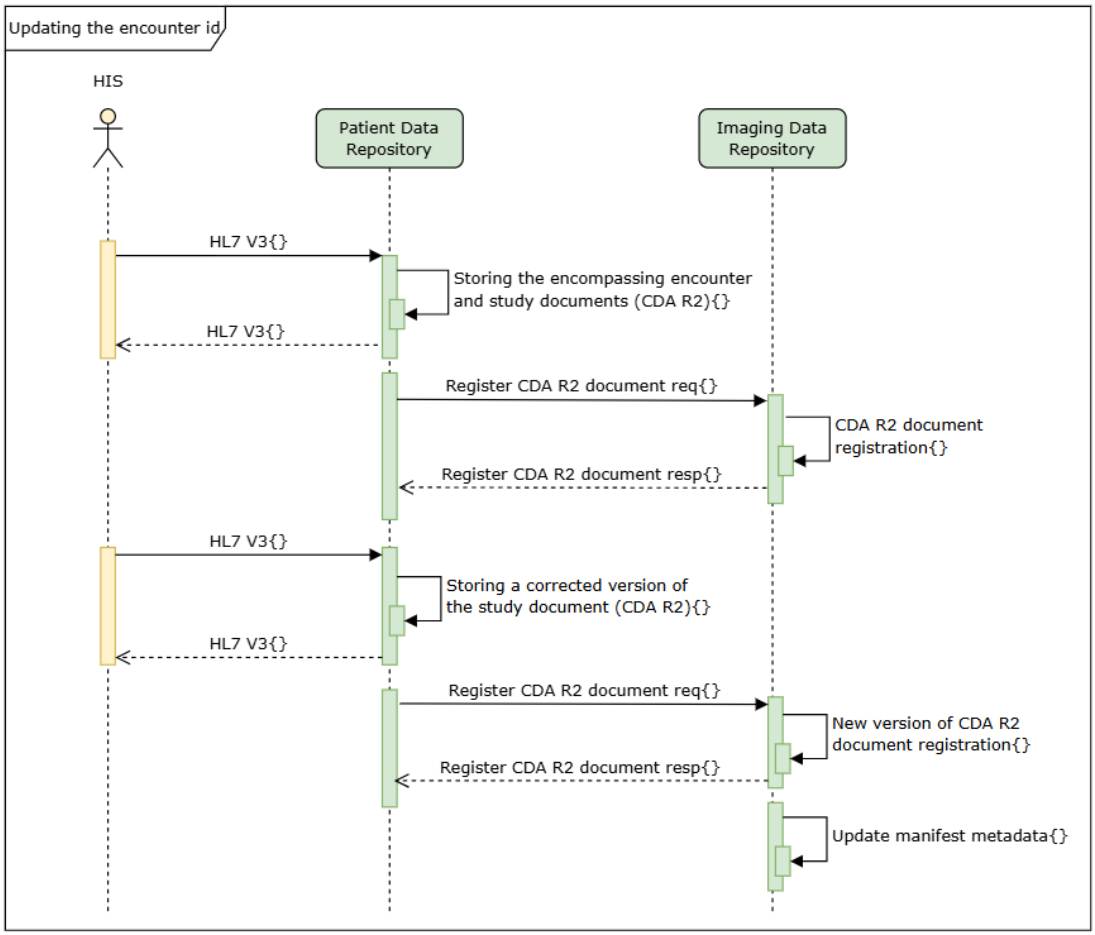

Figure 13. Change management of the encounter Id through the Patient Data Repository

The changes limiting the study contents of an imaging study as well as corrections are divided into the following change types, in which the interpretation of the change element, e.g. in a viewing situation differs from one another:

1. Marking of images as removed for quality reasons (“Rejected for Quality Reasons”)
    a. Images marked as removed are not returned to the person requesting the study in a query situation unless the queries are made especially for this reason to a specific AE Title that is configured for the subscriber for this purpose ([8], Chapter 4.66.4.1.3.1).
2. Marking of images/series as removed for patient safety reasons (“Rejected for Patient Safety Reasons”)
    a. Objects marked as removed are not returned to the person requesting the study in a query situation.

b. Any replacement objects are stored as part of the study (new series and image level IDs are created)

3. A wrong study has been carried out on a patient (“Incorrect Modality Worklist Entry”)
   a. Images marked as removed are not returned to the person requesting the study in a query situation.
   b. Any replacement images are stored as part of the study (new series and image level IDs are created)
4. Study object/s has/have been removed due to the termination of storage time. (“Data Retention Policy Expired”)

   Clients of the Imaging Data Repository are not allowed to send KOS objects of this type to the Imaging Data Repository since the data retention periods are maintained and controlled by the Imaging Data Repository only.

   a. Objects marked as removed and the KOS object used for their imaging are deleted from the study. (However, according to current IHE specifications, this will not remove the entire study, only the out-of-date objects).
   b. Handing related to the storage time and deletion of imaging documents is described in section 4.14 Retention control and deletion.

The following sequence diagrams describe typical change management situations in the Imaging Data Repository:

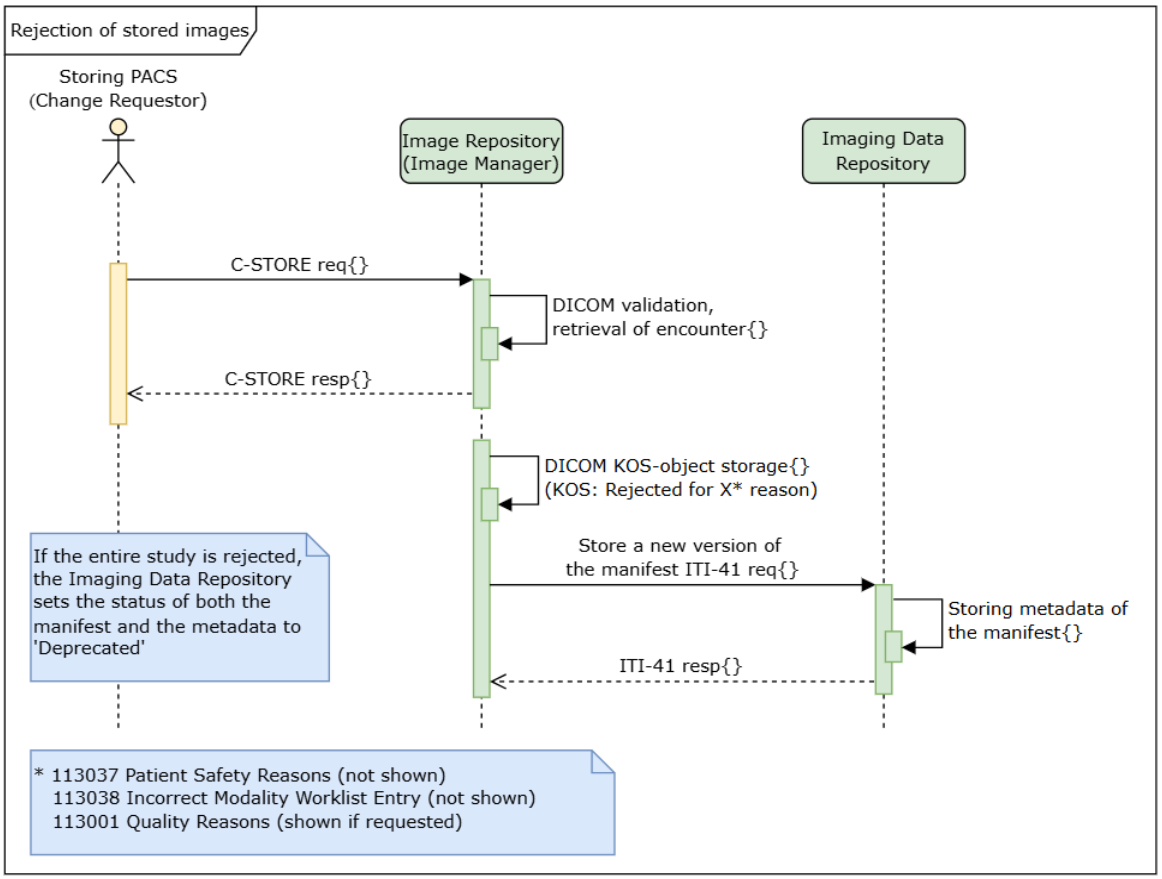

Figure 14. Rejection of stored images

4.6 Marking of the most valuable objects

The Imaging Data Repository enables the so-called tagging key images for an imaging study. References of the most valuable objects in terms of the use of the imaging study are stored in the study as KOS objects (key object selection). The selection and storage are normally carried out by the radiologist or other expert interpreting the study. The KOS types in accordance with the DICOM CID 7010 Key Object Selection Document Title are used as follows:

Code	Definition	Purpose of use
113000	Of Interest	Significant objects
113002	For Referring Provider	

113003	For Surgery	
113006	For Therapy	
113007	For Patient	
113008	For Peer Review	Objects that are significant in terms of a second opinion reques
113013	Best In Set	Best objects in terms of their technical quality entered by the person carrying out the study
113020	For Report Attachment	Objects that are the basis for a report or that are referred to

4.7 Description of search functions and use of search criteria

The search for imaging studies takes place in accordance with the IHE specifications in a three-phase process on the XDS interface. At first, the metadata of the studies is searched, and then the documents to be retrieved are selected from the search result, as well as the actual imaging studies. XUA validation and consent management checks of the message are performed in connection with XDS interface queries. These operations are described in chapter 7 and appendix 2.

4.7.1 Retrieving metadata

The metadata search from the Imaging Data Repository takes place via the XDS interface with ITI-18 (Registry Stored Query) or ITI-38 (Cross Gateway Query) query. Supported query types for metadata queries from the Imaging Data Repository are:

- findDocuments (urn:uuid:14d4debf-8f97-4251-9a74-a90016b0af0d),
- findDocumentsByReferenceId (urn:uuid:12941a89-e02e-4be5-967c-ce4bfc8fe492),
- getDocuments (urn:uuid:5c4f972b-d56b-40ac-a5fc-c8ca9b40b9d4) and
- getAll (urn:uuid:10b545ea-725c-446d-9b95-8aeb444eddf3).

All queries are patient-specific i.e. the patient's id is a mandatory search factor (excluding the getDocuments query). The search factors and mandatories to each query message type are in accordance with the IHE definition [9]. The query criteria which is possible to use has also been described in further detail for each metadata in connection with the metadata model

(chapter 8). The technical query mechanisms are described in further detail in chapter 4.1.2 of this specification.

In a metadata query, clinical query criteria of query types findDocuments and findDocumentsByReferenceId include PracticeSettingCode, HealthcareFacilityTypeCode and EventCodeList metadata, of which the latter is multivalued in the document and may include coded values (see chapter 8). EventCodeList allows for multiple coded values to be included in the metadata, of which some are XDS-I -specific and others may be used as the Affinity domain sees fit. The codes can be used as a search criteria together and separately, which enables searches with coarser or finer search limits.

ID values like the Study Instance UID, the AC number, the referral ID and the encounter ID are available as a query criterion of findDocumentsByReferenceId query type. If a study entry obtained from the Patient Data Management Service or a study document retrieved from the Patient Data Repository is in use, the encounter ID and the Study Instance UID can also be used as search criteria of the metadata query.

IHE specification does not allow for the extra metadata attributes to be used as query criteria, the metadata is just returned in the query results. The metadata query results in a list (LeafClass) of documentEntry metadata or the references (ObjectRef) to the objects. In the search result, only metadata for which consent mangement permission is granted is returned.

4.7.2 Retrieving documents

Based on the metadata query result, the query performer chooses the relevant documents to retrieve. The selected document, the manifest of the imaging study or the CDA document is retrieved with the document query ITI-43 (Retrieve Document Set) or ITI-39 (Cross Gateway Retrieve). The search factors and mandatories of the query are in accordance with the IHE definition [9].

As a result of the search, the requested document is returned, if the consent management does not limit the result set. Querying application will show the returned document to the user according to its implementation.

4.7.3 Retrieving the imaging study

The DICOM objects of the study can be retrieved with XDS-I mechanisms using the reference data of the manifest returned in the document query with RAD-69 (Retrieve Imaging Document Set) or RAD-75 (Cross Gateway Retrieve Imaging Document Set) query. The search factors and mandatories of the query are in accordance with the IHE definition [9].

To ensure user experience and performance, it is recommended that

- all the transfer syntacies supported by the viewer are used in RAD-69 request to prevent unnecessary and time consuming conversions,
- Imaging Document Consumer prevents repeating the same query at the same time the execution of the previous one is in progress and
- large imaging studies are technically not requested for in one search.

The number of parallel searches targeting the same study should be configurable, if of the Imaging Data Repository provides instructions for this later.

4.7.4 Especially protected information

According to the Kanta specifications, certain views (psychiatry and clinical genetics) constitute especially protected information. Information about the special protection of the view can be found in the national code service (kansallinen koodistopalvelu). The view data is stored in the metadata of the imaging CDA documents in addition to the entry itself. The Ministry of Social Affairs and Health may prescribe by a decree in further detail regarding which client documents shall be classified as especially protected information. The metadata of the Imaging Data Repository does not directly show whether or not a document registered in the Imaging Data Repository contains especially protected information. The client system is responsible for deducting this with the aid of the view title of the imaging document.

An Imaging Document Consumer must use the view data obtained from the CDA documents also when deducting the especially protected information of an imaging study. The standard view 'RTG' without additional views is registered in the metadata of the manifest of the imaging study, and therefore the imaging study itself cannot be handled as especially protected without separate operations.

4.7.5 Technical solution and implementation

The implementation of the Imaging Data Repository has some special features related to the search functions of the XDS interface, which must be taken into account in the implementation of the related system.

Only part of the query types for metadata query are supported in the Imaging Data Repository (see chapter 4.7.1). In addition, wildcards are not supported at all in query parameter values.

In the Imaging Data Repository, the $MetadataLevel parameter value 1 according to IHE XDS Metadata Update [10] is supported, so that only the latest (Approved) and available (Online) documentEntries are returned as a result of the metadata query.

The IHE specification recommends the use of only the query that returns the object references (ObjectRef) if the result set may be large. However, it is not possible to further limit the query with object references on the basis of data contents, but only to reduce the metadata queries into smaller units. It is possible to limit the result set of a metadata query in advance with specified query criteria, but further instructions will be issued separately if the expanding result sets will cause problems at some stage. It is possible to set a maximum value for the number of search results in the Imaging Data Repository. When the size of the result set exceeds the set value, an error code is returned, along with an instruction to limit the query with search criteria. So far, the size of the result set is not technically limited, but it is recommended to limit the result set of the metadata with search criteria. Large imaging studies are recommended to be searched with several separate technical image object searches.

4.8 Technical retrieval of own studies

PACS system keeps the imaging studies for a certain period of time (e.g. for three years) in the local active storage. All study material is stored in the DICOM repository for long-term archiving where they are available within the scope of the retention period. Studies that are older than a certain period (e.g. three years) are removed from the active PACS, but a reference pointing to the DICOM repository of the Imaging Data Repository may remain in the PACS system database.

Imaging data systems usually store references that enable, for example, re-retrieval of a study copy that has been stored or removed from the system without using XDS-I and XCA-I

mechanisms of the Imaging Data Repository. Due to the implementation method complying with XDS-I, the DICOM-connection between the PACS and the DICOM repository has been configured for storing purposes, which means that the connection is technically available for retrieving studies. The Imaging Data Repository is unable to prevent this method of use, but healthcare organisations must ensure the manageability of the usage and the legal aspects for it. When a PACS queries only own images located in the DICOM repository, the PACS system will retrieve the imaging study from the DICOM repository using direct DICOM C-MOVE transfer [RAD-16] from the Imaging Document Source (the DICOM repository).

Retrieval of own studies is described in the sequence diagram below (Figure 15):

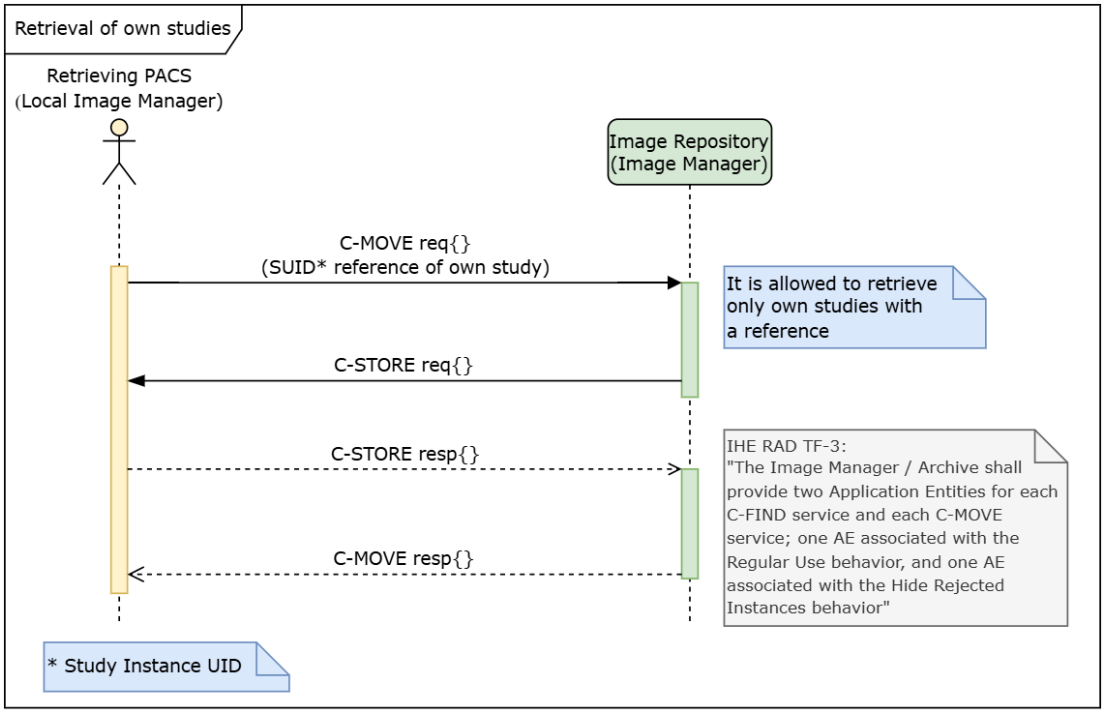

Figure 15. Technical retrieval of own studies with a retained reference

The consent management of the Imaging Data Repository cannot be attached to a query made with DICOM operations. Healthcare organisations need to operate with stored references in a way that only own studies are retrieved and to take care of the consent management verifications and the formation and storing of the sharing document on sharing taking place between custodians within the same domain. Ultimately, queries made by a client organisation can be established from the Imaging Data Repository logs.

4.9 Searching for and utilizing comparison images

The Imaging Data Repository enables sharing of comparison images and other imaging documents across regional boundaries. When searching for comparison images, follow the basic model described in chapter 4.1.2 for searching for studies from the Imaging Data Repository.

The key data on imaging in the Patient Data Management Service include the entries of all imaging CDA documents stored in the Patient Data Repository, and this can be a starting point for utilising the comparison images. From the comparison studies found, more detailed search criteria can be extracted for searching studies from the Imaging Data Repository.

The search for imaging studies can be limited, e.g. on the basis of modality, anatomic region and the required time frame. As a result of the query, the user will see the metadata of the studies in different areas matching the search. On the basis of the result a document query of selected studies can be carried out.

The study selected by the user is retrieved to the workstation application for viewing from the Imaging Data Repository. Locally stored studies are potentially utilized directly from PACS. If a comparison study has been produced by another custodian and it is necessary to make additions to it, it is stored as a local imaging study copy under the local name with new identifying information. Local copies of comparison studies shall not be stored in the DICOM repository of the Imaging Data Repository unless there are notes made to a study copy that should be added as a part of patient care data.

The reports of comparison studies can be retrieved with the services of the Patient Data Repository or via the XDS search. Retrieved reports are not edited and the copy is not stored. Comparison studies and their reports are referred to from the study and report entries of the CDA documents of the study to be produced. The reference is included in the description written by the user or similar, and the Imaging Data Repository is not able to understand or monitor the reference. If necessary, a query on the study referred to is made manually on the basis of stored reference data.

4.9.1 Management of retrieved study copies

Study copies retrieved by XDS-I and/or XCA-I are normally stored in the retrieving system for the needs of patient treatment. During retrieval, it is not known whether the study will be used in reports or treatment decisions. Retrieved studies must be handled as temporary in

the Document Consumer and they must be deleted as soon as the study has been completed.

If a study is utilised in reports as a comparison study or for clinical decisions, it should be referred to in the study or report entry of the imaging CDA document in a way that it is possible to find the original study on the basis of the reference and retrieve it again. An organisation utilising for the purpose of use at a later date will not store the imaging study referred to. If there is a need to make notes on the study retrieved as a comparison study, the operating model described in chapter 4.9.3 is followed for storiring the notes.

4.9.2 Handling of studies obtained from external media

External studies refer to images brought up by the patient's own media and produced by an actor outside the Imaging Data Repository environment. These images include, e.g. studies containing images taken at a private (not joined in the Imaging Data Repository) medical centre or overseas or studies produced by a healthcare organisation that has not yet joined the Imaging Data Repository entity. The images are brought into the organisation's own system (often PACS) and attached to the patient's active encounter, within the scope of which the patient has brought the images. The images are stored in the same way as own images so that the organisation using them will act as the custodian of the images. However, the information of the organisation that produced the images will be retained with them. The principle is that the images are brought to the Imaging Data Repository environment, after which they will be accessible for all.

4.9.3 Technical solution

The workstation application acts as an XDS Document Consumer role and performs the retrieval of studies in accordance with the XDS-I specifications and section 4.1.2 Retrieval of study. Any creation of new IDs and storage to PACS carried out after the retrieval are the functions of the workstation or another local system.

When using an imaging study produced in the organisation's own PACS as a comparison study, the study can be viewed from PACS. Editing of the imaging study requires that a copy is made of it and not only the new IDs but also the ID of the current encounter are set in it. Without these measures, the imaging study cannot be connected to the imaging study entity of the encounter that has produced and is currently using it. The study copy is stored only in the local PACS system. Alternatively, it is possible to retrieve for editing the organisation's own imaging study which has been stored in the Imaging Data Repository.

A study with entries, brought from another XDS domain, is stored by the workstation application as a study of the local custodian in the same way as a new study. The DICOM repository of the Imaging Data Repository requires a new unique Study Instance UID and unique object IDs for all imaging study objects to maintain the integrity of the DICOM repository in all supplementing, correction and retrieval situations. Before the storage, the DICOM TAG values of the study are replaced, e.g. as follows:

- DICOM tag, Original Attributes Sequence (0400,0561), Study Instance UID of the original study

4.10 Access control

Access control of the Imaging Data Repository is based on similar mechanisms as with the Patient Data Repository. The following is a rough description of the access control that takes place in storage and retrieval situations in the Kanta architecture.

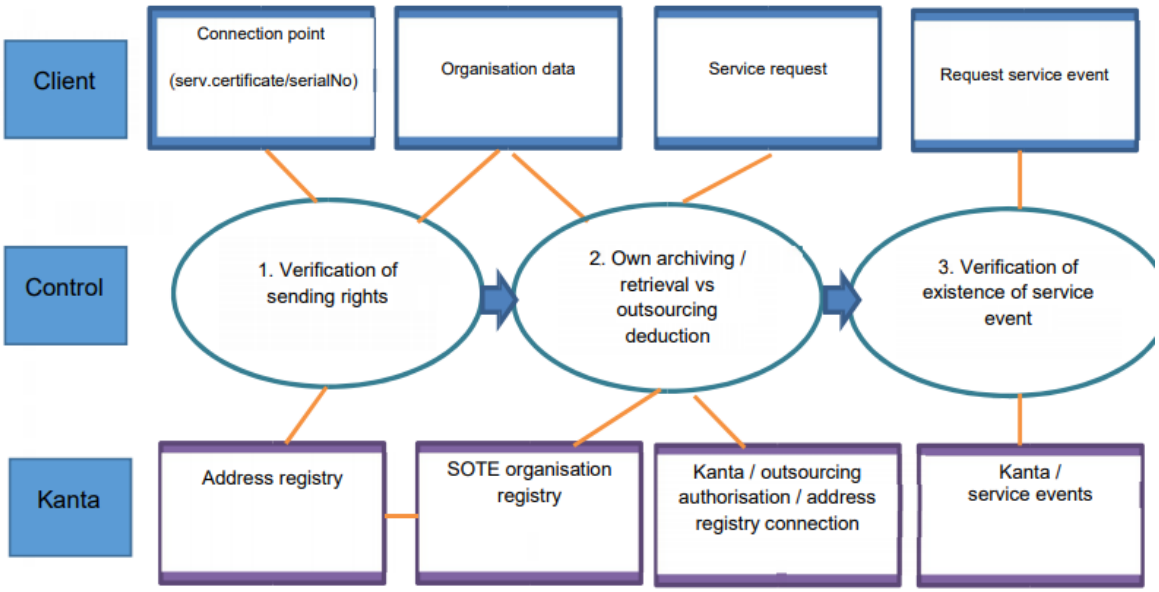

Figure 16. General principle of access control in storing

The client's right to send messages to the Kanta is verified in 1st control.

2nd control is implicit when storing a DICOM study. An actual 'own storing vs outsourced service' deduction is not made, but the imaging study can be attached to an existing encounter (service event) in the Patient Data Repository and the target register of storing is

determined in accordance with the encounter as described in the chapter 4.3 on outsourced services (alternative 3).

3rd control is required in all storing and searches. In connection with storing, the verification of the existence of an encounter means that it is verified that the encounter in which studies or other documents are being stored has been established. In connection with searches, an encounter means a so-called encounter in the patient care context.

Data communications with the Imaging Data Repository must always be TLS-based. The basic principle is that the message includes the information about the sender of the service request and that the service request arrives in the Patient Data Repository via a connection point defined in the addressing service. That way, it is also possible to identify a situation where the sender of the service request does not match the custodian in whose register the document is being stored. The user right of the sender of the service request is configured separately for each transaction.

Access control checks of the Imaging Data Repository are made for the XDS transactions. The access and use management of the DICOM interface is system-specific and based on the AETitle used in the study storing. The AETitle used determines what is returned by DICOM interface interactions. The system joining to the Imaging Data Repository is responsible for the registry-specific delimitations.

4.10.1 Identification and verification of parties, and trust relationships

Certification, administrative processes, etc. provide the basis for the trust relationship between the parties mainly at the organisation level. The procedures ensure that a joining organisation and the systems used by it meet connection requirements of the Imaging Data Repository. As a result of these and the connection process, the party will be recorded as a user of the Imaging Data Repository and to be added to the address directory.

The author of the storage, query and retrieval request have to be identified with sufficient reliability. A technically reliable procedure is used at runtime in order to identify the server of the other party. The other party is expected to use a certificate granted by a reliable certificate authority, in practice, the healthcare server certificate of the Digital and Population Data Services Agency (DVV). Based on the Kanta address directory it is verified that the organisation is entitled to use the connection point in a technically reliable way, identified with the certificate. When building a system configuration and installing certificates, verifications on the technical validity are made. Connection point requirements and principles

for integrators of the Imaging Data Repository are the same as in the Kanta services in general [6].

TLS identification (two-way authentication) and encryption are used in all DICOM traffic in the Imaging Data Repository. In addition, identification of parties is also based on configured Application Entity (AE) data. It is possible to use tunnelling in the connections, which is also sensible, depending on applicability.

The personal-level identity notified in the XUA element of XDS and XDS-I transactions of the user sending the request is not verified at the server. The owner of the sending system that sends request is responsible for the validity of data in the request.

With respect to the services in the Patient Data Repository, identification of parties in HL7 V3 connections takes place in accordance with the Kanta specifications.

4.10.2 Technical solution and implementation

Author of search or share request query has to be identified with sufficient reliability. With respect to servers, the identification of parties is based on a certificate-based procedure also supported by the ATNA profile. In addition, the Imaging Data Repository also uses the IHE XUA profile designed for this purpose to identify the calling organisation and user in other than DICOM traffic. The profile defines SAML 2.0 as the technology to be used, as well as mandatory and optional elements of XUA in addition to the assertion elements required by SAML.

Data transferred by XUA is not expected to be fully obtained from the user identification and verification, but the data set by the sending system is trusted. It is ensured in a technically reliable way that the assertion received has been created with a trusted system, implemented by server certificates and TLS (two-way authentication). Two-way TLS has been implemented in the same way as in other functionalities of the Kanta as a two-way function, i.e. the Kanta is responsible for the fact that connection of the organisation party to the connection point will be verified in message traffic. In practice, the ID of the connection point is the same as the SerialNumber of the Subject section of the server certificate and the organisation ID is obtained from the SAML element *urn:oasis:names:tc:xspa:1.0:subject:organization-id* (see further in section 7.2 SAML table). In addition, the right of the organisation party and the connection point to use the requested XDS transaction is verified, for which the systems must produce the transaction ID in the SOAP Header wsa:Action field in accordance with the IHE definitions. Every XDS

transaction must include a unique WS-Addressing wsa:MessageID for logging purposes in Kanta system. The verification is based on the use of the Kanta address directory.

In web service transactions, the Imaging Data Repository expands the SAML elements used so that information about the patient care relationship is transferred with assertion, in practice, the encounter id of the care context and information about the organisation sending the request. Information about the connection point is obtained from the TLS certificate. Based on this data, the organisation's right to use the connection point is verified from the address registry.

Authentication is managed with a two-way TLS procedure in the same way as with the Patient Data Repository. Therefore, there is hardly any difference between XDS-based traffic and the Patient Data Repository.

As stated above, in the case of DICOM it is not possible to use SAML assertions. In DICOM based communication the joining systems are identified with the server certificate and the DICOM repository and the systems joining it identified with the AE Title. Based on the AE Title, the Imaging Data Repository can limit the rights of using DICOM services and obtaining the studies, and it can write both use logs and technical logs from the transactions. The joining PACS system can use its existing AE Titles in the Imaging Data Repository. THL's policies are complied with in access control in DICOM traffic:

1. The use of the Image Repository (DICOM repository) is permitted only for PACS systems operating from an identified connection point (= systems with IDs (AE Title) specified as permitted in the DICOM repository).

2. The PACS system may use one or several IDs (AE Title) for calling (Service Class User - SCU) and providing (Service Class Provider - SCP) DICOM services.

3. One or several organisations can use the same PACS system. The user rights in the DICOM repository are limited for each PACS system/AE Title, not for each organisation.

4. An organisation may have several PACS systems that can store and search for the same material with the configuration of the DICOM repository access control.

5. Only the PACS system that has produced the data or other PACS system used by the same organisation has access to material stored in the DICOM repository. The user

rights of the DICOM interface must not be extended to storing PACS system and, with respect to searching, the PACS system of another organisation.

6. The producer of the imaging material cannot move a study it has produced to the PACS system of another organisation through the DICOM interface.

The user rights of DICOM commands are configured for each AE Title when joining the Imaging Data Repository (Figure 17). An individual (one or more) corresponding AE Title (Called AET) is created for each AE Tile (Calling AET) of the client at the Imaging Data Repository side, and the client's system uses this title as the DICOM call ID towards the Imaging Data Repository. No other client has a right to use it. If an organisation is using several PACS systems, they can be connected to the same call ID at the Imaging Data Repository side, in which case the different PACS systems of the organisation have access to the same studies stored in the Imaging Data Repository.

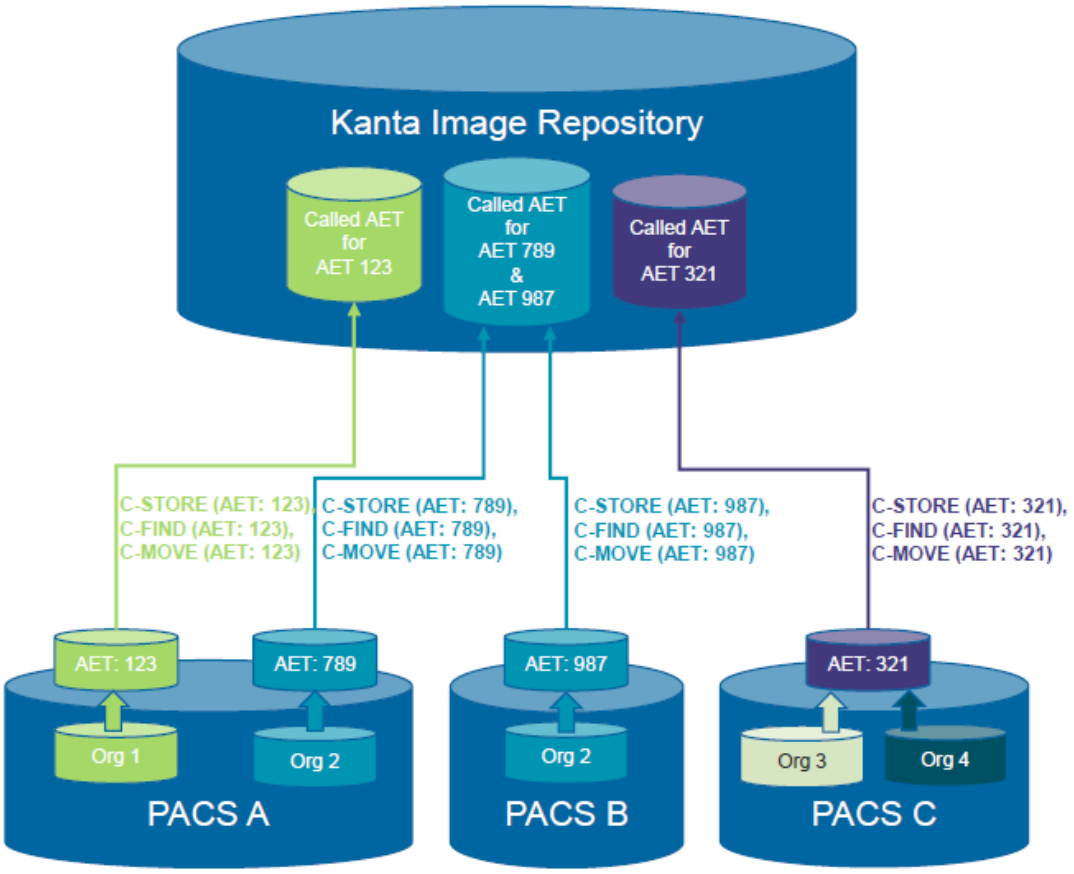

Figure 17. The use of AE Title in DICOM requests in the Imaging Data Repository

DICOM traffic in the client's direction from the Imaging Data Repository with respect to C-STORE and Instance Availability Notification services requires a IP address/DNS name and port-specific Called AE Title at the client's side. If for example, the client wants to receive IAN notifications in a different gateway (IP address/DNS name) than the C-STORE commands arriving from the Imaging Data Repository, the Imaging Data Repository needs from the client dedicated calling AE Titles and gateways for both services. A response to the Storage commitment request is always sent back to the AE Title (and the gateway specified for the AE Title in question) that it was requested from. If all of the client's DICOM reception services operate in the same IP address/DNS and gateway/port, a minimum of one AE Title at the client's side is sufficient. The use of C-MOVE commands is technically limited as a default and therefore it is not possible to carry out unlimited commands to move studies into any PACS system using the C-MOVE command. As a default, the C-MOVE command can be used for moving studies only into the PACS system where the study was produced. There also can be multiple allowed C-MOVE destinations in the configuration.

4.11 Digital signature

In the digital signature of study documents and messages, different solutions are followed on a case-by-case basis:

- Imaging studies in DICOM format are not signed digitally, but the transmission and storage solutions are trusted to ensure the data integrity.
- Imaging CDA R2 documents are signed as specified in the Kanta specifications.
- The XUA signature of XDS requests is described in chapter 7.2.

4.12 Logging of data sharing and use

Statutory security requirements are followed for the log entries in the Imaging Data Repository. The security of the Imaging Data Repository is based on the restriction of advance use and on monitoring and control that takes place after the event. To enable control after an event, the system maintains logs in which the information required by monitoring is stored with respect to all events [11].

Logs related to imaging studies are maintained at two different levels, in the Kanta services and in the regional imaging systems. The sharing of data between the custodians is documented with a sharing notification to Kanta or, in sharings through Kanta, directly with sharing log (disclosure log) entries. Sharing information stored in both ways is e.g. available to MyKanta.

The Imaging Data Repository records the use of the custodian's own data in the usage log (operation log). Similar systems using the information will record the use of own and shared data user specifically in the usage log. The log is stored securely in the organisation that produces the log.

4.12.1 Share log

Sharing events logged in the Imaging Data Repository include XDS interface queries that returns imaging study information stored by another custodian. The share object is logged with the accuracy of the encounter and the view of the document. The system sharing the data is responsible for recording the share (the Patient Data Repository or the Imaging Data Repository).

Sharing of material between custodians within the same area (regional common registry) will produce a sharing event, which must be forwarded to the Patient Data Repository with a sharing notification. It is not necessary to submit a sharing notification for every single sharing event from the common registry, as sharing carried out for the same sharing recipient per each patient and 24-hour period can be gathered into a single sharing notification. The updated sharing notification (eArkisto/Lomake – Luovutusilmoitusasiakirja) is available in the National Code Service (kansallinen koodistopalvelu). Logging of sharing is the responsibility of the system that shares or requests the sharing of material, depending on the solution.

4.12.2 Usage log

All use of patient data must produce a usage log that is stored in the system presenting to the user of the data. The log entry of use is the responsibility of the systems using the data however the requirement can also be fulfilled by other systems than systems presenting to the user of the data. Systems using the data shall record in the log the use of own and shared data user-specifically. With respect to data pertaining to the national solution, the use log data must include, e.g. an encounter ID and the user’s entitlement to use the data. Especially the use of imaging documents obtained through sharing must always be identified with an accuracy of the encounter ID and possibly also the document.

The usage log is stored reliably in the organisation that produces the log, and the patient’s checking right also applies to this log data. In accordance with the specifications, the patient administration events required for the verification of the care relationship are also recorded in the local usage log.

The usage log is the responsibility of the Document Consumer system. The specification of the Imaging Data Repository does not include requirements or recommendations on the technical implementation of usage logging.

4.13 MyKanta

The study entries of the imaging studies are available to patients in the MyKanta (OmaKanta in Finnish) in the same way as other patient records. There will be no special functionality in the MyKanta with respect to documents stored from an imaging study into the Patient Data Repository. The viewing of imaging studies (referrals, study data and reports) in the MyKanta can be delayed by the professional. Images of the imaging studies are not shown in the MyKanta. They can only be obtained by searching through the information systems of a professional from the Imaging Data Repository.

MyKanta will show the sharing of the metadata and documents in the imaging study entity together with other shares (chapter 4.12.1). For shares of imaging data, the recipient of the sharing and the information of the shared study are displayed. Regarding the sharing of metadata, only the information that the metadata of the studies has been shared is displayed.

4.14 Retention control and deletion

Retention control and deletion of imaging documents take place in accordance with the Kanta principles and Finnish act on processing of social and health care customer data a.k.a. asiakastietolaki (703/2024). For the time being, nothing will be removed from the Imaging Data Repository until the national policy is completed.

4.14.1 Legal requirements

According asiakastietolaki (703/2023 §23-24) the custodian of patient documents is responsible on the proper storage and disposal of patient documents in accordance with the retention periods [12]. The Kanta services and the Imaging Data Repository takes care of the retaining and the deletion functionality of documents stored in Kanta services. In the case of storing, the retention period is automatically calculated for the imaging studies by the rules of the decree mentioned above.

The determination of retention time and the rules for calculating the termination date are described in the Metadata model of the Imaging Data Repository published at kanta.fi web

pages. The information needed to determine the retention period is described in the chapter 4.14.3.

4.14.2 The principles of retention control in the Imaging Data Repository

In environments in accordance with the Imaging Data Repository architecture, there are references and/or copies of individual studies in several different data systems. When deleting study data from the local systems, the deletion of references or copies of all studies must be ensured. Imaging study entity documents retrieved from the Imaging Data Repository for viewing must be handled in the Document Consumer as temporary documents to be deleted soon after patient's care is completed, in which case they will be deleted before the retention period ends.

The DICOM standard does not specify a mechanism where two systems can share data concerning substitutive changes made on the study, only the new objects of the study can be shared between systems. XDS-I does not contain a record of retrieval from the repository and of the study copies created as a result. The control of retention and deletion of copies is not centralised in the Imaging Data Repository, and therefore systems storing the retrieved documents for treatment needs must ensure that the copies are deleted within the specified periods.

The IOCM (Imaging Object Change Management) profile has been added to the radiology specifications in IHE to enable sharing of changes made in the study (removal/amendment/addition) between systems [7]. IOCM support is required from all of PACS systems integrating with the Imaging Data Repository. One of the change cases covered by the IOCM profile the deletion of a study (or its part) made due to the end of the retention period. Sending of such KOS objects to the DICOM repository is however prevented because retention control is handled automatically by the Imaging Data Repository. Other cases of IOCM use are dealt within the chapter 4.5.

4.14.3 Technical solution and implementation

The Imaging Data Repository deducts the statutory retention sub-category for a study according to the Finnish legislation on the basis of the metadata of studies. The metadata needed to determine the retention time class are:

- Study date
- Patient's date of birth
- Modality (e.g. Electrocardiography [ECG])

- Study codes (e.g. dental imaging study from which the person can be identified)

The retention time is given in years. The calculation basis for the storage period indicates what information is used to calculate the end time of the retention period (e.g. birth date of the patient + 12 years). The expiry date of the retention period includes information on the date when the retention period for the document or imaging study expires. The Imaging Data Repository automatically calculates the end time of the retention period. At the end of the retention period, the data will not be returned in the search results of the Imaging Data Repository.

5 Management of the imaging study entity

In the Imaging Data Repository, an imaging study and related documents are linked together using the metadata of the documents. The key connecting metadata is the encounter ID that is used both in the Imaging Data Repository with the metadata of the imaging study and documents and in the Patient Data Repository with encounter and patient care documents.

In case there are several imaging studies for one encounter, the studies differ by their Study Instance UIDs which are also metadata elements for the manifest and CDA documents. The format of the Study Instance UID should be compatible with CDA requirements and the DICOM standard:

- max. length is 64 characters,
- only numbers (0…9) allowed and point (.) as a separator and
- preferred format is the ISO OID but also the DICOM UUID format is allowed.

The Study Instance UID links the documents to the imaging study entity at the metadata level. However, a CDA document with just a referral entry does not have a Study instance UID, and therefore it is linked to the encounter and with the referral id to the study entry.

The manifest of the imaging study contains references to the actual imaging studies and links them to the imaging document entity. Registered documents have the encounter ID as metadata, which can be used by the system searching imaging studies as a query parameter for the Patient Data Repository or other systems.

The imaging study and report documents stored in the Patient Data Repository contain the study identifiers (Study instance UID and possible AC number) as well as the encounter ID. Using these, the system that has retrieved an imaging study or report document from the Patient Data Repository can also search and retrieve an imaging study from the Imaging Data Repository.

5.1 Second opinion

According to the imaging CDA document specification, an imaging study can have a preliminary, final or second opinion report status, and they can be included in the same document or in separate documents. The report may also apply to several imaging studies. [3]

Second opinions are linked to the imaging document entity as a document in the same way as the original report. The link to the entity is formed on the basis of the encounter ID and the study instance UID of the second opinion. Any entries made in the imaging study created while producing the report are stored as additional objects into the Imaging Data Repository as an imaging study update described in chapter 4.5.1.

5.2 References to comparison studies

In order to refer to a comparison study used in connection with an imaging study, a free-form reference, which enables locating the study, shall be attached to the study or report entry of the imaging CDA document in question.

5.3 Technical implementation

The encounter ID is included in the documentEntry metadata in the Imaging Data Repository. In the Patient Data Repository, the encounter ID is a key metadata. Therefore, the encounter ID can connect the study documents to each other, but an encounter may have several imaging studies, and their separation from each other using metadata is not without gaps. Imaging studies are identified by the Study Instance UID.

To maintain the correct encounter ID on all documents related to an imaging study entity, including the metadata of the manifest, the imaging study can only be changed in the encounter producing the study. All subsequent updates of the study, for example, planning of an operation or the use of an imaging study as a comparison study supplemented with entries, are made on a copy of the study in question.

The Study Instance UID that identifies the study is obtained from the DICOM tags of the imaging study into the manifest's XDS metadata and inside the entry of the imaging CDA documents, from where it is extracted into the metadata of the CDA document. The Study Instance UID is picked to the uniqueId metadata of the referenceIdList from the manifest and the CDA document.

6 Identification and management of patient data in the Imaging Data Repository

In the Imaging Data Repository, the basis for patient data management is that the official personal identifier is used in as straightforward and efficient way as possible. In Finland, the identifier codes produced by the Digital and Population Data Services Agency (DVV) are generally and commonly used in all healthcare (and other) systems.

6.1 Temporary identifiers

There are imaging related patient data created also with temporary identifiers in healthcare. A temporary patient identifier is needed in the treatment of, e.g. unidentified/new-born/foreign patients. The imaging study is stored to the Imaging Data Repository when there is the official patient identifier available.

When storing CDA R2 patient care documents to the Patient Data Repository, it is possible to use either the temporary identifier or the official personal identity code. Documents in the imaging study entity that have been stored using a temporary identifier shall not be shared with other custodians, but they are only meant for own use by the custodian that produced them. CDA R2 documents of imaging study stored with a temporary identifier are also not registered in the Imaging Data Repository.

A risk has been recognized in the Imaging Data Repository: temporary identifiers are not always unique and they are sometimes even recycled. This may lead into a problematic case where two different patients' data would get merged in the Imaging Data Repository. Before national solution is introduced, imaging studies with temporary identifiers cannot be stored in the Imaging Data Repository.

6.2 Patient data management in the Imaging Data Repository

The Imaging Data Repository supports a model where two official patient identifiers of the same patient can be merged together in the DICOM repository and in the metadata of the imaging studies. A case like this would be e.g. gender reassignment where the patient receives a new patient identifier. The technical implementation model works according to the HL7 V2.x ADT-A40 message (see appendix 5). The ADT-A40 message may not be used to transfer data from one patient to another or to combine temporary IDs in the Imaging DataRepository. ADT-A40 functionality does not include transmitting the information to all required systems e.g. the Patient Data Repository. Organisations must update their CDA R2 documents in the Patient Data Repository separately by versioning them. It is noticeable that

the ADT-A40 message sent to the Imaging Data Repository will merge two patient identifiers despite who is the custodian of the data. In the Patient Data Repository custodians are able to update only their own data. The Imaging Data Repository also supports ADT-A08 messages if it is needed to update patient information (patient name) in the DICOM repository which is described in appendix 5.

The ADT message updates the metadata of the DICOM studies' manifests but not the content of the manifest (KOS object) tags. The ADT-A40 messages updates also the metadata at the Imaging Data Repository. E.g. the old name will remain in the manifest's DICOM tag as long as the study is updated e.g by adding objects and the manifest is updated. Only then will the update of the manifest with new information start.

In order to retain the integrity of the data between the Imaging Data Repository and the Patient Data Repository, organisations must take care that their data is always up-to-date in the Patient Data Repository if patients' identifiers change in their registries. The use of the Patient Data Repository requires the custodian to update an official personal identity code for a document as soon as it is available. The temporary identifier will also remain on the document. A document that has been updated with the official personal identity code will not be returned in the results to queries using the temporary identifier as a search criterion. The organisation that has stored the study is obliged to verify that the patient data of a study is as up-to-date as possible, i.e. the use of temporary identifiers should be eliminated as soon as it is possible.

7 Consent management

The Act on Electronic Processing of Client Data in Social and Health Care [12] and the Health Care Act set out the preconditions for sharing patient data and the mechanisms for informing patients, as well as the patient's consent and consent restrictions management in a centralised way. Data about the information given to the patient, consents and consent restrictions given by the patient are stored in the Patient Data Management Service of Kanta. A more detailed description of the use of the consents and consent restrictions and other expressions of will is described in the document "*Sosiaali- ja terveydenhuollon tahdonilmaisuja käsittelevien tietojärjestelmien vaatimukset ja toiminnallinen määrittely*" [13].

In the Imaging Data Repository when a document is shared between custodians, consent management verifies the conditions of sharing on the basis of the informing, consent and consent restriction documents stored in the Patient Data Management Service of Kanta. It is the responsibility of the healthcare service provider to check and take into account the Kanta consent and possible consent restrictions set by the patient in Kanta on any data transfers made outside Kanta [12].

In the Imaging Data Repository, deduction of consent management is performed in transactions returning patient data. The deduction is based on the data of the requesting organisation and the patient care context obtained from the query message, on the custodian and encounter data of the document to be returned and the consent management documents stored in the Patient Data Management service. As a result of the deduction, documents without consent are filtered from the result set. Own use and rights obtained with outsourced certification are taken into account in the verification.

Sharing of documents stored with a temporary identifier and documents stored only for the custodian's own use is excluded from the consent management verification.

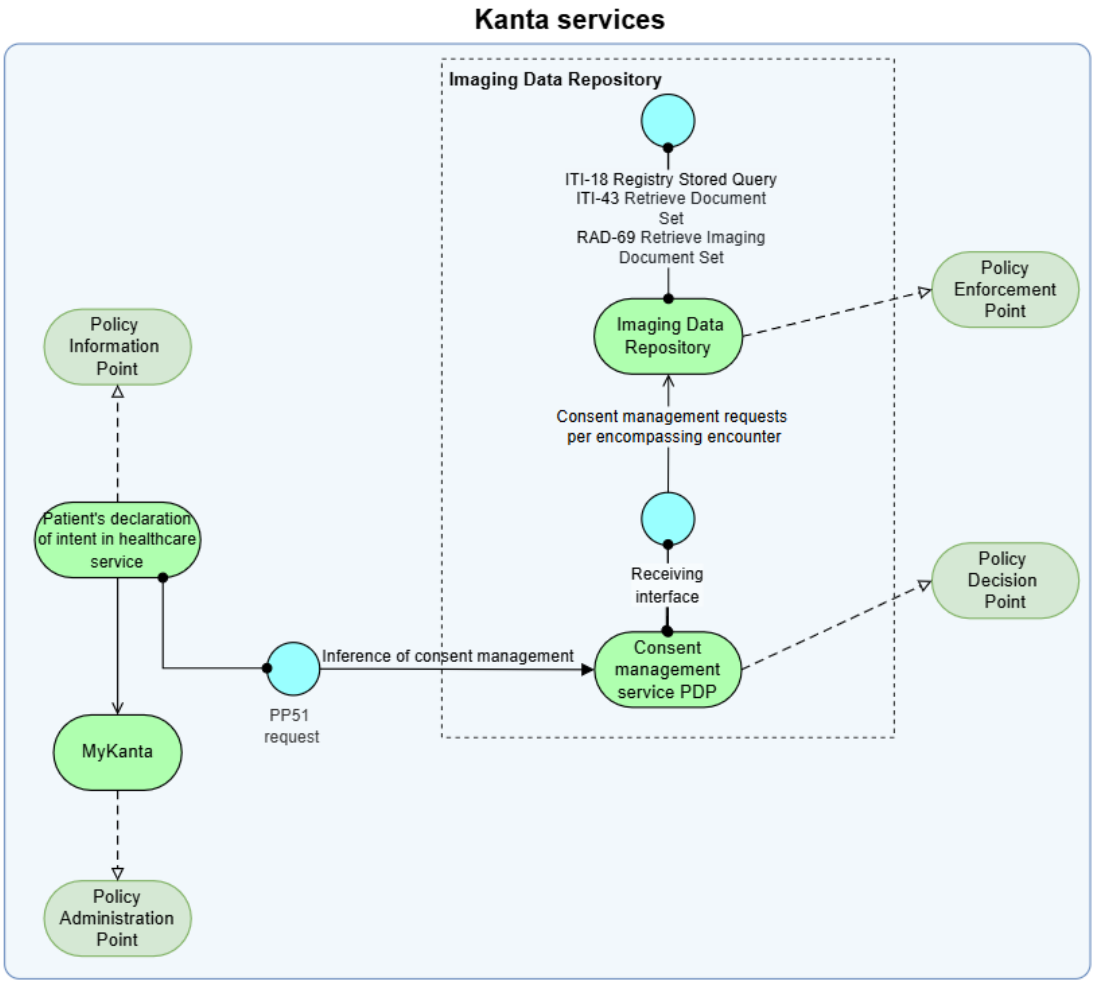

Figure 18. The consent management scheme of the Imaging Data Repository

The consent management verification is done in all the XDS Interface queries except for those that are recognised as ‘own’. In practice, this means ITI-18 (Registry Stored Query) and ITI-43 (Retrieve Document Set) and RAD-69 (Retrieve Imaging Document Set) queries. These queries are enclosed in queries ITI-38 (Cross-Gateway Query) and ITI-39 (Cross-Gateway Retrieve) and RAD-75 (Cross Gateway Retrieve Imaging Document Set) between XCA gateways, but the actual consent verification is not done at the gateways, but in each actor sharing the data.

7.1 Consent management of retrieved studies in subsequent use

The Kanta principles and requirements, which are described in the Kanta specifications and Ministry of Social Affairs and Health’s decree on the processing of client data (Sosiaali- ja terveysministeriön asetus asiakastietojen käsittelystä), are complied with in the utilisation of

in imaging study entities or documents included in them, which have been retrieved from the Imaging Data Repository.

When using imaging studies and other documents retrieved from the Imaging Data Repository and temporarily stored, it must be noted that they have been handed over for a specific encounter (service event). In addition, the patient may have changed the consent restrictions after the retrieve.

7.2 Technical solution and implementation

In the Imaging Data Repository there is an adopted framework that is partially used in XACML (eXtensible Access Control Markup Language) which identifies the following roles:

- PAP (Policy Administration Point) - MyKanta or HIS
- PDP (Policy Decision Point) - Consent Management Service
- PEP (Policy Enforcement Point) - Imaging Data Repository
- PIP (Policy Information Point) - Patient Data Management Service of Kanta
- PRP (Policy Retrieval Point) - Interface of the Kanta Patient Data Management Service

Corresponding roles are utilised in consent management of the Imaging Data Repository. In practice, only the PDP interface or, if PDP is implemented in a distributed setting locally, the PIP interface, is visible outside of the consent management component of the Kanta services.

XUA with its data content extensibility is included in the IHE requirements and therefore it enables the sharing of data of the requesting body and the user context needed in the deduction of consent management in the Policy Enforcement Point (PEP) and Policy Decision Point (PDP). The IHE specification also allows for metadata extension with the data required in consent management deduction. Consent management deduction is implemented with a component tailored for the Imaging Data Repository, using the sharing permission request of the Patient Data Management Service.

The tailored consent management is a component implementing the PDP role, verifying the sharing rights when documents or their metadata are returned from the Imaging Data Repository. The component discovers the returned encounters on the basis of the metadata or search criteria of the returned documents. The return permission of returned encounters is

requested from the patient data management service, and the returned document set is filtered on the basis of the response.

In the Imaging Data Repository, the Policy Enforcement Point is implemented in the XDS services returning the data to the requesting organisation. Due to the IHE specifications, implementation has to be based on product specific characteristics, which enable linking of a tailored handling component. PEP uses the Policy Decision Point component in accordance with the architecture description.

The authorisation to share documents is requested with the service request PP51 (sharing authorisation request) from the Patient Data Management Service. The functionality corresponding to the consent management component must be implemented in every system that shares patient information, and it must call the above-mentioned PP51 service request from the Kanta services. The PP51 service request is described in further detail in a separate specification [5].

The data needed for the deduction of the sharing rights in consent management is added in each transaction in accordance with the IHE XUA profile to the Security element of the Soap header section, which complies with the SAML2 specification [14], page 15.

The Basic Attribute Profile of SAML2 [15] is used in the Imaging Data Repository. This is an Attribute assertion statement in accordance with the SAML Core specification:

> *This SAML specification defines three different kinds of assertion statements that can be created by a SAML authority. All SAML-defined statements are associated with a subject. The three kinds of statement defined in this specification are:*
>
> - *Authentication: The assertion subject was authenticated by a particular means at a particular time.*
> - *Attribute: The assertion subject is associated with the supplied attributes.*
> - *Authorization Decision: A request to allow the assertion subject to access the specified resource has been granted or denied.*

In connection with XDS, assertion is shared in accordance with the Provide X-User Assertion transaction (ITI-40). Assertion is signed with the XML signature in the required by ITI-40: *Assertion shall be signed by the X-Assertion Provider as defined in SAML Core*. A system signature certificates granted by the Digital and Population Data Services Agency (DVV) is used as the signature certificate of Assertion, and it is verified in the Imaging Data

Repository. Kanta's specification for digital signature (Sähköisen allekirjoituksen määrittely ja soveltamisohje) and appendix 2 of this specification document, a application guide for digital signatures, is complied with in the technical formation of the signature. Assertion must be signed in all IHE XDS Transactions (ITI-18, ITI-43 & RAD-69), although with RAD-69 the signature is not technically validated for the time being. The message attributes required by the Assertion element in accordance with the SAML2 specification.

The Assertion element attributes in accordance with SAML2 specification are:

- Version
- ID
- IssueInstant
- Issuer

SAML2 elements and attributes (according to the IHE IT-Infrastructure Volume 2 [9] and the SAML v2 specification [14]) used in the context of the Imaging Data Repository. The implementation has to support all the elements and attributes, optionality is connected only to information's mandatoriness in different situations.

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
Validity period	SAML generic, SubjectConfirmation: NotBefore and NotOnOrAfter	At most for 8 hours from creation	P	SAML
Service provider's organisation ID	Attribute: `urn:oasis:names:tc:xspa:1.0:subject:organization-id`	AttributeValue: organisation OID character string (service provider level). When Joint connection according to the codeSystem 1.2.246.537.5.40200.2014 is in question, AttributeValue as instructed: • Case 1: Private service provider's OID who has joined Kanta services directly • Case 2: Private service provider's OID who is hosting the joint subscription	P	IHE

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
		E.g. `<saml2:AttributeValue> 1.2.246.10.1234567.10.0< / saml2:AttributeValue>`		
Service provider's organisation name	Attribute: `urn:oasis:names:tc :xspa:1.0:subject: organization`	AttributeValue: organisation name as character string E.g. `<saml2:AttributeValue> Sairaanhoitopiiri X</ saml2:AttributeValue>`	O	IHE
Service provider's service unit	Attribute: `urn:kanta:kvarkki: organization-unit`	AttributeValue: organisation's service unit OID as character string E.g. `<saml2:AttributeValue> 1.2.246.10.1234567.10.1. 10.1</ saml2:AttributeValue>`	O	Imaging Data Repository
Name of professional	Attribute: `urn:oasis:names:tc :xspa:1.0:subject: subject-id`	AttributeValue: name of retrieving person as character string E.g. `<saml2:AttributeValue> Pekka Lääkäri </ saml2:AttributeValue>`	O	IHE
National personal identity code of professional	Attribute: `urn:oasis:names:tc :xspa:2.0:subject: npi`	Coded with HL7v2 CX data type. AttributeValue: ID of retrieving person in the format `'121212-923A^^^&1.2.246.2 1&ISO'` If the personal ID of the professional is not available, the Terhikki number (registration number of the professional may be used in the format `'01234567890^^^&1.2.246. 537.26&ISO'` where 1.2.246.537.26 indicates the root of the Terhikki number	P	IHE
Patient identifier	Attribute: `urn:oasis:names:tc`	Coded with data type HL7v2 CX. AttributeValue: patient's	P	IHE

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
	:xacml:2.0:resource:resourceid	personal identity code in the format '170474-970K^^^&1.2.246.21&ISO' where DVV's root 1.2.246.21 indicates the official identity code.		
Specific reason for viewing patient data	Attribute: urn:oasis:names:tc:xspa:1.0:subject:purposeofuse	The field is conditionally required. Purpose of use is always patient care when queried through this interface, and as a default, the field will not be submitted. The original purpose of use of the PurposeOfUse element has been applied to better meet the Kanta context. If the sharing query is based on a specific reason, the field value is given from the code set Specific reason for viewing patient data - 1.2.246.537.6.240.2012 If the code value is 99 (Other reason), an explanation must also be entered in the field urn:kanta:kvarkki:special-reason-expl (described later in this table) AttributeValue: With the code, codeSystem, xsi:type and xml namespace (xmlns) data E.g.: Whether it is emergency case, attribute shall have the code value '13' from the code system 1.2.246.537.6.240.2012 E.g.: <PurposeOfUse xmlns="urn:hl7-org:v3" xsi:type="CE" code="13" codeSystem="1.2.246.537.6.240.2012"	O	IHE

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
		`codeSystemName="THL - Potilastietojen katselun erityinen syy" displayName="Hätähaku" syy"/>`		
Professional's role	Attribute: `urn:oasis:names:tc:xacml:2.0:subject:role`	If used, shall be given as specified in the IHE specification chapter 3.40.4.1.2.1 Subject-Role Option [9]. However no validation is done to this attribute because the Imaging Data Repository does not utilize the Subject-Role Option, see section 12.3	O	IHE
HomeCommunityId	Attribute: `urn:ihe:iti:xca:2010:homeCommunityId`	Home Community Id, no particular use, but required by the IHE specification	P	IHE
Custodian	Attribute: `urn:kanta:kvarkki:custodian-id`	AttributeValue: service provider's custodian's OID as character string When Joint connection according to the codeSystem 1.2.246.537.5.40200.2014 is in question, AttributeValue as instructed: • Case 1: Private service provider's Custodian OID who has joined Kanta services directly (same as `urn:oasis:names:tc:x`	P	Imaging Data Repository

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
		`spa:1.0:subject:organization-id`) • Case 2: lessee organisation's Custodian OID (same as `urn:kanta:kvarkki:private-hosted-organization`) E.g. `<saml2:AttributeValue>1.2.246.10.1234567.19.1</saml2:AttributeValue>`		
Registry	Attribute: `urn:kanta:kvarkki:registry-code`	Value according to the registry code of the patient document of the service provider (1.2.246.537.5.40150). AttributeValue: with the code, codeSystem, xsi:type and xml namespace (xmlns) data (see the xml example below) E.g. `<RegistryCode xmlns="urn:hl7-org:v3" xsi:type="CE" code="2" codeSystem="1.2.246.537.5.40150.2009" codeSystemName="KanTa-palvelut - Potilasasiakirjan rekisteritunnus" displayName="Julkinen terveydenhuolto"/>`	P	Imaging Data Repository
Registry specifier	Attribute: `urn:kanta:kvarkki:registry-specifier`	AttributeValue: Registry specifier in occupational healthcare. Given according to the JHS recommendation: from the employer's business ID (Y-tunnus) in ISO OID format E.g. 1 `<saml2:AttributeValue>1.2.246.10.1234567</saml:AttributeValue>` If business ID is not available the official personal ID can be used	O / P mandatory if attribute `urn:kanta:kvarkki:registry-code` has value ‘4’	Imaging Data Repository

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
		E.g. 2 `<saml2:AttributeValue>170474-970K^^^&amp;1.2.246.21&amp;ISO</saml:AttributeValue>`		
Care context encounter ID (OID)	Attribute: `urn:kanta:kvarkki:encounter-id`	The field is conditionally required. Encounter during which sharing request (urn:kanta:kvarkki:sharing = true) is made. In an outsourced situation, the service organiser's encounter ID. AttributeValue: encounter OID as character string E.g. `<saml2:AttributeValue>1.2.246.10.1234567.30.12345</saml2:AttributeValue>`	O (compulsory after all in sharing situation or outsourced situation)	Imaging Data Repository
Special reason explanation	Attribute: `urn:kanta:kvarkki:special-reason-expl`	The field is conditionally required. AttributeValue: Free text explanation when the patient records have been viewed without verification of care context. E.g. `<saml2:AttributeValue>Reason for viewing patient's data</saml2:AttributeValue>`	O (must be used if the special reasons is of type 99)	Imaging Data Repository
Joint connection	Attribute: `urn:kanta:kvarkki:private-hosted`	The field is conditionally mandatory depending on the joining model. AttributeValue: Value according to code 1.2.246.537.5.40200.2014, or empty. Kanta services - Connection models for private service providers:	O / P mandatory if attribute urn:kanta:kvarkki:registry-code has value '3'	Imaging Data Repository

Data	SAML attribute	Use at the Imaging Data Repository	(P) Mandatory (O) Optional	Reference
		1.2.246.537.5.40200.2014 values 1 = Private service provider joined Kanta services directly 2 = Private service provider joined Kanta services through joint subscription E.g. `<PrivateHosted xmlns="urn:hl7-org:v3" xsi:type="CE" code="2" codeSystem="1.2.246.537.5.40200.2014" codeSystemName="Kanta-palvelut - Yksityisten toimijoiden liittymismallit" displayName="Yksityinen toimija yhteisliittyjänä"/>`		
Lessee	Attribute: `urn:kanta:kvarkki:private-hosted-organization`	The field is conditionally required. AttributeValue: lessee organisation OID as character string E.g. `<saml2:AttributeValue>1.2.246.10.89101112.10.0</saml2:AttributeValue>`	O (mandatory if Joint connection has value 2)	Imaging Data Repository
Lessee's service unit	Attribute: `urn:kanta:kvarkki:privatehosted-organization-unit`	AttributeValue: lessee organisation's service unit OID as character string E.g. `<saml2:AttributeValue>1.2.246.10.89101112.10.1.1</saml2:AttributeValue>`	O	Imaging Data Repository

8 Metadata model for the imaging study entity

The set of specifications of the Imaging Data Repository contains a tabular presentation (Metadata model) of metadata correspondences and the requirements resulting from the specifications. The information extracted from the DICOM data elements of the imaging study in the registration of the manifest and from the CDA documents stored in the Patient Data Repository in the registration of the referral, study and report entries has been compiled into the metadata model. CDA documents and DICOM tags of the imaging studies are mainly examined as a source of XDS metadata, i.e. the equivalent to XDS metadata in these documents are specified. The metadata model also describes the code sets to be used for metadata in code form. The metadata model also describes which registered metadata are possible search factors in the ITI-18 metadata request.

8.1 Rules for using data fields

The XDS specification includes a group of metadata and their semantic definition. In the Imaging Data Repository, it is aimed to use metadata in accordance with the IHE semantics as far as possible.

Solutions with respect to metadata for which the application of the instructions in the IHE specification is not trivial in terms of their contents and source are described in the following. The main principle in the solution has been to use the eventCodeList attribute for coded data and to use the refrenceIdList attribute for ID data as these can be used flexibly for multivalued metadata. When these metadata attributes are used, it is possible to set general national metadata for the metadata model that are specific for imaging. These attributes also enable the use of this metadata as query parameters.

The metadata referenceIdList is specified by the Reference ID option in the XDS profile, and the option must be available with support in the XDS registry products. According to the XDS rules, products that do not support the referenceIdList will handle its data as XDS extra metadata elements and the FindDocumentsByReferenceId-type registry query is not available.

Extra metadata is utilised certain special cases, mainly when it is not necessary to use metadata as a query criterion (extra metadata attributes cannot be used as a limiting query criterion). It must be noted with respect to extra metadata that only ebRIM Slot compliant data coding is available. According to Finnish legislation, all health information is

permanently confidential, which is why metadata related to the period of confidentiality restriction is no longer included in the extra metadata [12].

8.1.1 Documentary metadata

Documentary metadata in this connection includes: the service organizer, service provider, service organizer's unit, encounter, custodian, registry, registry specifier. The encounter document stored in Kanta is the master for 'documentary' metadata.

In the storing of an imaging study, the Imaging Document Source (the DICOM repository) retrieves the documentary metadata from the Patient Data Repository on the basis of the encounter ID (which is retrieved with the help of Study Instance UID found from the DICOM study) and sets them in the metadata of the manifest of the imaging study.

In order to conclude the sharing permit in consent management, no other documentary metadata for the document is needed, but only the encounter identifier as the function can be established in the centralised sharing permit query service.

According to the XDS the author is repetitive, hierarchical and in composite format metadata that presents the data of organisations and professionals including their roles. Organisation and custodian data constitute their own author recurrences, and their data (ID and name) is presented in the authorInstitution substructure. Different structures are identified with the authorRole substructure in the same author recurrence. It is also possible to provide the data of professionals related to the document in the authorPerson subelement in the same author element. The author element is used as follows:

- Professional's data: own author recurrence with an authorPerson substructure that includes the professional's data, authorRole substructure gets the value 'Professional'. If the document has several professionals, the entire author recurrence (authorPerson is not recurred).
    - It should be noted that the professional who produced the study entry can also be a medical device or software. In this case, the authorPerson structure contains the information of the EUDAMED or other medical device or software that produced the entry.
- Service organizer (service provider): own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Service organizer'.
- Service provider: own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Service provider'.

- Service provider's service unit: own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Service provider's unit'.
- Custodian: own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Custodian'.

Out of this data, only the data concerning the professional (authorPerson) may be used as a query parameter in ITI-18 queries. Other author substructures (e.g. authorInstitution) cannot be used as query parameters.

The encounter ID is mandatory for all registered documents and stored in the referenceIdList metadata in the document entry. The encounter ID can therefore also be used as a query parameter in an ITI-18 FindDocumentsByReferenceId query.

In the XDS solution, Kela is obligated to also manage the metadata in change situations (custodian changes, etc.).

8.1.2 Substance data

The metadata classifying the document type are classCode, typeCode and title. Metadata in classCode in given the document's 'rough' type, the code set for this classification is 1.2.246.537.5.5001.2011. Metadata typeCode describes 'a fairly detailed' document type and specifies the classCode value; the code set for this classification is also 1.2.246.537 5.5001. In addition to these, the document type is specified further by giving it a study code in the title metadata.

The metadata healthcareFacilityTypeCode includes a division into public healthcare, private healthcare, occupational healthcare and self-employed service provider. The method of use complies with the Patient Data Repository and the used code system is 1.2.246.537.5.40150.2009.

In the CDA R2 documents, the main view of the document is given in the practiceSettingCode metadata. The main view is determined by the document source code set AR/YDIN – Näkymät 1.2.246.537.6.12. For documents other than CDA R2 documents, the standard value 'RTG' of imaging is used. Views other than the main view of the CDA R2 document are set in the metadata eventCodeList. These are obtained from the tableOfContent element in the CDA R2 header. It is necessary to bring all views into the

metadata to evaluate especially protected information because especially protected information is based on the view data of the CDA R2 document.

The procedure code for THL's radiology procedure is stored in the eventCodeList metadata in accordance with the code set THL – Toimenpideluokitus. In connection with registering, the Imaging Document Source will deduct the corresponding code values from the anatomical region and modality code sets on the basis of the procedure code, and these are also stored in the eventCodeList metadata. EventCodeList contains coded values according the metadata specification of the Imaging Data Repository. The metadata stored in the EventCodeList is:

- modality code (only DICOM metadata),
- procedure code,
- anatomical region,
- tooth number (only CDA metadata since the definition collection 2023.1),
- view (only CDA metadata) and
- templateId (only CDA metadata).

Regarding the modality, only the modality codes according to the CID 29 Acquisition Modality set [16] are registered.

Documentary data of the encounter ID is stored in the referenceIdList metadata (see the metadata model for a specific listing). Possible referenceIdList search parameters in ITI-18 query are:

- encounter ID
- registry specifier
- Study Instance UID
- referral ID (note. a new metadata)
- AC number
    - and the issuer (if available)
- ClinicalDocument ID
- ClinicalDocument Set ID

A combination of demographics data is stored in the metadata sourcePatientInfo in accordance with XDS.

9 Content requirements of studies

In the architecture of the Imaging Data Repository, local PACS systems store the imaging studies into the DICOM repository by moving them to the Imaging Document Source. The studies are stored in the Image Repository (DICOM repository) in DICOM format in the way described in the DICOM standard. The organization that performs the storage of the imaging study is responsible for the conformity of the contents. Imaging studies must include data, which is described in connection with the metadata model, in DICOM tags.

Imaging studies must be stored using a format in which all systems retrieving studies from the Imaging Data Repository will show the key contents of the imaging study in full and in the correct way. Especially all information used as a basis for reports must be shown correctly. The inclusion of manufacturer-specific elements in an stored study is permitted, provided that the data contained in them is also included in elements that are in accordance with the standard and required by the specifications of the Imaging Data Repository. A unit producing imaging studies to be stored must not use only entries (sticky notes, etc.) recorded in the PACS database in the imaging study entries. Marking the most valuable objects is described in chapter 4.6.

The requirements for systems showing imaging studies are presented in section 13.4.

The following diagram describes the DICOM data model at the upper level:

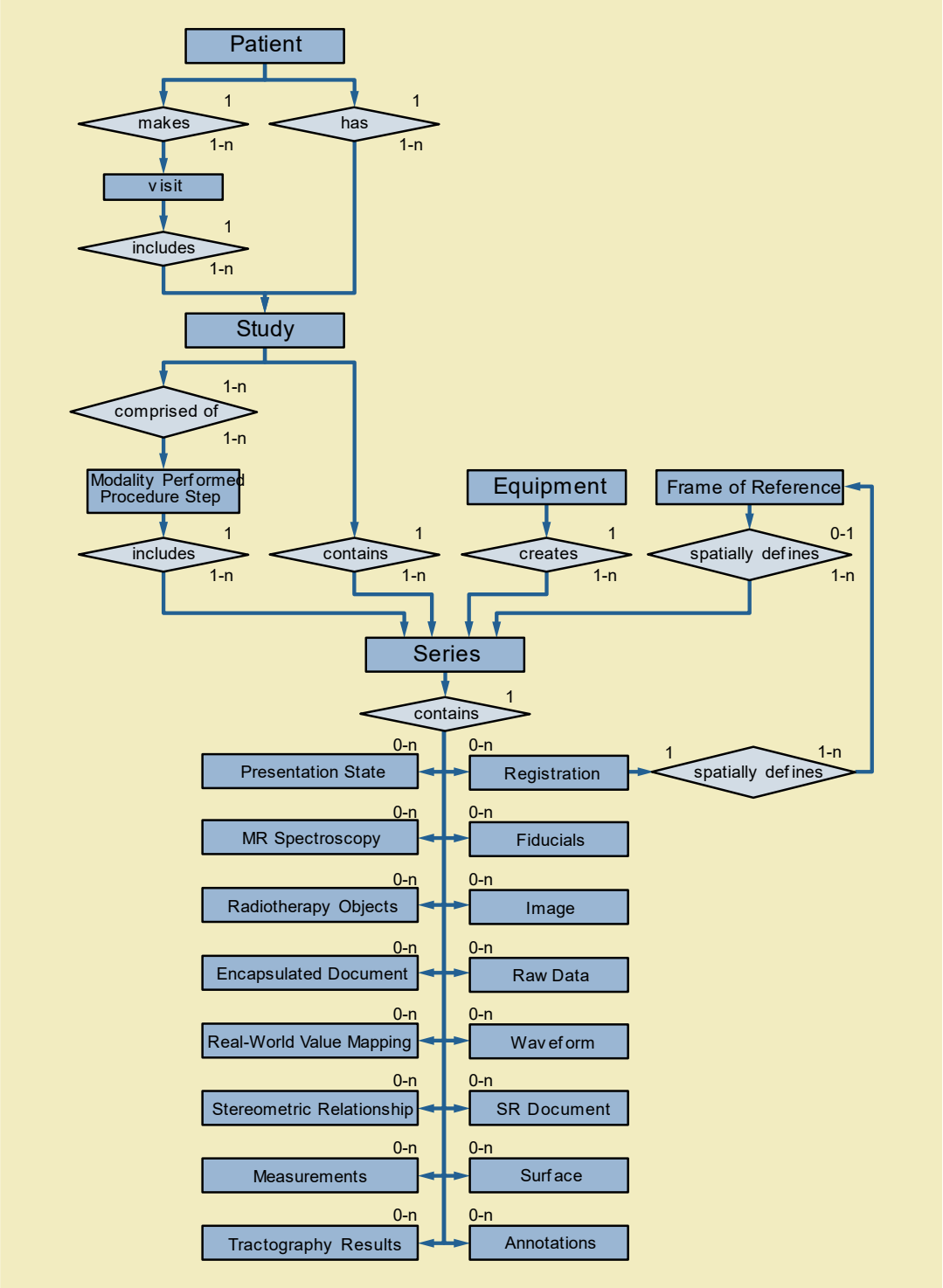

Figure 19. DICOM Model of the Real World, DICOM PS3.3 2024c [16]

Any permanent changes made in the imaging stage, such as a correction of a side marker, must be done directly to the pixel data of the image before the images are stored.

Annotations, grayscale alterations and other values related to showing the images are stored as the DICOM Presentation State objects.

The DICOM standard specifies that all instances pertaining to the same study must have identical study level data. Correspondingly, all series instances must have the same series-level data.

The supported character sets to be used are Latin-1 (ISO_IR 100) and Unicode UTF-8 (ISO_IR 192). Latin 1 is the recommendation of the ENV 41 503 standard for the Western European region.

9.1 Some notes of different content types and study groups

The study stored into the Imaging Data Repository should be in DICOM format. The valid version of the functional requirement specification of the Imaging Data Repository specifies the study groups whose storing in the Imaging Data Repository is possible.The following sub-chapters defines clarifications related to different content types and study groups. Radiological image materials are subject to the general technical requirements of this document and are not separately described in this chapter.

9.1.1 Studies in non-DICOM format

Studies that are natively in non-DICOM format can be converted to the DICOM format and store via the local/regional PACS in the DICOM repository of the the Imaging Data Repository in DICOM format. The stored study is processed in the Imaging Data Repository in the same way as normal imaging studies, and they must have the data that complies with the specification in DICOM tags and study entries stored in the Patient Data Repository. The Imaging Data Repository specifies the contents permitted in further work to enable management of uniform use of metadata (practiceSettingCode, classCode, formatCode, typeCode, mimeType) in document grouping and the utilisation possibility of studies. For the time being, the storing of video studies in the Imaging Data Repository is prohibited.

9.1.2 ECG studies

ECG studies are stored as a signal waveform. Supported transfer syntaxes are:

- 12-lead ECG Waveform Storage (1.2.840.10008.5.1.4.1.1.9.1.1)
- General ECG Waveform Storage (1.2.840.10008.5.1.4.1.1.9.1.2)
- Ambulatory ECG Waveform Storage (1.2.840.10008.5.1.4.1.1.9.1.3)

Exceptions for these are long term ECG recordings and Cardiac stress tests which may use PDF as a final reports. In this case, DICOM format of storing the study is:

- Encapsulated PDF Storage (1.2.840.10008.5.1.4.1.1.104.1)

9.1.3 Dental healthcare imaging studies

Imaging examinations taken in dental healthcare are stored in the same way as other radiological native X-ray studies. In addition, in the intra-oral dental images, the information of the tooth (e.g. tooth number) to which the imaging study applies must be produced for the imaging cda document related to the study. The Patient Data Repository supports the storing of tooth information for the imaging cda document starting from the specification collection MK2023.1 [3].

The tooth number information can be used as a search parameter (eventCodeList) in the ITI-18 query when searching for cda entries related to intra-oral dental images. When narrowing the search, it is good to note that the tooth number information may be missing from the study entry.

9.1.4 Eye healthcare imaging studies

Eye healthcare (optometry and ophthalmology) imaging studies, such as fundus imaging studies, are stored in Kanta as are radiological imaging studies. If the study involves image data to be stored in the Imaging Data Repository, the imaging report according to the cda specifications for imaging must be stored in the Patient Data Repository before the image data is stored in the Imaging Data Repository. Imaging study entries can be stored in the Patient Data Repository either for the radiology (RTG) view or for any report-type view, for example the ophthalmology (SIL) view. The image data is stored in the the Imaging Data Repository in the DICOM format. In addition, it should be noted that storing video studies in the Imaging Data Repository is prohibited for the time being.

9.2 Technical inspection of the study content

The Imaging Data Repository controls the integrity and conformity of imaging studies to be stored by carrying out validations in connection with storing. The Image Repository of the the Imaging Data Repository is connected to a validation component, which carries out the inspections. The inspection includes the following:

- Verifying with the patient's personal identification code, Study Instance UID and the imaging study entries that an encounter (service event) for the patient has been recorded in the Patient Data Repository
- It is noticeable that from the Modalities in Study (0008,0061) tag only values from CID29 are registered in the Imaging Data Repository [16]
- Requirements of the study in accordance with the metadata table of the Imaging Data Repository are verified:
    - Study description (0008,1030)
    - Patient ID (0010,0020)
        - What is also notable about the Issuer of Patient ID (0010,0021) handling in the Imaging Data Repository: at the first phase the tag is not checked and it is assumed that an official patient identifier is used. As specified in chapter 6 temporary patient identifiers are not supported in the Imaging Data Repository.
    - Study Instance UID (0020,000D)
    - Study Date (0008,0020)
    - Study Time (0008,0030)
    - Study code is verified (studyDescription 0008,1030, 5 first characters are validated study code)
        - The value used must be valid in the code set: THL – Toimenpideluokitus (1.2.246.537.6.2.2007).
        - The anatomic area (XX345) and the specifier for the anatomic part (XXX45) are picked from the study code and they are mapped into the code set for the anatomic part and set in the XDS metadata

10 Transfer and storing formats, and compression

The architecture of the Imaging Data Repository aims to minimise delays caused by data transfer and data conversions by recommending a common storing and transfer format for DICOM image files used in every DICOM repository. The architecture of the Imaging Data Repository recommends 1.2.840.10008.1.2.4.80 – JPEG-LS Lossless Image Compression file format as the storing format. However, images are stored in the format that Service Class Provider (SCP) sends them to the Imaging Data Repository.

It is also recommended to use the same storing format and transfer syntax in local PACS systems. Using lossy compression as a transfer syntax is permitted when storing imaging studies in DICOM format only if the lossy compression is used natively in the PACS system.

The DICOM standard also allows a few other storing formats and transfer syntaxes. According to the standard, some of these must be supported in any case, for example, the native format Implicit VR Little Endian. However, as the files are in a compressed format in the repositories, the images must first be uncompressed when sending in native formats and only after that sent on, and therefore it is recommended to use as the transfer syntax the same format in which the repository stores the images.

See the up-to-date list about transfer syntaxes of the Imaging Data Repository here: http://dcm4chee-arc-cs.readthedocs.io/en/latest/networking/specs/storage/storage.html#scpimagets

When selecting the storing format used in local PACS systems, the storing format used by any current DICOM repository implementations, the practices in the transition period and any conversion needs must be taken into account.

11 Affinity domain specifications

A separate document, which is available at kanta.fi webpages, has been drawn up on affinity domain specifications. The document consists of a nationally defined section that supplements this specification, as well as of a guide for the contents of a regional affinity domain specification.

12 Utilisation of IHE profiles and their options

Due to Finnish legislation and the architecture principles of national healthcare systems, profiles that support the functional entity are to be used in the Imaging Data Repository. As an example, the identification of the person carrying out a query on data required by consent management needs the XUA profile and the correction of stored material needs the IOCM profile of change management.

Many profiles include options, each of which is utilised according to the functional or contentual need of the Imaging Data Repository. Many profiles also have plenty of application alternatives. According to the IHE principles, the affinity domain provides instructions for the application of profiles.

The Imaging Data Repository does not directly utilise IHE profiles related to the workflow. Imaging also involves profiles (Access to Radiology Information (ARI), Consistent Presentation of Images (CPI), Consistent Presentation of Images (CPI), NM Image (NM)), which are not utilised by the Imaging Data Repository or the compliance of which is not required.

IHE specifies a number of content profiles in relation to imaging. The content profiles concerning the imaging studies themselves, i.e. the DICOM objects, are suitable for use in the Imaging Data Repository. Content profiles concerning CDA documents define contents on which HL7 specifications have been drawn up in Finland, e.g. in connection with the Kanta services. With respect to imaging CDA documents, the Imaging Data Repository utilises existing Finnish content formats specified by HL7.

Profiles in the IHE draft level (trial implementation) are utilised where it is required by the functionality of the first stage of the Imaging Data Repository.

The following sub-chapters present the extent and method of utilising each profile in the Imaging Data Repository.

12.1 Cross-Enterprise Document Sharing for Imaging, XDS-I.b

The Cross-Enterprise Document Sharing for Imaging profile is important with respect to the model of the Imaging Data Repository [2]. The profile defines the formation and content of the manifest formed from the stored imaging study by the Imaging Document Source, as well as its storage and further its registration. The Imaging Document Consumer is required to

support the option transaction of the Retrieve Imaging Document Set [RAD-69] in order to be able to retrieve the imaging studies from the Imaging Document Source of another domain.

The profile defines three alternatives for the structure and saving of the report. Instead of these, the Imaging Data Repository uses the imaging study document defined in connection with the Patient Data Repository and its storage in the Patient Data Repository. This solution is closest to the CDA Imaging Report with Structured Headings alternative of the profile, but the document is not stored in the repository.

12.2 Cross-Enterprise Document Sharing, XDS.b

The profile is essential in terms of the model of the Imaging Data Repository; it is a content-neutral profile that forms a basis for a similar profile in imaging [1]. The Imaging Data Repository implements the Asynchronous Web Services Exchange option

The Imaging Data Repository implements the Reference ID option, which enables storing a reference from outside the domain and using it as a query criterion in document retrieval.

12.3 Cross Enterprise User Assertion, XUA

The Imaging Data Repository transmits the data of the service request sender and patient care context to the actor offering the service for using in the consent management deductions. The data is transmitted in a way specified by XUA, i.e. with SAML 2.0 technology [15].

In XDS and XDS-I transactions implemented in a concrete way as a web service in the Imaging Data Repository, the specified XUA assertion elements are located in the header section of the SOAP query message, while the message content specified by the functional XDS and XDS-I profiles is in the body section of the SOAP message. The same XUA element content is used in all transactions.

12.4 Consistent Time, CT

CT specifies the use of Network Time Protocol (NTP) servers in the clock settings. NTP works well in the Imaging Data Repository, and it is also in accordance with the operating model required by Kanta.

12.5 Audit Trail and Node Authentication, ATNA

The identification and authentication of parties takes place in the Imaging Data Repository in accordance with the ITI Audit Trail and Node Authentication profile.

The audit trail specified by the profile does not meet the requirements of share and use logging, and it is not utilised in the Imaging Data Repository for these purposes. The audit trail produced by the systems in accordance with the profile has a technical log status in the Imaging Data Repository.

12.6 Key Image Note, KIN

The principles of the profile are utilised in the study content requirements with a purpose of supporting interoperability in the processing of entries.

12.7 Evidence Documents, ED

The principles of the profile are utilised in the study content requirements with a purpose of supporting interoperability in the processing of entries.

12.8 Imaging Object Change Management, IOCM

IOCM covers changes for object rejection for quality or patient safety reasons, as well as corrections resulting from carrying out an incorrect study [7]. Furthermore, removal of objects after the retention period is included in the profile but it is not implemented. A profile included in the radiology specifications approved from the Imaging Data Repository point of view specifies the changes to be made in the imaging study.

Changes made by the organisation in the imaging studies produce an altered content in the Imaging Data Repository in accordance with IOCM. The Imaging Data Repository requires that changes in the correction of imaging studies and in other change management are stored as DICOM objects in the studies in accordance with the IOCM principles, and the changed imaging study is stored into the Imaging Data Repository. Information about the changes is stored in the Imaging Data Repository in accordance with the IOCM expansion proposal.

Due to storing of imaging CDA documents in the Patient Data Repository, a change in accordance with IOCM will not cover them, and this has been specified separately.

12.9 Patient Identifier Cross-referencing, PIX and PIXV3

The PIX profile transactions, i.e. HL7 version 2.5 messages are used as they are in use in the current systems.

13 Software requirements

The functional and technical requirements of the Imaging Data Repository subsystems and systems integrated in the Imaging Data Repository from the viewpoint of these systems are compiled in this chapter. The chapter does not include requirements that have not been presented in the previous chapters, but it describes them from a different perspective as a kind of reference list with a purpose of facilitating the entity of the Imaging Data Repository and the systems connected to it, as well as the preconditions for introducing the Imaging Data Repository.

13.1 XDS profile options and expansions

The Imaging Data Repository uses the referenceIdList metadata to connect documents to an encounter and to connect imaging documents with the Study Instance UID. The ReferenceIdList metadata is specified by the Reference Id option of XDS.

The software used must support the Reference Id option. With respect to the XDS registry, support means the possibility of using the FindDocumentsByReferenceId format in the registry query (ITI-18) in addition to saving the multivalued referenceIdList metadata. The encounter and Study Instance UID linking in registry queries can only be utilised with this query format.

With respect to viewers and other systems acting as a Document Consumer actor, the support for the Reference Id option means an ability to use the FindDocumentsByReferenceId format in registry queries.

The Imaging Document Consumer is expected to support the option transaction of the Retrieve Imaging Document Set [RAD-69] in order to be able to retrieve the imaging studies from the Imaging Document Source of another domain.

It is recommended that the Document Consumer and Imaging Document Consumer support the Asynchronous Web Services Exchange option, which enables the management of delays in the retrieval of large documents.

XDS determines the Document Metadata Update option, which is in the trial implementation stage. The option is needed in the document deletion functions after the end of the retention period and possibly in some change management functions.

13.2 Requirements for the support of non-IHE profile features in products

Implementation of consent management in the way described in this specification requires that the product used for the implementation of a domain-specific configuration of the Imaging Data Repository supports the connection of a tailored policy enforcement point implementation to the handling of metadata and document requests and Imaging Document Source queries.

The imaging document source must support the connection of the inspection of tailored saving right when storing an imaging study. Tailored implementation inspects the existence of an encounter and the storing organization right to store documents in it. The function has been described in chapter 4.2 of this specification.

The management of document retention time and deletion functions are not included in the IHE profiles. Due to national requirements, the implementation is tailored, but it requires that the product has service, e.g. to delete documents.

13.3 XUA support in the client program

In all XDS and XCA transactions, the inviting client must include in the query the information about the user's identity and patient care context, as well as other information specified by XUA. The patient care context is an addition to the data required by IHE XUA, specified in the Imaging Data Repository, and the Imaging Data Repository defines the specifications also with respect to other data contents.

The user's identity must be sufficiently reliable in accordance with the trust relationship and the principle of the identification of parties. The client software must be integrated into the patient care context so that the encounter ID and other patient care context data are available.

The client must be able to include in the query the specified SAML2 elements and the data required in them.

13.4 Reliable presentation of imaging studies in viewer functions

An application handling the contents of imaging studies and presenting to the user must present the contents of the study reliably and in their entirety. A study that meets the content requirements for studies must be shown correctly and consistently. The reject KOS must be

handled in the right way when handling objects that are in accordance with IOCM and removed for quality or patient safety reasons.

13.5 Production of an imaging study that meets the requirements

The modalities, PACS and radiology tool programs used must store the imaging study objects according to the DICOM standard applied and the content specification of the Imaging Data Repository.

The inclusion of manufacturer-specific presentation and storing formats in an stored study is permitted provided that the data contained in them is also included in elements that are in accordance with the standard and the specifications of the Imaging Data Repository.

14 Data communication encryption

The use of data encryption is required in service requests of the Imaging Data Repository. The traffic of XDS and XDS-I transactions is encrypted, using DVV's healthcare server certificates. TLS two-way authentication is in use.

Encryption takes place in accordance with the TLS 1.2 specification (or the latest Kanta data communications specifications). If PACS does not support this, the connection must be tunnelled.

15 Management of error situations

The Imaging Data Repository does not enable any manual error correction functions focusing directly at the repository.The correction of contentual or metadata errors in stored material takes place in the systems that have stored the material, e.g. as described in connection with change management in chapter 4.5. With respect to the Imaging Data Repository, content corrections constitute document versioning. The error codes of the XDS interface are described in Appendix 4.

The Imaging Data Repository can detect errors in the content of the imaging study being stored. Error situations detected in connection with studies made into the DICOM repository or the storing of new versions of studies are handled in the way described in the DICOM standard.

Sufficient technical control must be organised in order to detect technical malfunctions. Malfunctions must be remedied through routine procedures in service production while providing instructions for the operations. These kinds of error situations do not give rise to the need to correct the data contents of the repository.

15.1 Error codes returned by the DICOM repository

Immediate errors detected in connection with the storing and change processing of studies are returned as errors of FAILURE class in C-STORE processing in accordance with the DICOM standard, stating that the requested storing of the study has not been carried out. (DICOM standard section PS 3.4 [16]). The response statuses returned in the C-STORE processing of the Imaging Data Repository are described in the DICOM Conformance Statement: http://dcm4chee-arc-cs.readthedocs.io/en/latest/networking/specs/storage/storage.html#id10

Further revisions are also carried on studies stored in the Imaging Data Repository due to national requirements, in which case the status codes used also belong to the FAILURE error class defined by the DICOM standard (error reason):

- Error: Cannot understand (Cxxx)
    - Errors related to the sent contents, it is not worth trying to resend it as such. Storing of the study may only be successful through corrections of the contents carried out by the client with the aid of information obtained from the error code.

- Refused: Out of Resources (A7FF)
    - Technical errors within the Imaging Data Repository are always returned with the same Out of Resources code A7FF. In these cases, error correction is Kela's responsibility as one of the subsystems is not working correctly in this situation. The client may attempt resending once the error has been corrected.

Both of these enable returning of the code and the corresponding comment (error reasons). In the error reason, the error code and the reason for the error in question are returned to the client.

Dicom tags returned from further revisions in the Imaging Data Repository:

- (0000,0900) Status (of the format Cxxx or A7FF)
- (0000,0902) Error Comment (reason in English, a total of max 64 ASCII characters)

Error situations interpreted from C-STORE Failure due to extra verifications, and the corresponding error codes with their recovery instructions have been listed in further detail as an appendix to this specification (Appendix 1), which will be maintained as and when new revisions are taken into use. The errors are described in English.

Error situations interpreted from the DICOM Storage Commitment are described in the DICOM Conformance Statement of the Imaging Data Repository: http://dcm4chee-arc-cs.readthedocs.io/en/latest/networking/specs/storage/storage.html#id12

15.2 Technical error correction

At the technical level, it is possible to correct error situations that are mainly due to operational malfunctions. The mechanism used is almost exclusively retrying.

- The system may automatically retry to perform the service call
- A retry of the service call takes place as the user's manual function

15.3 Error situations in the operating processes

Error situations requiring corrections carried out by the operating process.

- Correction of errors detected in the verification of storing
- Described in connection with change management (chapter 4.5)
- Described in connection with temporary identifiers (chapter 6.1)

- Corrections of imaging CDA documents (correction procedure in accordance with the Kanta specifications)

In storing, the Imaging Data Repository may detect errors in the contents of an imaging study. The error is indicated with a structure according to DICOM Failure Status Class and specific error codes. An error situation must be followed by an indication to the body responsible for sending so that failed storing will be noted and reacted to in the appropriate way (e.g. correction and restoring of study).

16 References

[1] IHE International, ”Volume 1: Profile definition, use-case analysis, actor definition, and use of transactions and content. IHE IT Infrastructure (ITI), revision 20.0,” 2023. [Online]. Available: https://profiles.ihe.net/ITI/TF/Volume1/index.html.

[2] IHE International, ”Volume 1: Integration Profiles. IHE Radiology (RAD) Technical Framework, revision 21.0,” 2023. [Online]. Available: https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_TF_Rev21-0_Vol1_FT_2023-06-15.pdf.

[3] ”Kanta kuvantamisen CDA R2 merkinnät,” [Online]. Available: https://www.kanta.fi/jarjestelmakehittajat/kuvantamisen-cda-r2-merkinnat.

[4] IHE International, ”Volume 3: Document Sharing Metadata and Content Profiles. IHE IT Infrastructure Technical Framework. Revision 20.0,” 2023. [Online]. Available: https://profiles.ihe.net/ITI/TF/Volume3/index.html.

[5] ”Kanta-palvelut kevyet kyselyrajapinnat,” [Online]. Available: https://www.kanta.fi/jarjestelmakehittajat/kanta-palvelut-kevyet-kyselyrajapinnat.

[6] Kanta-palvelut, ”Tekniset liittymismallit Kanta-palveluihin -ohje,” 2021. [Online]. Available: https://www.kanta.fi/jarjestelmakehittajat/tekniset-liittymismallit.

[7] IHE International, IHE Radiology Technical Committee, ”Imaging Object Change Management Extension (IOCM Extension). IHE Radiology Technical Framework Supplement, Rev.1.7 - Trial Implementation,” 9 August 2019. [Online]. Available: https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_Suppl_IOCM_Extension_Rev1-7_TI_2019-08-09.pdf.

[8] IHE International, ”Volume 2: Transactions. IHE Radiology (RAD) Technical Framework. Revision 21.0,” 2023. [Online]. Available: https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_TF_Rev21-0_Vol2_FT_2023-06-15.pdf.

[9] IHE International, ”Volume 2: Transaction definitions and constraints. IT Infrastructure (ITI) Technical Framework. Revision 20.0,” 2023. [Online]. Available: https://profiles.ihe.net/ITI/TF/Volume2/index.html.

[10] I. T. Committee, ”IHE IT Infrastructure Technical Framework Supplement XDS Metadata Update Rev. 1.14 – Trial Implementation,” 4 August 2023. [Online]. Available: https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_XDS_Metadata_Update.pdf.

[11] Kanta-palvelut, ”Asiakas- ja potilastietojen luovutustenhallinnan yleiskuvaus versio 1.0,” 2021. [Online]. Available: https://www.kanta.fi/documents/20143/1842650/Asiakas-+ja+potilastietojen+luovutustenhallinnan+yleiskuvaus.pdf.

[12] ”Laki sosiaali- ja terveydenhuollon asiakastietojen käsittelystä 703/2023,” 14. 4. 2023. [Online]. Available: https://www.finlex.fi/fi/laki/alkup/2023/20230703.

[13] Kanta-palvelut, ”Sosiaali- ja terveydenhuollon tahdonilmaisuja käsittelevien tietojärjestelmien vaatimukset ja toiminnallinen määrittely,” [Online]. Available: https://www.kanta.fi/jarjestelmakehittajat/tahdonilmaisut.

[14] OASIS, ”Assertions and Protocols for the OASIS Security Assertion Markup Language (SAML) V2.0,” 2005. [Online]. Available: https://docs.oasis-open.org/security/saml/v2.0/saml-core-2.0-os.pdf.

[15] OASIS, ”Profiles for the OASIS Security Assertion Markup Language (SAML) V2.0,” 2005. [Online]. Available: http://docs.oasis-open.org/security/saml/v2.0/saml-profiles-2.0-os.pdf.

[16] NEMA, ”The DICOM Standard,” [Online]. Available: https://www.dicomstandard.org/.

Appendices

Appendices are mainly available in Finnish only.

Appendix 1: DICOM Error codes and recovery guide. Error codes and recovery instructions for national further revisions of DICOM validation in connection with C-STORE. The appendix is available at: https://www.kanta.fi/jarjestelmakehittajat/tekninen-maarittely-liite-1-dicom-validoinnin-virhekoodit%C2%A0

Appendix 2: XUA digital signature guide. The appendix is available at: https://www.kanta.fi/jarjestelmakehittajat/tekninen-maarittely-liite-2-xua-allekirjoituksen-maaritys

Appendix 3: XDS example requests. The appendix is available at: https://www.kanta.fi/jarjestelmakehittajat/tekninen-maarittely-liite-3-xds-esimerkkisanomat

Appendix 4: IHE XDS Interface error codes of the Imaging Data Repository. The appendix is available at: https://www.kanta.fi/jarjestelmakehittajat/tekninen-maarittely-liite-4-xds-rajapinnan-virhekoodit

Appendix 5: Definition of HL7 ADT messages of the Imaging Data Repository. The appendix is available at: https://www.kanta.fi/jarjestelmakehittajat/tekninen-maarittely-liite-5-hl7-adt-sanomien-maaritys