



# X-eHealth

Exchanging Electronic Health Records  
in a common framework

## **X-eHealth Deliverable D5.4 - Medical Imaging and Imaging Reports Guideline and functional specifications**

**WP5 - Definition of eHRxF Functional Specifications**

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## Abbreviations

Acronym	Description
AI	Artificial Intelligence
ICD-10	International Statistical Classification of Diseases and Related Health Problems 10th Revision
Radlex	Lexicon of radiological Information
SNOMED CT	Systematized Nomenclature of Medicine -- Clinical Terms
ESR	European Society of Radiology
CT	Computed Tomography
DVD	Digital Video Disc
ECG	Electrocardiogram
EEHRxF	European eHealth Record Exchange Format
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
EEG	Electroencephalogram
EIS	Enterprise Image Server
EMG	Electromyography
EMIR	Enterprise Medical Imaging Repository
EU	European Union
EUG	Electro-urogram
HIS	Hospital Information System
IMRT	Intensity-Modulated Radiation Therapy
JPEG	Joint Photographic Experts Group
MRI	Magnetic Resonance Imaging
MS	Member State
PACS	Picture Archiving and Communication System
PET	Positron Emission Tomography
PNG	Portable Network Graphics
RIS	Radiology Information System
RSNA	Radiological Society of North America
SPECT	Single-Photon Emission Computed Tomography
SR	Structured Report
SWF	Scheduled Workflow
EHR	Electronic Health Record
DICOM	Digital Imaging and Communications in Medicine
IHE	Integrating the Healthcare Enterprise
HL7	Health Level 7
FHIR	Fast Healthcare Interoperability Resources
CDA	Clinical Document Architecture
UI	User Interface
UID	Unique Identification Number
USB	Universal Serial Bus
VNA	Vendor Neutral Archive
XDS	Cross-Enterprise Document Sharing



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## Executive Summary

The document provides the functional specifications for cross-border and cross-enterprise exchange of medical imaging and reports. While mainly focused on semantic interoperability, the document also elaborates on some general legal, regulatory and organisational aspects that are important for sharing documents and data within the imaging domain. The scope of the document is focused on sharing of medical imaging and reports, including the sharing of only the report and only the image as the most common imaging use cases. IHE-profiles, DICOM, HL7 CDA and FHIR and LOINC, and SNOMED-CT are identified as baseline standards. A brief overview of the standards is provided, as well as some examples of implementation in various countries. Illustrative data models and process diagrams are presented. The document provides a broad overview of the imaging domain and guidelines for further development of functional building blocks and semantic elements.

# 1 Introduction

## 1.1 Purpose of this document

This document describes the business needs, use cases and functional specifications for the interoperable exchange of medical images and imaging reports between European Member States. These functional specifications constitute the foundation for the accompanying technical and implementation specifications that are described in this project. As a whole, these specifications (together with those for laboratory requests and results, hospital discharge reports and the ability to codify rare diseases) contribute to the growing family of the European Electronic Health Record exchange Format (EEHRxF) specifications, as agreed upon in 6 February 2019 by the EC Recommendation to build interoperable electronic health records ensuring adequate protection and security of data for citizens across the EU.

### 1.1.1 The imaging domain

Medical imaging encompasses a wide domain of techniques and procedures to visualise the internal structures or functioning of the body, that normally cannot be seen from the outside. It provides insight into the location, size, structure, density and movement of anatomical and other structures. Imaging techniques are used in all stages of the healthcare process, from prevention, diagnosis, intervention to follow-up. It enables healthcare professionals (increasingly assisted by image processing algorithms) to find the right diagnosis, guide therapeutic decisions and aide in surgical procedures.

### 1.1.2 Developments and innovation

Over the last decades, digital imaging and image processing techniques have provided new and highly improved ways to assess and improve the health situation of patients. Just a few developments that reflect the innovative power of this domain are: new imaging technologies such as MRI and SPECT, 3D representations and colouring of specific body systems, artificial intelligence to highlight and count specific body structures and tumours, reduced radiation exposure, increased processing speed and quicker viewing, higher image resolution, combined viewing of images from different sources and (interactive) reports, improved workflow support and integration with EHRs, extended availability of images and from any location are just a few examples of this innovative domain.

These innovations and improvements, together with the already existing imaging techniques, have drastically increased the use of imaging techniques, in the entire healthcare domain. Specialties where imaging is used extensively are radiology, nuclear medicine, cardiology, cardio surgery, dentistry and dental surgery, dermatology, gastroenterology, gynaecology, internal medicine, neurology, oncology, pathology, pulmonology, and surgery.

### 1.1.3 Sharing of medical information

Due to the growing number of age- and lifestyle-related diseases, healthcare has developed from a one-on-one, to a multi-specialty, multi-location process. For example, in the Netherlands, more than 20 % of the patients are treated in two or more hospitals within the same year. As patients can only be treated effectively when all the relevant medical information is available for the treating physician, this necessitates the sharing of medical data, including images.

#### 1.1.3.1 Standardisation

As soon as medical images were stored digitally, it became clear that they could be viewed from any computer in a hospital, or even across multiple locations, organisations and regions. But it also became apparent that you could only view these images if you owned proprietary hardware and software from the same vendor, and that a non-proprietary data format was needed. In 1993, vendor-neutral storage of digital data was facilitated by the DICOM<sup>1</sup> standard that enabled viewing of any kind of digital image or film using a

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<sup>1</sup> [DICOM \(dicomstandard.org\)](http://dicomstandard.org)

fully specified data format. DICOM has evolved along with the imaging technologies and has grown into the global standard format for sharing all types of medical images in healthcare. As medical imaging has become such an important part of the healthcare process, integration of imaging into healthcare information systems and standardisation of workflows also became critical. To further improve the alignment of the imaging processes with other healthcare domains, radiologists and imaging software vendors together founded Integrating the Healthcare enterprise (IHE) IN 1998<sup>2</sup>. The main goal of IHE is to improve the way IT systems in healthcare share information, to address specific clinical needs in support of optimal patient care. It does this by creating implementation specifications for standardised interfaces between IT systems, using existing standards in the process.

### **Need for further specification**

Standardisation has been very successful in the imaging domain and within an individual healthcare organisation. Picture Archiving and Communication Systems (PACS) in hospitals are closely connected to (or integrated in) hospital information systems that enable all healthcare professionals to quickly access and view the relevant information for the task at hand. But when information is to be shared in a regional, national or international setting, new interoperability requirements emerge. This document focuses on the functional specifications that support the international exchangeability of medical information and thereby enable the quick, safe and interoperable imaging information exchange in healthcare. These new requirements, which can be seen as extensions of the already available standards, will enable the seamless and immediate availability of imaging information at any location within the EU, allowing for better patient outcomes for its citizens.

The X-eHealth project has identified four topics that require further standardisation:

- Categorisation and naming of medical documents (findability)
- Structure and data definition of imaging reports (interoperability, reusability, translatability)
- Information exchange mechanisms and infrastructure (accessibility)
- Cross-organisational and cross-border imaging workflows (quality, efficiency)

Each of these topics explores new terrains in standardisation and therefore require a lot of work. However, the foundation has already been laid by existing standards and in several Member States initiatives. The X-eHealth project has used these initiatives to specify the necessary extra components of interoperability in the imaging domain.

### **Structure of the document**

This document describes the functional requirements and specifications for a structured and sustainable exchange of medical images and imaging reports among European countries. It is laid out as follows:

- Overview of the extensive imaging domain, its history and current developments
- Presentation of three priority use cases that describe the context for the functional specifications related to the four topics described above
- Exploration of existing standards and implementation best practices and guidelines that can be reused as input for the functional specifications

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<sup>2</sup> [Integrating the Healthcare Enterprise](#)

- Introduction and a methodology related to the four topics described above, combining existing materials and harmonising them into a proposal for new standards.
- Provision of the specifications for each of the topics
- Collection of the findings and identifying future challenges for the imaging domain.

## 1.2 Domain overview

### 1.2.1 Medical imaging

Medical imaging refers to technologies and processes used to create images of the human body for clinical analysis, diagnostic and treatment purposes. It encompasses many different purposes, techniques, specialties and procedures.

### 1.2.2 Purpose of imaging

Imaging techniques are used for many purposes and in all stages of healthcare. In public health and preventive medicine, in curative and in palliative care, effective decisions depend on correct diagnoses. Though clinical judgment may be sufficient prior to treatment of many conditions, the use of diagnostic imaging services is paramount in confirming, correctly assessing and documenting courses of many diseases as well as in assessing responses to treatment.

Imaging is used in the **prevention** domain for the screening of certain diseases such as breast cancer. As a **diagnostic** tool, imaging facilitates the accurate diagnosis, assessment of injuries and prognosis of the patient. Imaging procedures can also be used for combined diagnostic and therapeutic purposes (also called **theranostic**). **Therapeutic** interventions or image guided procedures include interventional cardiological and radiotherapeutic interventions.

### 1.2.3 Imaging technologies

From a science perspective, imaging technology uses electromagnetic, electric or mechanical signals to detect body structures or functions and processes these measurements into a visual representation.

Electromagnetic radiation is used to classify by wavelength into different 'bands': radio waves, microwaves, infrared, visible light, ultraviolet, X-ray, gamma radiation, positron radiation, see figure 1.

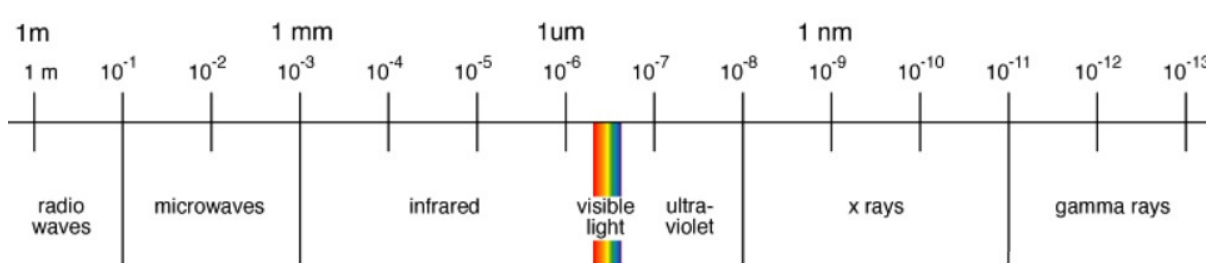


Figure 1 - electromagnetic spectrum

Almost the entire electromagnetic spectrum can be used for medical imaging. Examples are Magnetic Resonance Imaging (MRI), thermography, X-ray radiography, Computer Tomography (CT) and nuclear imaging that uses injected or ingested radio-opaque materials, such as Positron Emission Tomography (PET) and Single-Photon Emission Computed Tomography (SPECT). Medical photography uses the spectrum between infrared and ultraviolet waves, including visible light.

Examples of electric measurements are ECG, EEG, EMG and EUG. These can be recorded in graphs that allow interpretation of muscular activity.

Mechanical forces such as ultrasound or elastography can be used for echography.

## Image processing

The combination of hardware (machine, device) and accompanying software (that processes the electrical signals) used in imaging are called *modalities*. The software translates the “raw” measurements and recordings through medical processing techniques into visual representations such as images, movies, graphs or maps, which can then be used for analysis. The term *image processing* also includes technologies to further enhance the images, for the purposes of selective visualisation, colour-coded 3D visualisations, automatic measurements and other interpretation-enhancing techniques.

### 1.2.4 The DICOM standard

The global standard for medical images is DICOM (Digital Imaging and Communications in Medicine). It offers a standardised representation of images, together with related contextual information. It encompasses a uniform methodology for the capture, storage and distribution of medical images anywhere in the world. In other words: any DICOM-based image can be viewed by any DICOM-compatible application. Although originally created for radiological images, DICOM also provides services such as managing imaging procedure worklists, printing images on film or digital media like DVDs, reporting procedure status like completion of an imaging acquisition, confirming successful archiving of images, encrypting datasets, removing patient identifying information from datasets, organising layouts of images for review, saving image manipulations and annotations, calibrating image displays, encoding ECGs, encoding CAD results, encoding structured measurement data, and storing acquisition protocols. The overall logical structure of a DICOM file is represented by the schema and explanation below.

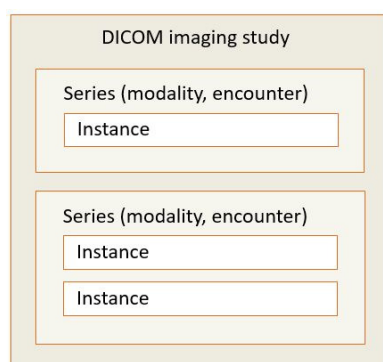


Figure 2 schematic overview of DICOM image study structure

## Imaging study

In DICOM, images are stored in container documents called *imaging studies*. An imaging study comprises a set of objects, including images and other objects, that were made for a specific purpose and usually in relation to a specific question from a healthcare provider. An imaging study consists of one or more imaging results (called *series*, see below), from one or more sources (called *modalities*, see below). It also records the necessary contextual information of the imaging study and of the images it contains, such as the hardware that was used to create them, the technologies and settings that were used, date, time and location, the healthcare professionals and organisation involved in the process and many more. An imaging study is identified with an *accession number*. This accession number is the link to the accompanying imaging report(s), which are (currently) separate from the DICOM imaging studies themselves.

## Series

Each DICOM study contains one or more *series*. A series is defined as a set of one or more DICOM *instances* (see below) that were generated by the one equipment (*modality*, see below) at one encounter/session with the patient. A single imaging study can contain different types of modalities in a series, for example, within a single study, there may be a PET series, a CT series, and a plain X-ray image.

## Instance

An instance is the smallest component of the DICOM world, representing a persistent storable object, such as a slice of a CT scan or 3D image consisting of many 'layers'. Each DICOM instance is a *composite object* containing the image itself, and the necessary metadata (header) information to describe that instance. For example, an MRI instance is not just pixel data. The "header" of the MR image contains the patients name, institution, imaging parameters, etc., thus it is a "composite object" which can be transferred and shared in its entirety (header plus pixel data). DICOM has defined specifications/templates for many different types of instances, such as Structured Report (SR), Radiation Therapy (RT), Waveform, Presentation State (PS), etc. These templates are called *Information Object Definitions* (IODs) and can be found in Part 3 of the DICOM standard.

## Modality

A DICOM modality represents either the equipment that was used to acquire the data (e.g., CT, MRI, X-ray), or describes the type of data (e.g., RadioTherapy object, Secondary Capture). The DICOM Modality is one of the contextual structured information elements (tag 0008,0060) that describes the combination of hardware (machine, device) and accompanying software used in the creation of a series and instances.

### 1.2.5 Image storage and categorisation

A Picture Archiving and Storage System (PACS) is a platform for the digital storage, retrieval, viewing and annotation of medical images, specifically DICOM studies. PACS makes it possible to handle huge volumes of data related to medical images. Any computer that is connected to a PACS server can retrieve, view and modify DICOM images. PACS servers can store and access at a local, regional or national level, or form a network of interlinked storage locations (federated model). The images are stored in high quality, allowing for what is called *diagnostic viewing*. Due to the standardised format, DICOM images can be viewed by any DICOM software, including zooming, panning, contrast enhancement, viewing separate layers, annotation and so forth. It also allows for additional annotation layers that allow healthcare professionals to add measurements, highlight sections, and add textual comments to the original image. In the DICOM format, images are stored with a predefined set of administrative, technical and medical contextual information (metadata).

Historically, images from non-radiology related sources (such as visible light medical photography, ultrasonic and electrographic images such as ECGs) were stored in different storage systems and usually in formats such as JPEG or PNG. However, there is a strong trend to store these images (and recently, also images of microscopy coupes) in the DICOM format. One of the reasons is the standardised metadata of the DICOM, that also strongly links to the patient. This increases patient safety.

### 1.2.6 Standardisation challenges

Although DICOM specifies an extensive range of metadata, there are still elements that have not (yet) been fully specified. The exponential growth of medical documentation warrants a closer look at those elements that have not been specified yet, where they may be used for quicker location of the right type of information. In general, this is the topic of *metadata*, which can be defined as information about the documented information and is the main topic of chapter 4 of this document. For the DICOM standard, one metadata element that is not defined yet is the standardised categorisation of the different kinds of imaging



studies. So far, this has been left to the discretion of the healthcare professional or organisation, leading to the proprietary naming of these studies. This may work within one healthcare organisation, but even at the local level there is a risk of missing information when images studies of a certain type are being stored under different categories. When expect to find an “Ultrasound of the upper abdomen” and a colleague has stored that study with the title “Stomach Echo”, information can get lost. At a regional, national, and international level, this problem increases exponentially. Extra standardisation of metadata, including a uniform naming and coding convention for the most frequently used imaging studies is needed for interoperable findability and sharing of imaging studies.

### 1.2.7 Metadata – a broader perspective

The metadata related to and embedded in DICOM objects are mainly image oriented. In healthcare, the number of health-related documentation is growing exponentially, not just in the imaging domain. A more generic and unified methodology for the categorisation of <any> document would help in this aspect. These external registries define the parameters needed to fill in the metadata for any document or information container. If present, these more generic metadata can be automatically provided by the already embedded metadata of the different structured and standardised document types (FHIR resources/bundles/compositions, for example). More on this topic can be found in chapter 4.

## 1.3 Image reporting

An imaging report reflects the observations and interpretations of an image study. It usually contains elements such as the reason why the study is requested, relevant contextual medical information, the used modality and its settings, procedures and body localisations that were used, a description of the observations and findings, and a conclusion and advice. An image report is part of the legal record of the episode of care and communicates the findings and recommendations to the referring physicians and to the patient. Some of the information for a standardised imaging report can be extracted from the structure of the DICOM study. Even though DICOM supports a structured report (SR) as part of its standard, imaging reports are typically stored separately from the images, within a radiology information system (RIS) or increasingly in an EHR environment such as a hospital information system (HIS). The link between an image study and the accompanying report is the so-called *accession number* of the imaging study that is stored within a PACS.

Reporting on image studies is usually performed by radiologists or other specialists. Many specialists use dedicated speech recognition software that enables reporting while simultaneously viewing the images. Currently, almost all imaging reports are unstructured. This is partly due to the narrative aspect of the report, which creates challenges for structured registration. Also, structured data entry requires a learning curve, another way of working and dedicated software. Speech recognition software has only recently developed possibilities for structured data entry and the user interface is not always very user-friendly. But mainly, a standard approach to imaging reports is needed, at the document, paragraph, and concept level.

## 1.4 Image viewing and sharing

Frequently patients are treated by more than one doctor and/or in more than one institution. Images and associated metadata should be shared between professionals on different levels: within an organisation, between organisations, regionally/nationally or across country borders. This can be accomplished in three ways:

- (1) sharing by copying data,
- (2) sharing by giving digital access to data in either the EHR or a (common) data storage(s) or
- (3) promoting complete interoperability. Each with its own level of interoperability.

### Local integration



Within healthcare organisations, the viewing, reporting and ordering of images and workflow support is increasingly integrated into the organisation's information system (or EHR). This allows for a seamless integration in the workstation of the healthcare professionals. Local agreements on naming conventions for the different types of imaging studies may become necessary. In many current systems, there is a large degree of freedom for the naming of such studies.

#### **Cross-organisational image and workflow sharing**

The benefits of inter-organisational image sharing include the immediate availability of medical images in all connected locations, teleradiology, the potential for external consultation and shared decision making. It also avoids the cumbersome, unsafe and costly physical copying of DICOM studies to USB sticks, DVDs, unsecure mail attachments, et cetera.

For the seamless integration of image sharing and common workflows between healthcare organisations, more alignment is needed than at the local level. Organisations must agree on the sharing of 'their' medical data, on responsibilities, on security and on authorisations. Common protocols for workflows are needed to guarantee an efficient workflow. Agreements must be made on how image studies are named, so that healthcare professionals can find image studies where they expect them to be in the list of available studies. As the scale of multi-organisational sharing increases and becomes regional or national, agreements will usually be replaced by robust and usually international standards.

#### **Cross-border sharing**

Cross-border exchange of imaging information requires agreements related to the understandability and translatability of imaging reports. Shared vocabularies, naming and coding conventions and the use of international standards and profiles are needed to enable the smooth exchange of imaging information.

#### **Sharing with the patient**

When images are available in a secure environment, healthcare professionals and patients alike can have access to these images. Citizens will only access their own images. Extra information and guidance may be provided to help patients understand what they see.

## **1.5 Challenges and opportunities**

### **Challenges**

The interoperable exchange of medical images across borders requires cross border alignment and standardisation, on all levels of interoperability. At each level, agreements and standards must be agreed upon and implemented, a process which involves close collaboration with all relevant stakeholders.

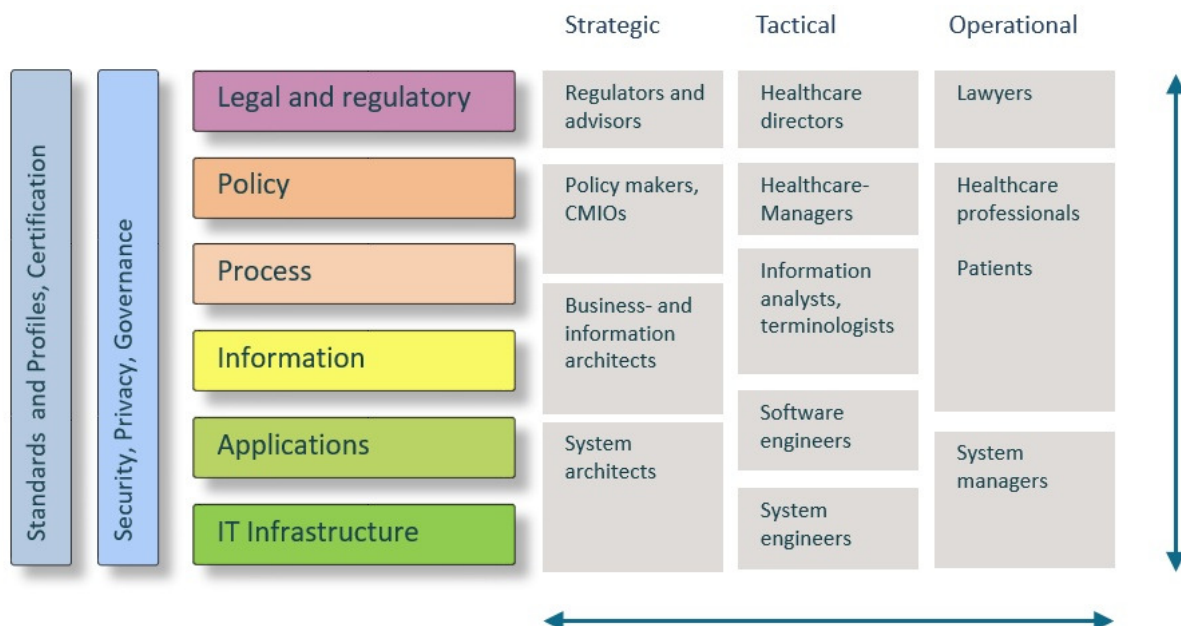


Figure 3 -ReEIF interoperability levels and stakeholders

For the imaging domain, some of the interoperability requirements have already been met, with the DICOM specification of the format of image studies, and with workflows supporting IHE profiles such as Scheduled Workflow (SWF)<sup>3</sup> within a hospital. However, more work is needed to create an ecosystem where imaging information can be shared and reused across the EU.

The main challenges for the interoperable exchange of medical images and imaging reports are:

Standardisation of the categorisation of imaging studies and imaging reports at the document level (document metadata);

- Standardisation of imaging reports at the section level (synoptic reporting);
- Standardisation of imaging reports at the concept level (structured reporting);
- Standardisation of exchange mechanisms for images and reports (application, infrastructure);
- Standardisation in security, privacy, quality and trust: identification, authentication, authorisation, patient consent, logging.

Apart from these interoperability gaps, there are legal, economical, practical, technical and ethical hurdles that may interfere with the cross-border exchange of imaging information, such as:

- Procedures or studies that are unknown in the receiving MS;
- Abbreviations in descriptive part of reports that are not understood by the receiver of the report;
- Translation errors of the free-text parts of the reports;
- Problems with workflow alignment due to different organisation of healthcare in different countries;
- Different (versions of) standards, coding and terminology systems in different MS;
- Missing information in imported images and other documents (Completeness);

<sup>3</sup> More information about SWF profile it is shown in chapter 3 of the present document.

- Traceability to the original author (provenance);
- Accountability – who is accountable when an image has been assessed remotely;
- MS regulations may define communication procedures regarding workflow (e.g., admission, intermediate results, final results) that do not match between MS;
- Possible lawsuits for wrong conclusions by AI;
- Economical or quality measures against image assessments performed by other MS.

### 1.5.1 Opportunities

The main advantages of the safe and timely availability of medical images and imaging reports throughout the EU are:

- More timely access to treatment, as the availability of previous, medical images, both in planned and unplanned care situation provide optimal care for patients.
- Reduce patient waiting times for diagnosis and treatment.
- Availability of high quality, timely and accurate data contributes to the reduction of duplication of services, reduced adverse events and more efficient use of resources.
- Reduction in the opportunities for error in the delivery of health services.
- Support the creation of, and addition of imaging to patient record.
- Facilitating cross border specialist consultation.
- By freeing up resources, clinical staff can devote more face time to patients allowing them to optimise individual care plans.
- Reduction in duplication of tests results in reduced costs for the healthcare organisation.
- Possibilities for secondary use through standardisation to improve health outcomes of patients.
- Standards-based software that will enable interoperability between systems.
- Standards based software will also help prevent vendor lock-in.
- Higher quality software for user-friendly data entry and for viewing images in combination with imaging reports to prevent errors and ease registration.
- Other opportunities for collaboration on the joint specification in the imaging domain include:
- Lifelong dosimetry passport
- Registration of adverse reactions to contrast agents and radiopharmaceuticals

## 2 Medical imaging use cases

The use cases described below support and facilitate the secured sharing of imaging studies and reports as well as their publishing, finding and retrieval. The use cases cover cross-border exchange of imaging studies and reports, but can also be used in a national, regional or local setting.

Until today, the exchange of medical imaging studies and reports on patients between the different actors is mostly non standardised and does not allow to determine their nature and an indication of their content, without opening and reading the document. In the use cases, we will address the metadata that are needed to retrieve the requested imaging studies as well as the corresponding reports. Metadata ensure that care providers can read the desired information in a targeted and more efficient manner. Metadata can also help setting up and monitoring accurate access rules. In the use cases and corresponding functional requirements, we will also address metadata.

Since most metadata apply to all four domains that are in focus of X-eHealth: laboratory results, medical imaging and reports, hospital discharge letters and rare disease information we describe these in document ID5.1 'Methodology'. Metadata that apply specifically to the exchange of medical images or reports will be described in this document, in chapter 5.

### 2.1 Business needs

Medical imaging plays an important role in healthcare; it allows the healthcare professional to get a better idea of the cause of the symptoms, the location of anomalies and it serves as guidance for treatment. Approximately 30% of EU citizens live close to member states borders, or travel between member states. Also, when a citizen is traveling from one EU member state to another, the ability to access previous medical images and reports is crucial in providing optimal care. There is a wide variety of imaging possibilities, both technically and purpose-wise.

The role of medical imaging in the healthcare process is to create images of various parts of the human body for clinical analysis, diagnostic and treatment purposes, to provide a better understanding of the patient's health at that point in time. This is mainly done in hospital or specialist settings but can be done within various other healthcare settings e.g., dentists, GP's and maternity centres.

Imaging techniques are used for many purposes and in all stages of healthcare. In public health and preventive medicine, in curative and in palliative care, effective decisions depend on correct diagnoses. The use of diagnostic imaging services is paramount in confirming, correctly assessing and documenting courses of many diseases as well as in assessing responses to treatment.

Imaging is used in the **prevention** domain for the screening of certain diseases such as breast cancer. As a **diagnostic** tool, imaging facilitates the accurate diagnosis, assessment of injuries and prognosis of the patient. Imaging procedures can also be used for combined diagnostic and therapeutic purposes (also called **theranostic**). **Therapeutic** interventions or image guided procedures include interventional cardiological and radiotherapeutic interventions.

### 2.2 Scope and Interdependencies

The objective of the document is to define the functional specifications for the exchange of Medical Imaging and Reports. For cross-border care in eHDSI, we have identified the following general high level use cases, which we'll describe in table 1 below:

#### Use Case 5.4.1 - Querying, retrieving, and viewing of Imaging Studies and Reports

**Use Case 5.4.2 - Imaging Report sending****Use Case 5.4.3 - Imaging Study sending**

Use Case 5.4.4 - Imaging Report sharing with patients

Use Case 5.4.5 - Multidisciplinary Board Meeting

Use Case 5.4.6 - Radiation Dose Report

**NOTE**

Although the use cases 5.4.1 to 5.4.6 are described in chapter 5, only the use cases 5.4.1, 5.4.2 and 5.4.3 will be in scope for further specification. In the table below, these are indicated as "In scope, Priority 1". Use cases 5.4.4, 5.4.5 and 5.4.6 are indicated as "In scope, Priority 2". These use cases will not be worked out further in the X-eHealth specifications.

**The scope of the use cases will include/exclude the following elements:**

**In scope for this the X-eHealth project:**

- Address the described use cases below which concern
  - Inpatient cases with a medical imaging exam previously done in another country and needed for comparison;
  - Emergency cases and urgent admissions which resulted in a medical imaging exam taken in country A and needed by the healthcare professional in the country B;
  - Special types of an inpatient cases, e.g., a breast cancer screening, when patient lives closer to healthcare facility in Country B;
  - Both cross-border exchange as well as national, regional and exchange within an organisation are considered. Some national healthcare systems are organised in a federation of regions, so all data collection and management need to be developed at a regional level. Therefore, it is important to also consider use cases that show added value on a regional level too;
- Define the minimal required set of metadata (related to the patient, encounter, procedure, etc.) associated with the above-mentioned use cases;
  - Identify the source(s) of each piece/set of metadata;
- Describe and define the required data to exchange in imaging studies and reports;
- Describe and define the harmonised process flows;
- Medical imaging studies refer to different types of techniques, see Chapter 1.

**Out of scope for the X-eHealth project:**

- Detailed specifications for use cases 5.4.4, 5.4.5 and 5.4.6
- The ordering and worklist workflow for the medical imaging;
- Advanced video management like editing and annotation;
- Definition of standard procedure codes;
- Imaging taken in country B and needed by the healthcare professional in the country of Affiliation, country A;

- Recommendations on user interface for the viewing of lists of available imaging studies and reports, sorted by time, purpose, author, modality or other metadata attributes or combinations thereof. In principle, all the metadata elements that accompany medical documents can be used for filtering, grouping and sorting these lists.

### Interdependencies

This document will be the main input for WP6 – Definition of EEHRxF Implementable Specifications, specifically Deliverable 6.2.1 – X-eHealth Implementation Guide: Diagnostic Imaging Report and Deliverable 6.2.2 – Technical Specifications for Images. This document will also be used by task T5.5 - Hospital Discharge Report and T5.6 – Rare Diseases (Patient Summary) It will also serve as a starting point for WP7: Deliverable 7.1 – X-eHealth Architecture definition to implement and deploy EEHRxF services. ‘Medical images and reports guidelines and functional specifications’ is not directly dependent on any other project task; however, it considers results of the surveys performed by WP1 regarding the current status of the laboratory domain in the participating EU member states.

## 2.3 Medical imaging and reports use cases for cross-border data exchange

High level use cases identified for cross-border EEHRxF are summarised in **Erro! A origem da referência não foi encontrada..** The use cases are classified from the project scope point of view and a working priority is assigned.

Several use cases could be performed on different scale levels: from cross-border, national/regional, to within an organisation or patient level. For the X-eHealth project we will focus on cross-border exchange, but we do acknowledge that the other levels may apply. Please find below the description of each level:

- Cross-border: exchange of imaging studies and reports from Country A to Country B
- National/regional: the use case is applicable nationally or at least in one or more regions.
- Within the healthcare organisation: exchange of imaging studies and reports in one organisation, from department X to department Y.
- Citizens at home and on the move: indicate that use case involves patients both at home and on the move

The detailed use cases and corresponding functional requirements can be found in Chapter 5.

**Table 1: List of imaging studies and reports use cases for cross-border EEHRxF**

Use case number	Use case name	Comments	Priority and scope
UC 5.4.1	Querying, retrieving, and viewing of Imaging Studies and Reports (pull)	Imaging studies and imaging reports need to be retrieved by the requesting Healthcare Provider:  When a previous published imaging study and report is needed for comparison to make the right clinical decision.  In case of emergency or	In-scope Priority 1

Use case number	Use case name	Comments	Priority and scope
		as continuity of care	
UC 5.4.2	Image report sharing (pull)	<p>Reports from the imaging examinations can be shared:</p> <ul style="list-style-type: none"> <li>reported to the ordering entity and/or reported to another than the ordering entity (e.g., in case of referral)</li> <li>report should contain machine and human readable content</li> <li>report could contain imaging data or references to it.</li> <li>In case of emergency or Continuity of care</li> <li>Findings of patient's examination</li> </ul>	In-scope Priority 1
UC 5.4.3	Imaging study sharing (pull)	<p>Images can be shared in order to provide clinical information for:</p> <ul style="list-style-type: none"> <li>Continuity of medical care</li> <li>Acute settings in case of emergency</li> <li>a second opinion</li> <li>an expert for image analysis and description</li> </ul>	In-scope Priority 1
UC 5.4.4	Image report sharing with patients	<p>Imaging reports that will be shared with the patient or his/her guardian</p> <p>The imaging report could contain imaging data or a reference to it.</p>	In-scope Priority 2
UC 5.4.5	Multidisciplinary board meeting	<p>Imaging studies and reports should be retrieved and available in a multidisciplinary board meeting: in these meetings different specialists work together closely sharing clinical decisions in care. The composition is variable, depending on the type of issue discussed.</p> <p>The availability of imaging studies and corresponding structured reports is crucial for the specialists to take the best possible decision on treatment.</p>	In-scope Priority 2
UC 5.4.6	Radiation dose report sharing	<p>The European Directive <a href="#">2013/59/EURATOM</a> sets out the basic safety standards for protection against the dangers arising from exposure to ionising radiation. This directive must be implemented by all EU M/S. This</p>	In-scope Priority 2

Use case number	Use case name	Comments	Priority and scope
		could also be an extension of the Patient Summary There is a need for a standardised Dose Report to ease registration and exchange	
UC 5.4.7	National Screening Program	This would require a central location for image and report storage. The 4 domains agreed this is not in our project scope	Out-of-Scope
UC 5.4.8	Timeline Overview	This is a wish for the future. Requirements need to be clarified.	Out-of-Scope

The priority levels are defined as follows:

1 – Priority 1- X-eHealth partners value the use case as most urgent as felt by the user community to be implemented within the imaging and reports domain.

2 – Priority 2 – X-eHealth partners value the use case as medium urgent as felt by the user community to be implemented within the imaging and reports domain. Although the use cases are described at a high level in this document (chapter 5), they have not been worked out into specification, due to the time constraints of the project.

3 – Priority 3 – X-eHealth partners value the use case as least urgent as felt by the user community to be implemented within the imaging and reports domain. These use cases have not been worked out, due to the limited time of the project.

Out-of-Scope: indicated as not relevant at this moment within the goals of X-eHealth Medical Imaging and Reports domain

Priority 3 does not apply to the domain of medical imaging and reports. It does, however, to the other domains; laboratory requests and reports



## 3 Overview of existing Standards and Guidelines

### 3.1 Work process and tools

Medical imaging is used to view the human body to diagnose, monitor or treat medical conditions. It is essential that the medical images produced are of the highest quality as they have a direct bearing on patient outcomes. From a workflow perspective, it's important to integrate image processing methods that are generating quantitative results into the workflow. These results then populate directly into radiology reports and graphic summaries, thus helping the healthcare professional. It's also possible that applications and algorithms analyse radiology reports and translate them into more useful summaries. For example, such applications could analyse reports such as the total amount of tumours in a body over time or indicate whether a particular drug is working as via reduced tumour size image. This kind of information could potentially be linked to a decision-support function that provides a differential diagnosis. However, workflow integration is a precondition that will be necessary before these types of applications become routine. There are many standards and formats available for storing and sharing medical images. The primary standard, used globally, is referred to as the DICOM format and nowadays most of the medical imaging equipment manufactured conforms to this standard<sup>4</sup>. Viewing of the images requires a special diagnostic medical imaging program known as a DICOM workstation.

#### Existing standards, profiles and terminologies

To achieve interoperability within and across disparate healthcare IT systems, existing standards, profiles and terminologies for both narrative and structured clinical information need to be synchronised across multiple applications (at a local, regional, national, or international level). Below we describe the most common existing standards, profiles and terminologies.

### 3.2 DICOM

The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) formed a joint committee in 1983 to develop a standard for image storage and distribution. The first and earliest publication of Official Standards entitled ACR/NEMA No. 300-1985, known as version 1.0, was released in 1985 with the aim of "promoting the communication and storage of digital image information, regardless of the manufacturer of the device".

In 1993, after several revisions, ACR-NEMA Standard 300 was substantially revised and replaced by this Standard, designated Digital Imaging and Communications in Medicine (DICOM).

The DICOM standard is an international standard that defines the formats of medical images that can be exchanged with the data and quality necessary for clinical use. DICOM is the most widely used and implemented imaging standard in the world. For more than 20 years this standard is being used worldwide and should be used for non-text (images, waves, photographs ...) data exchange. A medical image by itself does not provide enough information to be meaningful. For it to be correctly interpreted, it must be accompanied by patient and acquisition data (for example, demographic and patient identification data, information about the acquisition and about the exam). For this reason, traditional formats such as .jpeg or .png do not provide all the necessary information for the professionals who review them.

Therefore, the **DICOM standard is focused on the handling, storage, printing, querying and transmission of medical images.**

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<sup>4</sup> [Advances in Diagnostic Medical Imaging that have transformed Healthcare | PostDICOM](#)

The DICOM standard is divided in different parts, each one explaining different important features of the standard, like Part 3 where the different Information Object Definitions is defined, in Part 4 the characteristics that all service classes share, or Part 5 that specifies how applications construct and encode information. On the other hand, DICOM Part 18 defines DICOMweb<sup>5</sup>, which specifies web services using the HTTP family of protocols for managing and distributing DICOM Information Objects, such as medical images, annotations, reports, etc. to healthcare organisations, providers, and patients.

**DICOM Part 20<sup>6</sup>** includes a specification for transformation into CDA documents of DICOM Structured Report instances that represent imaging reports. Within this scope are clinical procedure reports for specialties that use imaging for screening, diagnostic, or therapeutic purposes. This Part (20) constitutes an implementation guide for CDA and is harmonised with the approach to standardised templates for CDA implementation guides developed by HL7. It also provides Business Names for data elements that links data in user terminology, e.g., collected by a report authoring application, to specific CDA encoded elements.

As an implementation guide for imaging reports, particular attention is given to the use and reference of data collected in imaging procedures as explicit evidence within reports. This data includes images, waveforms, measurements, annotations, and other analytic results managed as DICOM SOP Instances. These templates reduce variability, improve interoperability and standardise best practices. It also supports the automation of report production and the validation of the report content.

### 3.3 HL7

HL7 International is a non-profit Standards Development Organization for the health field, founded in 1987 that operates internationally, currently being one of the most important messaging standards in medical informatics.

HL7 International has developed a set of standards whose main objective is to specify messaging for the communication of clinical, demographic and financial information, between computer systems. There are some standards within HL7 that have other focuses, but messaging is one of the strongest aspects of HL7.

#### 3.3.1 HL7 V2.x

In March 1987 a committee of healthcare providers, vendors and consultants and other participants in the international healthcare market, shared a common goal of simplifying the implementation of interfaces between computer applications from different, and often competing, vendors. This committee, which subsequently became known as the HL7 Working Group, endeavours to standardise the format and protocol for the exchange of certain key sets of data among healthcare computer application systems.

From this joint work came the messaging standard HL7<sup>7</sup> for the electronic interchange of health data most widely used internationally in the health field.

HL7 messages allow embedded images to be exchanged between computer systems. These can be attached to a segment of type OBX-Observation (only in messages that incorporate this type of segment) encoding the image in Base64, incorporating a pointer (for example, a URI to a DICOM image stored in a PACS of a centre) or including the CDA that incorporates the image itself.

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<sup>5</sup> [The term DICOMweb is used to designate the RESTful Web Services described here](#)

<sup>6</sup> <http://dicom.nema.org/medical/dicom/current/output/chtml/part20/ps3.20.html>

<sup>7</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=403](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=403)

### 3.3.2 HL7 CDA Release 2

HL7 CDA R2 is the basic standard for document interchange that provides an architecture, coding, semantic framework and markup language for the creation of clinical documents, using the HL7 information model (RIM), the HL7 V3 methodology and controlled or local vocabularies (SNOMED CT, ICD, LOINC, etc.). HL7 CDA documents are encoded in XML (Extensible Markup Language).

CDA can support any kind of clinical information that can be included in a patient's medical record, like a discharge summary<sup>8</sup> prescriptions, history and physical examination, specialist reports, laboratory reports, diagnostics, immunisations or discharge letters, among many other possibilities.

In the HL7 website, the **Implementation Guide for CDA Release 2 - Imaging Integration** can be found. The purpose of this Implementation Guide is to describe constraints on the CDA Header and Body elements for Diagnostic Imaging Reports. It is intended to convey the interpretation to the referring (ordering) physician and become part of the patient's medical record. It is intended for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.

DICOM Part 20 (see chapter 4.2.1 DICOM) is a validated implementation guide for CDAR2: Imaging report.

### 3.3.3 HL7 FHIR

HL7 FHIR<sup>9</sup> (Fast Healthcare Interoperability Resources) is the HL7 standard for the exchange of healthcare data. It combines the best features of the HL7 V2.x, HL7 V3 and HL7 CDA R2 standards taking advantage of the latest web standards, being easy to design and implement.

The standard defines a set of resources that represent the information of granular clinical concepts, such as a patient, a medication, a medical device or a procedure performed for a patient.

FHIR defines the resource **ImagingStudy**<sup>10</sup>, which provides information on a DICOM imaging study, and the series and imaging objects in that study. It also provides information on how to retrieve that information in a native DICOM format, or in a rendered format, such as JPEG.

FHIR also defines the resource **DiagnosticReport**<sup>11</sup>, which includes clinical context such as requesting and provider information, and some mix of atomic results, images, textual and coded interpretations, and formatted representation of diagnostic reports.

One clear benefit with FHIR within the field of radiology is the ability to quickly probe for relevant clinical information. The power of FHIR comes from the simplicity of the queries to fetch specific data, eliminating the need for complex searches in the EMR. One example is the ability to query specifically for the presence of an iodinated contrast allergy, instead of authenticating with the EMR and searching through a list of all the patient's allergies. With FHIR, imaging software can query clinical information mined from the EMR and integrate it with other clinical systems used by the radiologist.

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<sup>8</sup> A sample of Discharge Summary can be found here: <https://confluence.hl7.org/display/CDA/Discharge+Summary>

<sup>9</sup> <http://www.hl7.org/>

<sup>10</sup> [ImagingStudy - FHIR v4.0.1 \(hl7.org\)](#)

<sup>11</sup> [DiagnosticReport - FHIR v4.0.1 \(hl7.org\)](#)

### 3.4 IHE

IHE (Integrating the Healthcare Enterprise) is an initiative of healthcare professionals and industry that improves the way healthcare information systems share information. It promotes the coordinated use of established standards such as DICOM and/or HL7 to achieve optimal patient care. IHE improves healthcare by providing specifications, tools and services for interoperability, and engages clinicians, health authorities, industry, and users to develop, test, and implement standards-based solutions to vital health information needs.

The Profiles can be considered in different classes<sup>12</sup>

#### Content Profiles

Content Profiles addresses the management of a particular type of content object. There are a number of content profiles describing the details of creating and storing various types of image or image related objects, and frequently they would be created in the context of IHE Scheduled Workflow<sup>13</sup> (SWF). Scheduled Workflow integrates ordering, scheduling, imaging acquisition, storage and viewing for Radiology exams. The profile addresses how the object is created, stored, queried and retrieved, but does not address the workflow management process.

Some of these profiles are:

- the Nuclear Medicine Image (NM) profile, which specifies how Nuclear Medicine images and result screens are created, exchanged, used and displayed;
- the Mammography Image (MAMMO) profile, which specifies how Mammography images and evidence objects are created, exchanged, used and displayed;
- the Evidence Documents (ED) profile, which specifies how data objects such as digital measurements are created, exchanged, and used;
- or the Key Image Note (KIN) profile, which lets users flag images as significant (e.g., for referring, for surgery, etc.) and add notes.

#### Workflow Profiles

Workflow Profiles addresses the management of the workflow process which typically involves providing worklists, and reporting/monitoring the progress and completion of work-items. Within this context, one or more content objects are generally created according to their content profile. Some of these profiles are:

- the **Scheduled Workflow (SWF)** profile, which shows how to integrates ordering, scheduling, imaging acquisition, storage and viewing for Radiology exams;
- the Patient Information Reconciliation (PIR) profile, which coordinates reconciliation of the patient record when images are acquired for unidentified (e.g., trauma), or misidentified patients;
- or the Post-Processing Workflow (PWF) profile, which provides worklists, status and result tracking for post-acquisition tasks, such as Computer-Aided Detection or Image Processing.

#### Infrastructure Profiles

Infrastructure Profiles addresses departmental issues. Some of these profiles are Cross-enterprise Document Sharing for Imaging (XDS-I.b) detailed in the section below “IHE profiles used for imaging”, which extends:

- XDS to share images, diagnostic reports and related information across a group of care sites;

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<sup>12</sup> [Profiles - IHE Wiki](#)

<sup>13</sup> [IHE Scheduled Workflow](#).

- Audit Trail and Node Authentication - Radiology Option (ATNA), which defines Radiology-specific audit trail messages and security measures to protect patient information confidentiality;
- or Cross-Enterprise Reliable Document Interchange for Imaging (XDR-I), which extends XDR to push images, diagnostic reports and related information between healthcare providers.

### Presentation Profiles

Presentation Profiles addresses the presentation of images. Some of these profiles are:

- the Consistent Presentation of Images (CPI), which maintains consistent intensity and image transformations between different hardcopy and softcopy devices;
- the Key Image Note (KIN) which lets users flag images as significant (e.g., for referring, for surgery, etc.) and add notes;
- or Presentation of Grouped Procedures (PGP), which helps view and report individual requested procedures (e.g., head, chest, abdomen) that an operator has grouped into a single scan.

### 3.4.1 IHE profiles used for imaging

IHE defines different profiles to standardise and share clinical images used in different domains and use cases. The most remarkable profiles are:

- *XDS-I.b Cross - enterprise Document Sharing for Imaging.b* is an interoperability profile that extends XDS (which provides a standards-based specification for managing the sharing of documents between any healthcare enterprise) to share images, diagnostic reports and related information across a group of care sites.
- *XCA-I Cross-Community Access for Imaging* profile supports the means to query and retrieve patient relevant medical imaging data held by other communities.
- *XDR-I Cross-enterprise document reliable interchange of images* profile provides DICOM®SOP instances and image reports using a reliable messaging system.

All the IHE profiles for imaging have been defined in Annex I of the present document.

### 3.4.2 National Extensions – IHE Technical Framework

National Extensions to the IHE Technical Framework address specific local healthcare needs and facilitate local implementation of the IHE Technical Framework.

They may add requirements to the Technical Framework generally or to specific Profiles, Actors, Transactions, or Content Modules. Since systems must still comply with the original Technical Framework, National Extensions may not rely on or introduce conflicting requirements.

IHE National Committees are responsible for drafting National Extensions. Typically, this happens after identifying a specific local healthcare need or implementation issue during the review, selection and promotion of Integration Profiles within their country.

### Selection and harmonisation process

### 3.4.3 Introduction

In this section, we describe two different ways to successfully introduce cross-border harmonisation. The first process is using the Guideline for interoperable XDS Affinity, and the second harmonising structured reports with DICOM.

### 3.4.4 Harmonisation using the IHE Guidelines

IHE describes the harmonisation process in the “Guideline for interoperable XDS Affinity Domains” document<sup>14</sup>. This document defines the XDS (Cross-Enterprise Document Sharing) and XDS-I profiles that facilitate the secure, reliable and interoperable exchange of medical documents and images within XDS Affinity Domains, based upon the profile interoperability requirements that vendors must follow in their implementations.

An XDS Affinity Domain is a group of healthcare enterprises that have agreed to work together using a common set of policies and share a common infrastructure.

Examples of XDS Affinity Domains include:

- Community of Care supported by regional health information organisations to serve all patients in a given region.
- Nationwide EHR
- Specialised or Disease-oriented Care
- Cardiology Specialists and an Acute Cardiology Centre
- Oncology network
- Diabetes network
- Federation of enterprises
- A regional federation made up of several local hospitals and healthcare providers
- Government sponsored facilities (e.g., VA or Military)
- Insurance Provider Supported Communities

These requirements specify actors and transactions that enable software products from different vendors to cooperate and exchange information. In the case of XDS, they also specify the document metadata concepts that constitute the XDS document registry. For some of these metadata elements, the values that can be assigned to these concepts are defined in the profile specifications. However, for other metadata elements, these values have not been defined and are left to the implementing parties to assign.

Within an Affinity Domain, this may work out fine, because the participating healthcare organisations draw up their own set of metadata as they go along. But as the XDS communities mature, share a broader range of health information and increase in number, these communities are interested in becoming interconnected. This is the point when cross-community IHE profiles such as XCA (Cross-Community Access) support information exchange between XDS Affinity Domains. However, the lack of a uniform definition of these metadata elements across communities becomes an obstacle for true interoperability. The current XDS metadata constraints set in the XDS and XCA profiles still leave too many degrees of freedom to enable 125 seamless interoperability between Affinity Domains.

In countries where XDS networks are being set up, initiatives have risen to establish national metadata definitions of these hitherto not sufficiently defined metadata elements. In 2016, IHE representatives from 10 different countries (Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, the Netherlands, Switzerland, United Kingdom), IHE Europe and the US have joined forces in the International XDS Metadata Taskforce, with the following goals:

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<sup>14</sup> Guideline for interoperable XDS Affinity Domains: [https://www.ihe-europe.net/sites/default/files/2017-11/IHE\\_ITI\\_XDS\\_Metadata\\_Guidelines\\_v1.0.pdf](https://www.ihe-europe.net/sites/default/files/2017-11/IHE_ITI_XDS_Metadata_Guidelines_v1.0.pdf)



- To share experiences on XDS implementation in European countries;
- To share views on how the metadata are used (use cases, terminologies, data);
- To find a common way to harmonise the metadata
- To build an implementation guide for those wanting to implement XDS metadata in future projects

### 3.5 Harmonisation DICOM Structured Reports (SR)

DICOM SR is a mechanism for encoding annotations that works with clinical PACS (encoded and stored like DICOM images).

The HL7 organisation has developed the CDA standard, which was initially known as the Patient Record Architecture (PRA), for the healthcare industry. The CDA standard is based on extensible markup language (XML) and is mainly designed to provide an exchange model for clinical documents such as discharge summaries and progress notes. The complete CDA will include a hierarchical set of documentation specifications.

The current CDA standard has defined only the top hierarchy, which is known as CDA Level One and became an American National Standards Institute (ANSI)–approved standard in 2000. It represents the first specification derived from the central HL7 Reference Information Model (RIM). CDA Level Two is a set of templates or constraints that can be layered on top of the CDA level. CDA Level Three will include a fully SR-compatible model to enable SR documents to exchange information with non-DICOM devices, such as information systems.

HL7 and DICOM have worked together to harmonise the CDA and SR efforts and to avoid gratuitous incompatibilities, but no mechanism of bi-directionally trans-coding SR to CDA with full fidelity is yet formally defined by either group or may never be.

CDA contains a means of encoding regions of interest in referenced images that provides similar mechanisms to those present in DICOM, as well as similar mechanisms for encoding concepts from controlled vocabularies. Similar graphic element types are used, and the same mechanism is used for referring to two-dimensional coordinates as column and row pixel offsets from the top left-hand corner of an image. CDA follows the HL7 V3 practice of using Unified Medical Language System (UMLS) Concept Unique Identifiers (CUI) as code values, rather than the traditional SNOMED code values that DICOM uses, but these can be mapped to one another with no information loss. The code system, which DICOM refers to as the coding scheme designator, is encoded as a globally unique identifier, specifically as an OID (Object Identifier), which is the same as a DICOM Unique Identifier (UID); these can also be mapped with full fidelity to and from the DICOM representation, and DICOM also has added specific mechanisms to encode the mapping of standard or private coding scheme designators to UIDs in a document instance.

### 3.6 Existing Implementation Best Practices and Guidelines

This section shows different implementation guides and other tools and methods elaborated in different projects, working groups and collaborations between different stakeholders in real life with the aim of improving and solving the exchange of imaging studies and reports.

The implementation guides specify a set of rules on how interoperability or standard problems can be solved using associated documentation to support and clarify the usage.

Below are examples of implementation guides and specifications that have been published to date:

- A great deal of work has already been done by among others the Radiological Society of North America (RSNA) and the European Society of Radiology (ESR). They developed globally harmonised

and standardised profiles for workflow in the Radiology domain. The major suppliers of PACS and RIS systems have implemented **scheduled workflow of IHE**. In **Austria**, for the project ELGA, an **implementation guide for hospital imaging diagnostic reports** was specified using standard HL7 CDA R2 standard. The aim of this implementation guide is to describe the structure, format and standards of medical documents in the electronic health record "ELGA" in accordance with the Health Telematics Act 2012 (GTelG 2012), but also for medical documents in the Austrian health system.

- The content requirements and the structure of the ELGA findings were developed together with numerous experts from the medical profession, nursing, hospitals, research as well as with representatives of the Austrian Medical Associations, standardisations and software manufacturers and adopted as the national HL7 standard.
- In **Belgium** there is a broad adoption of PACSonWEB which is a Secure Web-based System for the Distribution and Exchange of Medical Images. It is a platform that is connected to the local systems of the medical imaging departments. The purpose of the application is to visualise medical imaging examinations and to share them between healthcare providers and with the patient. Studies and reports in the cloud can be easily accessed by physicians and patients alike: anytime, anywhere. The platform is based on pure HTML5 web technology that lends support to all scenarios for the secure delivery of medical images and reports to extramural recipients. Integration is possible with all major RIS/PACS solutions in Belgium (AGFA, Carestream, Sectra, Fujifilm, etc.) communicating over DICOM and HL7 (or other report format) protocols.
- In the **Czech Republic**, two independent image sharing platforms are available. ePACS uses a VPN network, which interconnects medical care providers in the whole country since 2010 and uses peer-to-peer model. This solution became more popular than older ReDiMed, which uses end-to-end encryption and client-server architecture. Therefore, we can assume that the competition on the "market" of DICOM exchange, the peer-to-peer exchange has proven to be more viable solution.
- **HL7 Italy** has developed the **implementation guide** to define, according to the HL7 CDA R2 standard, the structure of the **CDA for Radiology Reports** that is valid in the Italian context. This document is one of the clinical documents considered strategic for the interoperability of the regional Electronic Health Records by the Technical Table coordinated by AgID (Agenzia per l'Italia Digitale) and MdS (Ministero della Salute) in which the representatives of the Regions, the Ministry of Economy and Finance, the CNR and the CISIS were actively involved. The Technical Table has given a mandate to some regions to coordinate 9 interregional thematic groups for the definition of information content and CDA specifications of documents deemed strategic for the interoperability of Electronic Health Records between regions. In particular, the Radiology Report document is one of the clinical documents' objects of the work of Group 1. Given the national importance of the activities, the process of developing the document in "Fast Track" was adopted.
- In **Catalonia (Spain)** an **implementation guide** for publishing imaging reports in a cloud repository (Shared Clinical History of Catalonia) using web services with the data of the report structured in the CDA was elaborated, as well as radiological image (studies) of a patient generated in the healthcare centre. In Catalonia the project SIMDCAT<sup>15</sup> (Digital Medical Imaging System of Catalonia), started in 2016 by the Department of Health of Catalonia<sup>16</sup>, aims to take advantage of the potential offered by Cloud-computing, and allows the digital medical images generated by the 450 centres and all the professionals of the SISCAT (Comprehensive Health System for public use of Catalonia) to be stored and shared safely. As a result, all medical imaging information is accessible to any SISCAT centre. The main added value that this solution brings to the Health System is that it transforms the large amount of information contained in medical imaging tests (X-rays, CT scans, PETs, Mammograms ...) into meaningful data that can be analysed by the HCP. All this information is centralised in the Cloud and

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<sup>15</sup> SIMDCAT Project (English): <https://ticsalutsocial.cat/wp-content/uploads/2021/12/Digital-Image-in-Catalonia.pdf>

<sup>16</sup> <https://www.ciospain.es/sanidad/cataluna-lleva-a-la-nube-su-sistema-de-imagen-medica> (spanish)



available to the Health System, and this opens the door to apply AI algorithms (one of the most promising fields in the world AI is precisely the medical image and having all this information centralised).

- In Catalonia (Spain) as part of the deployment of the SISCAT Information Systems Master Plan, a new specialised service, known as Pat-SIMDCAT came into operation on 24 January 2022<sup>17</sup> with the aim to manage, store and finally to distribute anatomical pathology digital images such as whole-slide images (WSI) in DICOM standard from the pathological anatomy services generated from SISCAT centres. Pat-SIMDCAT presents multiple benefits to the agents of the health system of Catalonia. On the one hand, professionals in this specialty are provided with a networked work environment based on cloud technology and the anatomo-pathological diagnosis process is optimised so that medical images are made available to professionals immediately and safely digitised. As for patients, quality of care is improved and patient safety increased. Finally, by offering a common and shared system for all providers, Pat-SIMDCAT yields a sustainability model reducing the cost of the whole system.
  - During 2022, 7 hospitals of the Catalan Institute of Health that are part of the DigiPATICS project<sup>18</sup>) are being connected gradually to Pat-SIMDCAT and it is expected to progressively integrate the rest of SISCAT centres in the coming years.
- **Slovenia** has a national portal Teleradiologija/Teleradiology,<sup>19</sup> enabling sharing of medical images. Three basic scenarios are supported: query at a distant healthcare provider for given patient ID (“pull”), transfer of digital images to a distant healthcare provider upon patient referral (“push”), and upload of digital image to the central national repository (accessible nation-wide). Imaging reports (pdf) are shared via the national EHRx platform (Central Registry of Patient Data). Sharing of medical images and reports is only accessible to authorised professionals within a secure national eHealth network zNET.
- **The government of Australia** developed the **CDA implementation guide** for diagnostic imaging report to take implementers step by step through mapping each data component of the DIR SCS (Diagnostic Imaging Report Structured Content Specification) to a corresponding CDA attribute or element.
- The implementation guide also contains descriptions of both constraints on the CDA and, where necessary, custom extensions to the CDA, for the purposes of fulfilling the requirements for Australian implementations of DIR. The resulting CDA document can be used for the **electronic** exchange of DIR information between healthcare providers. In addition, this implementation guide presents conformance requirements against which implementers can attest the conformance of their systems.
- In **The Netherlands**, currently there is no central infrastructure to exchange images and other documents due to historical reasons. Instead, exchange of such documents has been organised at the regional level. The exchange mechanism that is most widely used is based upon the IHE **Cross-enterprise Document Exchange (XDS)**.
- In 2020, the [Twiin](https://www.twiin.nl/) program delivered an exchange portal (sending images and reports) with the DVDexit project, as a first step towards Image Availability: retrieving images within the radiologist's work environment. During 2021, almost all 74 hospitals are connected, as well as a number of independent clinics and centres for medical diagnostics. A growing number of healthcare facilities is even able to share data with patients. The international IHE XDM standard and DICOM Mail standards are used for the communication. The project is finalised and maintenance of this national network is

<sup>17</sup> <https://salutweb.gencat.cat/ca/detalls/Noticies/anatomia-patologica-incorpora-sistema-imatge-medica-digital-catalunya>

<sup>18</sup> <https://www.mdpi.com/2075-4418/12/4/852/htm>

<sup>19</sup> <https://telerad.ezdrav.si>

now in the hands of [VZVZ](#). Further development takes place together with the users under the umbrella 'Twiin portal'. Around 100.00 results are being distributed on a monthly basis through the network.

- The Dutch association of Radiologists (NVvR) is aiming for a paradigm shift: instead of exchanging or retrieving imaging studies and reports, they want to move to a system where the medical images and reports are accessible/available to any Healthcare Professional who is authorised and needs these medical data to provide the best possible care. A precondition in this approach is what they call a 'timeline' or 'historic overview' where all earlier results of medical exams are available. This can only be achieved by applying and displaying the right metadata. Hence the metadata are seen as a key element in the project. The term 'exchange' according to the NVvR should be replaced by 'accessibility' or 'availability'. Currently the Dutch Standard for Medical Image Availability by [NEN](#), the NEN7541 is being set up by a group of experts from the Twiin program, the NVvR and from the supplier side.
- The Twiin program is in the process of setting up a framework of agreements on all five layers of the Interoperability Model to exchange data in healthcare, one of these exchanges being images and reports. Within this framework an implementation guideline for IT-suppliers and healthcare providers is available on the application and infrastructure layers. One of the starting points in the Twiin program is the application of international standards; this way it will enable the sharing of data across borders. The knowledge and experience achieved within the Twiin program is used in the creation of a quality standard for image availability and is closely working together with Nictiz in the creation of an information standard for image availability.
- According to the study<sup>20</sup> entitled '**Artificial intelligence in radiology**' released by Ahmed Hosy, Chintan Parmer et al, in Nature Reviews Cancer, AI methods excel at 'automatically recognising complex patterns in imaging data and providing quantitative, rather than qualitative, assessments of radiographic characteristics.
- Another study<sup>21</sup> – **Stand-Alone Artificial Intelligence for Breast Cancer Detection in Mammography: Comparison with 101 Radiologists** by Alejandro Rodriguez-Ruiz et al in Journal of the National Cancer Institute: The evaluated AI system achieved a cancer detection accuracy comparable to an average breast radiologist in this retrospective setting. Although promising, the performance and impact of such a system in a screening setting needs further investigation.
- **Cloud computing** allows radiology end users to use hardware and software stored remotely over the Cloud-based systems. In Cloud computing, various radiology and medical applications are delivered as a service over the Internet and this is known as a software as a service (SaaS)/on-demand software. A Cloud-based system provides a software platform for RIS, PACS, remote image review software (teleradiology), advanced 3D workstation software, and billing software, and this is actively accessed by end users remotely by using computers or tablets over the Internet. Special attention must be paid to legal obligations (such as where the cloud server is located), but also to security and privacy, failover systems, guaranteed up-time, clear responsibilities contracts and so forth.
- The Chaimeleon project<sup>22</sup> elaborated the **Chaimeleon Repository** that is expected to be used throughout the European Union as a common infrastructure that complies with all ethical and safety regulations of the countries involved. Clinical partners and external collaborators will populate the Repository with multimodality (MR, CT, PET/CT) imaging and related clinical data for historic and newly diagnosed lung, prostate and colorectal cancer patients. The project aims to incorporate about 40,000 cases in the repository, which will be contributed by eight clinical partners. In addition, to demonstrate the universality of the models developed, external collaborators will be sought to contribute more medical images and clinical data to the common repository. An ambitious

<sup>20</sup> <https://www.nature.com/articles/s41568-018-0016-5>

<sup>21</sup> <https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djy222/5307077?redirectedFrom=fulltext>

<sup>22</sup> <https://chaimeleon.eu/>

development and implementation of **AI-powered** pipelines will enable advancement towards automating data deidentification, curation, annotation, integrity securing and images harmonisation, the latest being of the highest importance for enabling reproducibility of radiomics when using large multi-scanner/multi-centre image datasets.

- The EU-funded **INCISIVE**<sup>23</sup> project aims to develop a toolbox for enhancing the accuracy, specificity and sensitivity of existing cancer imaging methods. The idea is to generate a pan-European repository of medical images that can be used for ML-based training for various types of cancer. The project's deliverables will assist the accurate prediction of tumour spread, evolution and relapse, in addition to helping stratify patients.
- The project **Trillium II**<sup>24</sup> has produced the “Imaging Results” component of the International Patient Summary. The Imaging Results component of a Patient Summary encompasses diagnostic observations based on medical imaging procedures such as X-ray, CT, MRI, Ultrasound and many more. The deliverable “Extending the Patient Summary with Imaging Results” defines the conditions and scope of integration of imaging results into international patient summaries and builds the standardised component that carries these imaging results, enables care providers to view them and to integrate them into their EHR systems. It presents the **information model and the interoperable FHIR artefacts** that represent diagnostic imaging results and references to original artefacts such as images or signals in an international patient summary. The FHIR artefacts include machine-processable FHIR resource profiles, as well as the FHIR ValueSet resources, which select the standardised vocabularies supporting the content.
- **MyPeBS**<sup>25</sup>, a European research project, is an international randomised, open-label, multi-centric, study assessing the effectiveness of a risk-based breast cancer screening strategy (using clinical risk scores and polymorphisms) compared to standard screening (according to the current national guidelines in each participating country) in detecting stage 2 or higher breast cancers.

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<sup>23</sup> <https://incisive-project.eu/>

<sup>24</sup> <https://trillium2.eu/>

<sup>25</sup> [The project - MyPeBS](#)

## 4 Metadata - categorisation of medical documentation

### 4.1 Introduction

Over the last decades, healthcare has transitioned from a one-on-one to a multidisciplinary and often multi-location situation, where information is stored in different systems. Healthcare information is entered by different people, from different perspectives, in different information systems and at different locations. It is for the most part stored and processed in a vast array of organisation-oriented, non-interoperable and unconnected software systems as there are separate software systems for hospitals (general, academic, specialised), general practices, diagnostic institutes, pharmacies, laboratories, radiotherapy centres, nursing homes, physiotherapists, dieticians, mental healthcare, social support, personal health records et cetera.

The information in these systems is also used to produce the many reports, summaries and letters in the context of an encounter, healthcare episode or a lifelong period. Their purposes are for internal and external accountability, and as a vehicle for the continuity of care. Depending on the level of structuration of the EHR data system, these reports can be partly generated from the already stored information, but another part is especially written for that report.

### 4.2 Need for categorisation

In most healthcare interactions, there is limited time to prepare a consultation and read the relevant information. Therefore, it is essential that such documentation can be quickly accessed. In a multidisciplinary and multi-location setting, the amount of available information increases. What also becomes apparent is that organisations use different naming and categorisation conventions (if any) for their documents. As a result, documents may easily be overlooked because they are not named or categorised in the way the end user expects them to be, which poses a real health risk.

This raises the need for an interoperable categorisation methodology for medical documentation that is both intuitive, practice-driven, consistent and flexible.

The methodology that is defined below defines and specifies a predefined set of parameters describing different aspects that can be linked to a document, and a set of rules that guide in the consistent use of these parameters, also known as metadata.

#### **Metadata**

Metadata can be defined as a set of data attributes that provide contextual information about a document, such as date, author, subject, purpose, specialism, healthcare organisation, events leading to the document, document type and size. Where relevant, these parameters are associated to a limited range of possible values, also called value sets. Metadata attributes are used to filter, group and sort the list of available documents, so that they can be found where the end user expects them to be. They also provide the possibility to use additional ad hoc filtering and sorting options.

EHRs often present the available documents/images related to patient in the form of lists, optionally distributed under a number of 'tabs'. Some also offer the possibility to change the order, filter on specific metadata attributes such as date, origin, topic, technique, purpose and so forth. A flexible, personally configurable user interface allows information to be looked up in different ways, making it easier to quickly find the desired information. After finding and selecting the desired item in the list, the end user can view the document itself.

Ideally, metadata attributes form a multi-axis, orthogonal, generic, logical and structured system that can be used to quickly and reliably locate the right information for the task at hand. And ideally, any health-related

document is always categorised in the same way. But because documents often have hybrid characteristics that make it hard to choose a value from a value set consistently, a decision supporting methodology, including definitions of terms and concepts is also required.

As an example, a discharge letter can be seen as a letter, a report, but also as a summary. It can be used for internal reference but also for transfer of care. It may have structured elements but also flat text parts. Another example: is a PROM report a *survey*, a *quality assessment* or a *research registration*?

Metadata are used in document management systems like hospital information systems or vendor-neutral archives. Standardised systems like those defined by IHE (XD\* profiles) have already specified most metadata attributes. However, further agreements and value sets must be worked out to accomplish true interoperability. A fully specified methodology opens the possibility to use software algorithms that optimise the interaction between end user and computer. Machine-readable metadata are essential for an intuitive and flexible user interface.

### 4.3 Expected benefits

The main expected benefits from a well-defined document functional categorisation methodology are:

#### **Market scale**

vendors can create international solutions based upon the standardised categorisation methodology; vendor can invest in developing a robust, configurable, user-friendly system for the quick overview of and access to the available documentation.

#### **Efficiency**

Uniform categorisation helps healthcare professionals to quickly find their way in any healthcare system (some HCPs work in different hospitals, for instance);  
Structured information enables the use of artificial intelligence to optimise the user interface through personalised configuration;  
Decision support can also assist the end user in quickly selecting the right classification.

#### **Reusability**

The attributes in the categorisation methodology can be used for fine-grained authorisation- and consent purposes;  
Attributes such as specialism/sub-specialism, healthcare facility type, functional document type/subtype can be used for many other purposes, for instance in the roles and right management of healthcare organisations, uniform locators for healthcare providers, lists of healthcare professionals et cetera.

### 4.4 Categorisation methodology

The categorisation methodology consists of three basic pillars:

1. Principles and requirements
2. Attributes and values
3. Guidance and decision support

#### 4.4.1 Principles and requirements

**Starting** principles for categorisation

The importance of a standardised use of metadata is nicely captured in the [FAIR](#) principles – they describe the need for a consistent set of metadata to make documents Findable, Accessible, Interoperable and Reusable. These principles are summarised in Annex II.

Further requirements have been collected from different sources and discussions<sup>26</sup>. They describe the ideal characteristics of a system and serve as a guide for the development of the categorisation methodology. Although these requirements are logical and make sense, in practice, it is much harder than it seems. The basic, ideal requirements are provided in the list below:

- **Completeness and genericity**

The methodology enables the categorisation of any type of (health-related) document by attaching contextual aspects related to the document: why, where, when, by whom, for whom, how, etcetera. These aspects can be used to filter, group, sort and select documents based on (combinations of) these attributes, providing maximum expression power and flexibility.

- The set of metadata attributes, including the associated value sets, describe all the relevant contextual aspects that can be described about any (type of) document. Keeping the scope of the methodology as broad as possible avoids architectural errors that must be corrected afterwards - avoid low hanging fruit or project-driven scope reduction. After the definition of the methodology, project-related implementation should always fit the methodology.
- All elements of the methodology are fully specified and linked to a terminology (or terminologies).
- The level of interoperability is proportional to the level of specification.
- All the elements (attributes and values) are clearly and unambiguously defined, with inclusion and exclusion criteria, and with examples of document types that fall (or do not fall) within the definition.

- **Consistency and orthogonality**

The methodology should be as intuitive as possible, with the least amount of ambiguity. Therefore, it ideally follows the following characteristics:

- Each metadata attribute describes one clearly defined and mutually exclusive aspect or dimension – attributes are orthogonal, there are no ambiguities.
- When metadata concepts are linked to the values of a value set, the values within that value set are also mutually exclusive.
- Decision trees and guidelines for the proper selection of metadata values are provided where unclarity may arise in the selection of the correct value.

- **Usability and flexibility**

- Documents should be findable where they are expected. The attributes and their values must make sense to the end users, from a medical perspective.
- Attributes describing the functional type and subtype of a document help end users to quickly locate the right documentation at the expected place. The use of tabs and sorted lists etcetera can also help in this process.
- Documents that are associated to each other (such as an image study and the study report, linked by an accession number) should be proposed as a set.
- Additional searching and viewing modes should be offered, including a complete list with different order options, search phrases etcetera.
- A simple decision supporting tool for the proper categorisation process at the moment of registration is recommended.
- A balance between granularity and usability is recommended. The main purpose for categorisation is to facilitate end users in the quick identification of the right information. Related

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<sup>26</sup> For more information, look at <https://www.ihe-europe.net/node/162>

to attributes with value sets: as a rule, the number of items in value sets should not exceed 20 to 30. Not just because it takes more time to look at all the options, but also because the chance for ambiguity grows with the number of options. For attributes with value sets that need more options, a hierarchical main- and subcategory can be devised.

- Although the categorisation methodology must be strict and unequivocal in its setup, it also must be flexible in practice. Sometimes, attributes cannot be given a value because the information is (still) missing or unclear. Sometimes, the possible values within a value set cannot accommodate what needs to be expressed. In such cases, a flexible solution such as an 'Other' or 'null' value must be allowed. To paraphrase Postel's law: be strict in your specification, but flexible in what you accept.
- Where applicable, attributes may have more than one value (cardinality). A medical specialist, for instance, can both be oncologist and neurologist and surgeon.
- Addition of user-specified 'tags' or 'flags' can catch specifics that have not been specified within the methodology. These can be linked to value sets (extensible or closed lists) or free text.

- **Interoperability**

- The methodology is linked to internationally proven and accepted standards and terminologies.
- Standardised attributes and value set items can be used throughout the healthcare domain.
- Standardisation of information starts at the document level. Especially when there is no structuration yet (like is the case with imaging reports), the preferred approach is to start at the document level, then at the paragraph/section level, and lastly at the concept level.
- Standardised value set items are linked to terminologies. This enables machine processability and the possibility to link the terminology codes to different descriptions and languages, including individually preferred descriptions. As an example: some prefer the label 'Echo' (echography), others 'US' (ultrasound) for the same concept.
- Interoperable attributes and value sets are conditional for secondary use such as scientific research, management- and administrative analysis, workflow support. They can also be used for finely grained document access control (authorisation and consent).
- Learning from other domains (book libraries, art collections) may also help in broadening the perspective and reusability of the methodology.

## 4.5 Attributes and values

The categorisation methodology uses the ancient Problem Analysis perspectives from Cicero and others (1<sup>st</sup> century BC) as its basis as depicted in figure 3:

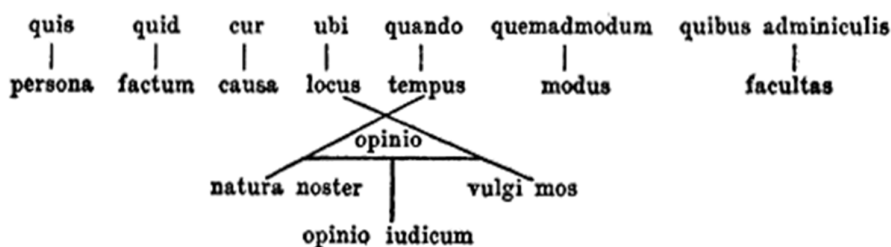


Figure 4 - who, what, why, where, when, in what way, by what means (cf. Cicero)

Working out these basic parameters leads to the following parameters for categorisation:

- Why
  - Purpose of the document



- Event leading to the document
  - Link to order / request / workflow / care pathway / episode leading to the document
- Who
  - By whom (author, creating application)
  - Under the authority of whom (legal authenticator)
  - For whom (intended recipient)
  - About whom (patient, relatives)
- What
  - Document ID
  - Document type (main functional category)
  - Document subtype (hierarchical functional subcategory)
  - Document language
  - Document file name
  - Document version
  - Document status (published, replaced, transformed, deprecated)
  - Document confidentiality status
  - Document integrity checksum
  - Document size
- How
  - In what way (method of creation)
  - By what means (modality or application that created the file)
  - In the context of what procedure(s)
  - In the context of what workflow event
  - By what technology – (document technical format, MIME type, structure template)
- When
  - Date and time of creation, last changed, last opened (for each document status/version)
  - Date and time of storage/publication
- Where
  - Country
  - Health domain
  - Organisation
  - Organisation facility/location
  - Organisation department
  - Storage reference ID

## 4.6 Categorisation specification

A methodology for the categorisation of medical documentation has already been created in the form of standards and implementation profiles. IHE has specified the contextual information that can be used in their XDS and other XD\* related integration profiles. DICOM is the global imaging standard.

## 4.7 Existing standards

The XDS (Cross-Enterprise Document Sharing) and XDS-I profiles facilitate the secure, reliable and interoperable exchange of medical documents and images within so-called XDS Affinity Domains. Different vendors can implement software based upon these requirements. These requirements specify interfaces and communication protocols between software products from different vendors to cooperate and exchange



information. The basis of the XDS profile in enabling categorisation methodology are related to the XDS registry.

Although the XDS integration profile specifies most attributes mentioned above, some of the values linked to these attributes are left to the organisations that exchange information in an Affinity Domain. However, for interoperability to work, all possible values of each attribute must be specified. Unless the same metadata are used, the possibilities for sorting, filtering and grouping will be seriously jeopardised, reducing the possibility for cross-border information exchange. This problem has been recognised by different countries where XDS infrastructures have been deployed and where organisations want to transparently exchange medical information. As a result, countries in Europe and the United States have compared their national agreements on how these different metadata value sets should be further specified. In 2016, IHE representatives from 10 different countries (Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, the Netherlands, Switzerland, United Kingdom), IHE Europe and the US joined forces in the International XDS Metadata Taskforce, with the following goals:

1. To share experiences on XDS implementation in European countries;
2. To share views on how the metadata are used (use cases, terminologies, data);
3. To find a common way to harmonise the metadata
4. To build an implementation guide for those wanting to implement XDS metadata in future projects.

This has resulted in the IHE Document Sharing Metadata Handbook<sup>27</sup>

More information on the IHE profiles relevant for image- and document sharing can be found in Deliverable 6.1. Further refinement of the XDS specifications would greatly enhance interoperability across the EU, allowing images, discharge summaries, laboratory results and patient summaries to be successfully exchanged.

For international interoperability, the X-eHealth project has further refined the requirements of the original XDS and XDS-I specification. These refinements make use of the original specifications, some of which are extended, others have used existing value sets from SNOMED, LOINC, HL7 or other standards, and some have been added after discussion with several experts from different member states.

The extended specifications allow truly interoperable international exchange, not only of medical images, but of any type of healthcare-related documentation.

The metadata set of attributes is available in D6.1 X-eHealth Services Specifications and is published via Art-Décor.<sup>28</sup>

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<sup>27</sup> [https://www.ihe.net/uploadedFiles/Documents/ITI/IHE\\_ITI\\_Handbook\\_Metadata.pdf](https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Handbook_Metadata.pdf)

<sup>28</sup> <https://decor.nictiz.nl/ad/#/ihexds-/datasets/dataset>

## 5 Functional Specifications

### 5.1 Common aspects of medical imaging and reports use cases

The functional specifications have been set up in close cooperation with WP6 and WP7.

The Imaging specific information models can be found in this chapter.

The entire information model for all X-eHealth domains can be found in browsable form at <https://x-ehealth.min-saude.pt>.

### 5.2 Imaging Study data (DICOM)

The information that each DICOM file contains is organised into 4 levels of hierarchy<sup>29</sup>: **Patient**, **Study**, **Series** and **Instance**.

Each **patient** can have one or more **studies**, each **study** can have one or more **series**, and each **series** can have one or more **instances**.

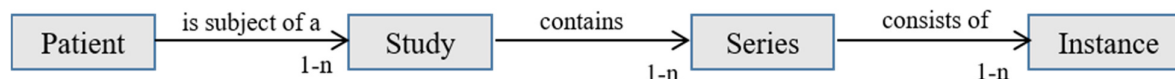


Figure 5: Image study data (DICOM)

#### Definitions: Patient

The Patient is the person receiving the examination.

For the definitions of imaging study, series and instance we refer to Chapter 1, paragraph ‘The DICOM standard’.

DICOM includes a robust UID mechanism to guarantee universal uniqueness. DICOM uses UIDs to identify information objects, such as images, reports, or transfer syntax. The UIDs are unique for every single patient, series, and study performed at a hospital.

Every imaging study has unique StudyInstanceUID (Dicom tag 0020,000D) and a locally unique Accession Number (0008,0050). These identifiers can be used for querying for the images as well as for the identification of the studies which should be sent to the recipient

The form of the UID conforms to an international standard: 1.2.840.10008 is the root and is the same for each DICOM UID. The UIDs are not actually random numbers, they encode information about the identity of the file, and even how it’s compressed.

### 5.3 Imaging Report

Structured reporting is seen as a way of improving the quality of imaging reports and of the imaging domain as a whole. It increases consistency, completeness, readability, and reusability. Structured information

<sup>29</sup> <https://towardsdatascience.com/understanding-dicom-bce665e62b72>

elements can be reused for many different purposes: production overviews, benchmarking, quality assurance, statistics, and scientific research. It also opens the possibility for decision support, workflow optimisation and improved user experience. Special user interfaces can be developed for frequently used types of imaging studies to increase quality and speed of reporting. According to the European Society of Radiology (ESR) quality, quantification, and accessibility are the main functional needs for moving from traditional free-text to standardised and structured reporting. The ESR also states that this should be an international effort, with international design and adoption of structured reporting templates that can be translated and adapted into local environments as needed. The main driving factors for further standardisation are a clear and supported business case, proof that it increases quality and efficiency and evidence of additional benefits of reuse.

### **Image Report Information**

As indicated above, there is a need to capture image reports in a structured process. This will support easier exchange of the reports and enable comparison between healthcare providers in a local, national and cross-border setting. Various initiatives have been undertaken by professional unions like RSNA and ESR to set up a report 'template'. In X-eHealth we agreed on a common set of elements that a report should contain to best facilitate structured reports.

The common agreed on report should reflect the following elements:

- Who (patient information header)
- What (modality, body part etc)
- Why (reason for the study)
- How (technique)
- Results
- Conclusion
- Next steps (recommendation)
- By whom (signature)
- When (timestamp of the report)

A structured report may contain all elements mentioned above, or just a sub-set of them. For example, in case of a potential broken bone where the entry can be very short: patient, not broken, signature.

The various data elements that a structured imaging report can contain are described in the Imaging Information Model, see below.

#### **Connection with imaging study data**

Currently the imaging report typically does not contain a link to DICOM study, but only where the examination was performed and the time of finalisation of the report (which may be in some cases different from the acquisition date). In the HIS, the imaging study is linked with DICOM study typically by means of Accession Number (see above) as it is shorter than Study Instance UID.

### **5.3.1 Information**

The required information needed to support the three Use Cases will be described below and is based on the Information Model created for Medical Imaging and Reports.

We will describe the minimal data requirements from a functional perspective in the Information Models that will support the use cases described above.

The data requirements are described in detail including their definition, cardinality, and conformance in the various information models.

Below we describe two of the models that are crucial for the use cases. All other Information Models for medical imaging and reports can be found in Annex III.

### 5.3.1.1 Imaging Result Report Information Model

Below is a high-level view of the Imaging Result Report Information Model. The most important part is the “DICOM Study Metadata”, which contains a selection of the metadata extracted from the DICOM study and “Examination Report”. The top-level of the model may contain as well an OrderID, data for radiation exposure evaluation as well as previous Examination reports. Please note that this information model does not contain the image study itself, which is only referenced!

We propose that the link to both AccessionNumber and Study Instance UID should be a mandatory part of the model.

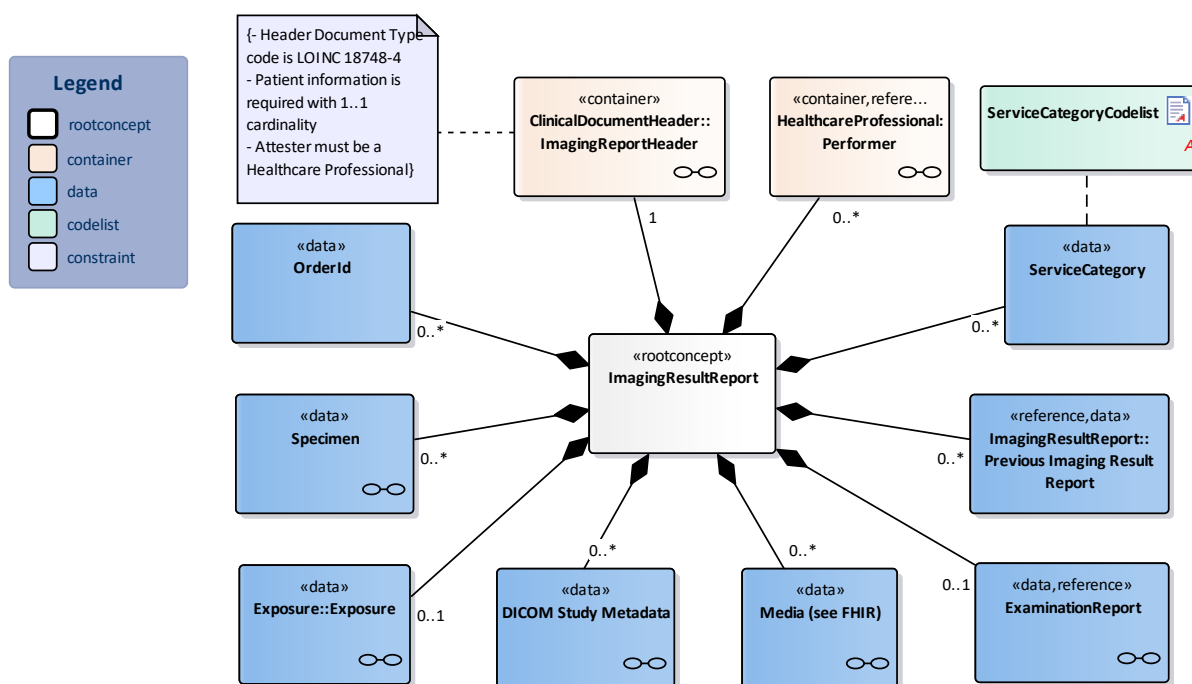


Figure 6: Imaging Result Report Information Model

### 5.3.1.2 Examination Report Information Model

The Examination Report model should be read from the top left corner clockwise. From the parts of the report mentioned above, “Who” (patient information header), By who and When (timestamp) information is stored on the top-level of the model. All others are reflected on this level of the model - What (modality, body part, compulsory Imaging Study Type), Why (reason code and text, clinical question), How (examination

procedure, medication including possible adverse effects), Results have to be in the text form (Result text, together with Imaging Study part the only two compulsory part of the Examination Report model) and may contain coded results (see the full model for details, users should be encouraged to use this feature). The separate model is created for Conclusion and Next steps (CarePlan:recommendation – this is a sub-model shared with e.g. discharge letter – one of the outputs of the Imaging Report may be a coded action as well).

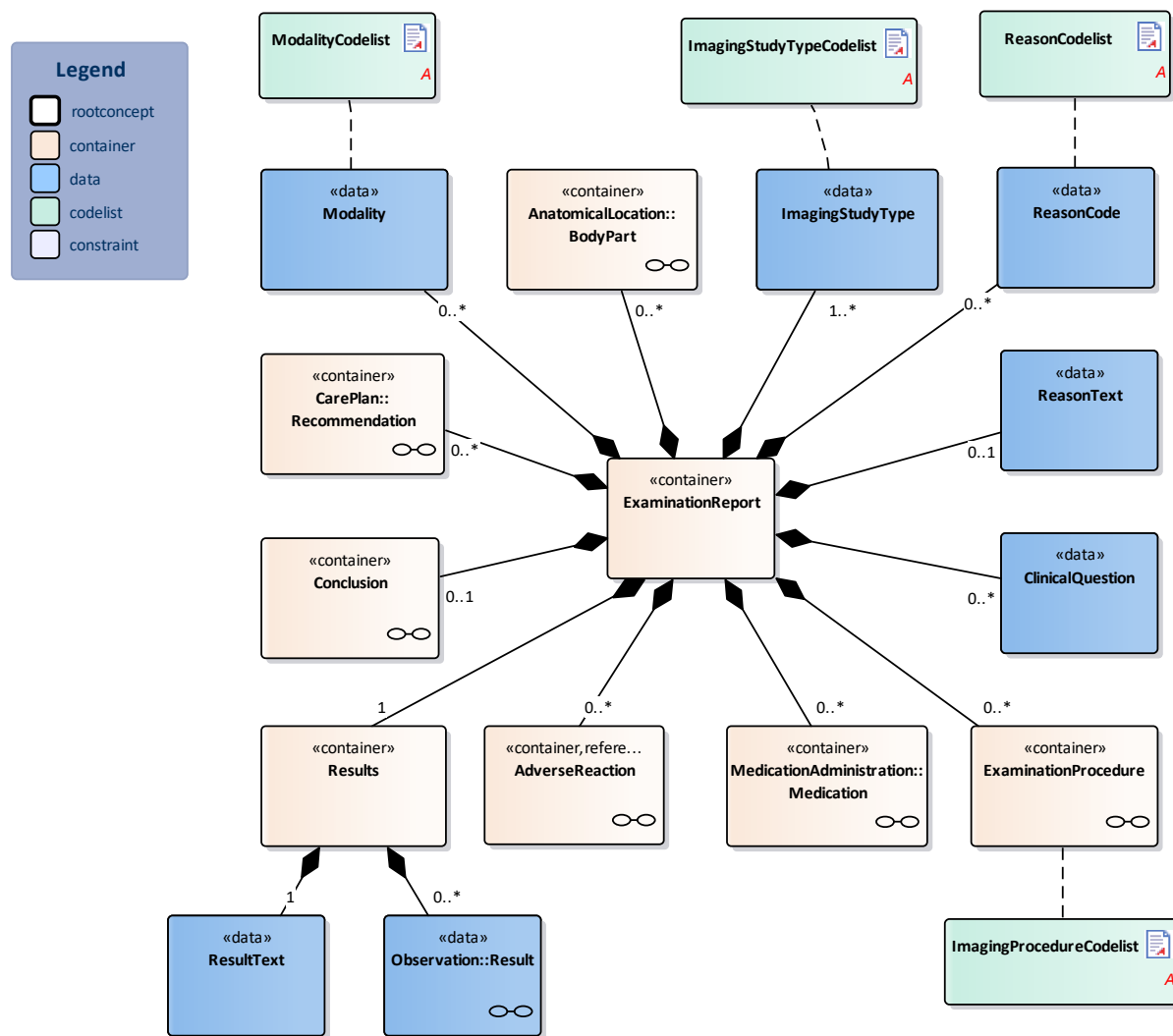


Figure 7: Examination Report Information Model

See Annex III for the complete set of Information Models that apply to the domain of imaging and imaging reports.

## 5.4 eHDSI

The eHealth Digital Service Infrastructure (eHDSI) is responsible for the set up and deployment of the core and generic services, as defined in the CEF, for PS and eP/eD. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of CBeHIS<sup>30</sup>.

<sup>30</sup>[https://www.ihe-europe.net/sites/default/files/KI%C3%A1ra\\_Jir%C3%A1kov%C3%A1\\_CBeHIS\\_Security\\_Requirements\\_and\\_Impact\\_compressed.pdf](https://www.ihe-europe.net/sites/default/files/KI%C3%A1ra_Jir%C3%A1kov%C3%A1_CBeHIS_Security_Requirements_and_Impact_compressed.pdf)

The core eHDSI services are summarised in the Figure x. They are set-up and deployed by the European Commission using its own resources and through calls for tender financed by CEF. The generic services are funded from the national sources and supported by grants from the CEF through a call for proposals.

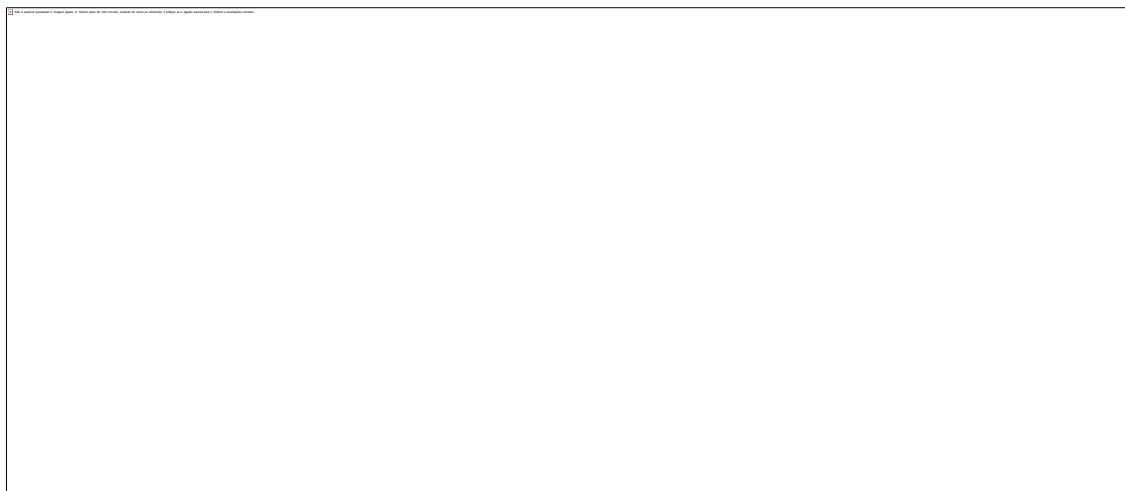


Figure 8: Core Services facilitating cross-border / cross sector technical interoperability<sup>31</sup>

For Member States to successfully exchange data, a common framework of standards is required. The eHDSI uses The Refined eHealth European Interoperability framework<sup>[3]</sup> ReEIF model, which is based on a system of agreements, on several levels, to ensure secure and reliable data exchange and process alignment between Member States.

These services are being expanded to include the domains of Hospital Discharge Report, Laboratory reports and Imaging.

The authorised user of the system should be able to search for all examinations of a given patient and select one, or more, exams for retrieval. The presentation of the data should allow sorting, at least by date and time (e.g., using timelines), and filter at least by imaging modality and body part examined Example: show only MRI examinations of the spine in given patient, newest first. Relevant data (e.g., where the examination was performed) should be presented along with the possibility of the fast preview of the data (e.g., non-diagnostic preview of the DICOM images, with the basic viewing functions such as zoom, move, window, distance measurement ...). The retrieval of the data should seamlessly integrate the data into local DICOM storage (see Infrastructure paragraph below).

### 5.4.1 Image Report exchange

Along with the retrieval of the DICOM data, the system should be able to download the imaging report(s) into the local HIS/RIS

The search and retrieval process within the EU is defined within the eHDSI guidelines. For the exchange of medical images and reports this is described in D7.1 X-eHealth Architecture definition to implement and

<sup>31</sup> Source: <https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/eHDSI+SERVICE+OFFERING> [eHDSI page with restricted access]

<sup>[3]</sup> [https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/DEPRECATED-Requirements+and+Recommendations?preview=%2F888804719%2F888804720%2Fev\\_20151123\\_co03\\_en.pdf](https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/DEPRECATED-Requirements+and+Recommendations?preview=%2F888804719%2F888804720%2Fev_20151123_co03_en.pdf) [eHDSI page with restricted access]

deploy EEHRxF services, D7.2 X-eHealth Testing strategy and D7.3 Possible upgrades of eHDSI core and generic services.

## 5.5 Infrastructure

The imaging and imaging reports cross-border will be exchanged via the eHDSI. In D7.1 the implementable specifications are available and these will be applied during the implementation process by the Member States. All functional and technical specifications will be compliant to the EEHRxF which will facilitate the exchange. The Member States National Contact Point for eHealth (NCPeH) is the entry point for the cross-border exchange of both images and their accompanying reports.

DICOM is a standard for medical data file formats, and for their exchange. For the end user, the easiest way to access any DICOM documentation is via the use of a local Picture Archiving and Communication System (PACS). The most natural way of data transfer between any PACS nodes (including central nodes of healthcare providers) is DICOM SEND (PUSH) or QUERY/RETRIEVE (PULL) method. To achieve a secure connection and use the pure DICOM standard, a lower-level secure infrastructure is needed (typically VPN).

### 5.5.1 Examples of current national infrastructures

#### Czech Republic

The majority of the larger Czech institutions and several Slovak institutions share DICOM via a system called ePACS. Local dedicated PACS servers accept PUSH requests from the local institution (DICOM send with a 'AE TITLE' which is equal to the ID of a remote recipient) and send the data over VPN to the target node. The target node stores incoming data to a cache, separated from the main local PACS storage and makes the DICOM data available to local users.

This approach may be easier to implement compared to alternative methods of data transfer.

In the Czech Republic there are currently 570 healthcare providers connected through the ePACS infrastructure that was started in 2007 and the number of connected providers is still growing. These providers vary from large University Medical Centres to independent healthcare professionals.

The ePACS project is compliant to national regulation. An overview of healthcare providers in the Czech Republic connected via ePACS can be found here<sup>32</sup>

#### Estonia

In Estonia 90% of GPs have the possibility to access the nationwide PACS to view digital images made/taken in different hospitals". We have to take into account that the number of inhabitants is less than 2 million people and therefore a central system is more likely to be in place<sup>33</sup>.

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<sup>32</sup> ePACS: [www.epacs.cz/epacs/faces/pages/index.xhtml](http://www.epacs.cz/epacs/faces/pages/index.xhtml)

<sup>33</sup> More information is available here: [Estonia\\_CountryBrief\\_eHS\\_FinalEdit.doc \(ehealth-strategies.eu\)](http://Estonia_CountryBrief_eHS_FinalEdit.doc(ehealth-strategies.eu))

## Ireland

In Ireland all public hospitals using the National Integrated Medical Imaging System NIMIS<sup>34</sup> are connected on a single imaging platform to enable closer collaboration between clinicians, particularly those in more remote locations. It allows the secure, electronic sharing of images between specialists for faster and improved diagnosis and therefore improves patient experience and care for all.

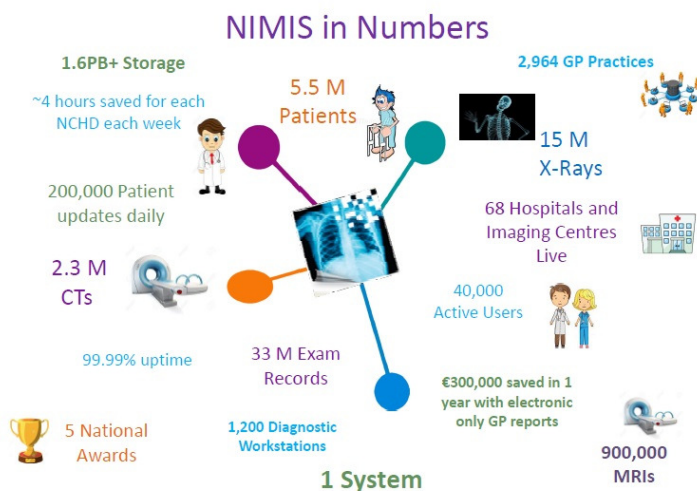


Figure 9: NIMIS in Numbers

## Catalonia

In Catalonia the project SIMDCAT<sup>35</sup> (Digital Medical Imaging System of Catalonia), started in 2016 by the Department of Health of Catalonia<sup>36</sup>, aims to take advantage of the potential offered by Cloud-computing, and allows the digital medical images generated by the 450 centres and all the professionals of the SISCAT (Comprehensive Health System for public use of Catalonia) to be stored and shared safely. As a result, all medical imaging information is accessible to any SISCAT centre. The main added value that this solution brings to the Health System is that it transforms the large amount of information contained in medical imaging tests (X-rays, CT scans, PETs, Mammograms ...) into meaningful data that can be analysed by the HCP. All this information is centralised in the Cloud and available to the Health System, and this opens the door to apply AI algorithms (one of the most promising fields in the world AI is precisely the medical image and having all this information centralised).

### 5.5.2 Risks

All information sharing in healthcare introduces risks, for example for information integrity, privacy, misinterpretation, or reliance on information that may be missing. Sharing of information cross-border may increase the element of risk while making mitigation of problems harder due to issues ranging from language and culture to use of different coding practices and systems.

<sup>34</sup> <https://www.ehealthireland.ie/strategic-programmes/nimis-national-integrated-medical-imaging-system/>

<sup>35</sup> SIMDCAT Project (English): <https://ticsalutsocial.cat/wp-content/uploads/2021/12/Digital-Image-in-Catalonia.pdf>

<sup>36</sup> <https://www.ciospain.es/sanidad/cataluna-lleva-a-la-nube-su-sistema-de-imagen-medica> (spanish)



In addition to generic risks present in sharing of information cross-border, transmitting imaging studies and reports also have specific risks:

The delay of the transfer in the acute settings (use case 5.4.3)

### 5.5.3 Actors common for all medical imaging and reports use cases

All use cases involve the following actors:

**Requesting specialist** (information seeker) who uses an information system, which enables querying for imaging studies available for a given patient. The query contains a unique ID of the subject, the reply of the server lists the studies and the location of the data.

**Owner**, (Custodian) who is the Healthcare organisation or Healthcare professional who has the requested studies and reports in his/her systems and is authorised to send the data to the

**Final recipient (Recipient)** using a fast and secure channel to the requesting healthcare provider, who further guarantees the safety of received data, which can be both imaging studies and imaging reports. All three actors can be different, or the requesting specialist may be related to a healthcare provider who is either owner of the data or the final recipient.

### 5.5.4 General requirements

For all use cases described below we distinguish common requirements that apply as follows:

#### 5.5.4.1 Patient Identification

The procedure for identifying patients must be unique, unambiguous and error free. Alphanumeric encoding, barcode, or a computerised process can be used.

X-eHealth follows the ISO Definition for patient identification: any person who uses, or is a potential user of, a health care service

The verification of the identification of patients must be done at the time of obtaining and by the registered HCP who performs it. Some countries have a national method to identify patients. In the Netherlands, the 'BSN, the social security number is used to identify patients.

#### 5.5.4.2 Future development

##### Europe's Beating Cancer Plan

Within the European initiative 'Europe's Beating Cancer Plan'<sup>37</sup> a service or repository of medical images for central access will potentially be covered. In further development of X-eHealth use cases this initiative must be considered.

##### AI4HI

During the X-eHealth project there has been a joint meeting with the AI for Health Imaging initiative, AI4HI; a cluster of 4 European projects that work on harmonisation.

Heterogeneity of data models across clinical centres and the lack of a single, adequate, standardised data model resulting in fragmentation of data repositories presents a challenge for AI projects. Data integration and transformation to a common data model are the cornerstone of the data harmonisation which is

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<sup>37</sup> Beating Cancer Plan: [Europe's Beating Cancer Plan](#)

necessary to later search the data for AI model development. One of the challenges faced by the AI projects is that the structure and semantics of the data including images and their metadata are not harmonised between data providers by default. This is an extra task to take care of.

Synergy between X-eHealth that is focussing on primary care data while AI4HI focuses more on secondary data, is encouraged and both teams plan to stay in touch and provide mutual updates and explore ways of further cooperation.

#### Use of value sets and terminologies

There are certain value sets that we refer to from the use cases, such as ‘body parts’ that also apply to the other three domains being developed within the project X-eHealth. Some code lists are internationally standardised but there are also proprietary code lists in place, created by suppliers or on a national level. Internationally standardised and adopted code lists are the preferred option. Please see the Information Model for the identified value sets.

#### Cross-border

When we speak of ‘cross-border’ we address the fact that a European citizen is travelling from one EU Member State to another. We use the following terms:

Country of affiliation (Country A)  
 Country of treatment (Country B)

## 5.6 Functional requirements for the use cases

### 5.6.1 Priority 1

**Table 2: UC 5.4.1 - Querying, retrieving, and viewing of imaging studies and imaging reports – detailed description**

Title	5.4.1 - Querying, retrieving, and viewing of imaging studies and imaging reports
Purpose	The Healthcare provider can query and retrieve across cross-border healthcare institutions to view the imaging studies and reports at the moment they are needed, including insight in the workflow. This is a so-called ‘Pull’ model or in DICOM known as ‘QUERY/RETRIEVE’ mechanism for the imaging studies. Both images and reports will be exchanged via the eHDSI/NCPeH.
Relevance	This use case supports the secured retrieval of imaging studies and imaging reports across hospitals and practices within a region, nation or cross-border. It provides ambulatory healthcare professionals with secure yet easy online access to patients’ imaging results, as well as to any prior diagnostic examinations from imaging departments which can be used either for comparison or to avoid duplicating imaging procedures. This prevents not only economical loss, but also unnecessary harm to the patient because of diagnostic irradiation.
Domain	Radiology, cardiology, medical photography, pathology, and many other clinical departments
Scale	Cross-border, National/regional, within organisations
Context	Patient care benefits from the results of previous examinations (both imaging studies in DICOM format and imaging reports). The knowledge that they exist (in DICOM language Query) as well as the ability to retrieve them is covered in this use case. The Healthcare Professional will be able to select or download the

	whole study or the specific series and/or reports that he/she wants to access to achieve a good view of patients' condition and to make the best possible decision for treatment together with the patient if possible.
Information	The basic information is the imaging study stored in DICOM format in a PACS node. Additional information, which may not be available in some of the use cases, is the imaging report, which can be stored in HIS/RIS and/or in DICOM SR (structured report) document type. Metadata play an important role in enabling the search and retrieve functions.
Participants	Specialist or other Healthcare Professional – requests the imaging study/ies and reports HCP – general practitioner or specialist – sender(s) of the results of the diagnostic study/ies and reports Recipient HCP (can be different from the one who requested the data transfer, e.g., GP asking for images to be sent to another hospital where his patient is going to be operated)
Preconditions	To query the existence of one or more imaging study/ies requires the possibility, to search for studies of given patient, identified by unique patient ID in all via the eHDSI connected systems across Europe. Then, a secure and audited channel for sending medical documentation in DICOM format and using DICOM protocol is needed. For the imaging reports another pathway is to be defined. The system must be able to send the images even if the imaging report is not available for any reason (see further use cases). Patient consent is already arranged for beforehand in the Country of Affiliation. Requesting and receiving Healthcare Professional need to be connected via their Healthcare Organisation to the eHDSI/NCPeH.
Functional process flow	Requesting specialist sends the request(s) to list all imaging studies available for given patient As a reply, the list is given, containing information on: What is in the study (body region if available and protocol name) Where is the study (country, city, hospital) Ideally also fast preview of the series available From the list, specialist can select which studies/series are relevant to the patient care and ask for their retrieval This assumes not only the correct classification of imaging modality (MR, CT etc) but also what body part(s) is/are covered by the examination The sender(s) send the imaging studies and imaging reports (if available) to the requesting specialist Specialist is informed that a study has arrived and is available for viewing using local PACS system and software he is familiar with (no central browser etc) and is able to use diagnostic software/screens for evaluation of the studies. The reports can be imported in local HIS/RIS.

Below we describe a couple of scenarios based on UC 5.4.1

**Table 3: Examples of scenario's based on UC 5.4.1**

Title	Multiple Sclerosis Attack
5.4.1.1 Multiple Sclerosis Attack	A patient comes to a hospital in country B (where he works) with acute new symptoms – double vision. He has a known diagnosis of multiple sclerosis with mild weakness of the upper limb. On admission, a neurologist asks for a MRI scan. As the treatment should be fast and depends on the diagnostic criteria involving

	dissemination in space and time, comparison with previous studies is crucial. The previous radiology report may help confirm which lesions on the previous study were stable. The patient remembers he had previous examinations in his home country, country A. The radiologist queries for both imaging reports and imaging studies of the modality MRI and body part brain and spine. A long list of the examinations is retrieved since the patient had many follow-up studies during his lifespan. The radiologist selects the latest one for retrieval. After comparison of the studies, he decides that he also needs the one-before to make a better clinical decision and retrieves that study as well. The patient gave prior consent with use like this in his home country A before.
<b>Title</b>	<b>Trauma outside country of affiliation</b>
5.4.1.2 Out-of-Scope (not part of GA assignment)	<p>A patient from Country A goes on Holidays to Country B and while visiting the Cathedral he falls from the stairs and hurts his leg. In the hospital an X-Ray is performed and the report is created stating that a fracture is not visible. Patient asks to send the X-Ray and report to their HCP in their home country. Once back home his leg still hurts and the HCP checks the received images and report that the patient asked for.</p> <p>This scenario can be seen as a need for future development.</p>
<b>Title</b>	<b>Acute MRI of spinal cord</b>
5.4.1.3	Saturday evening, A French citizen comes for an acute MRI of spinal cord in Prague (CZ). He reports that he already had some imaging of spine in Paris, <b>probably</b> (he is not sure) Pitié-Salpêtrière hospital. Previous images may substantially help to evaluate current examination. The imaging report is not necessarily needed, as both imaging studies will be read and compared by a radiologist.

The detailed process steps for the scenarios are **described** in D7.1

**Table 4: UC 5.4.2 - Imaging report sharing – detailed description**

<b>Title</b>	<b>5.4.2 Imaging report sharing</b>
Purpose	Sending of imaging reports and insight in the workflow, across healthcare institutions cross-border. In this use case we describe the requesting of the report by a HCP in country B to a HCP in country A. The HCP in country B sends the report to the HCP in country A.
Relevance	This use case supports the secured sharing of imaging reports (including their requesting and sending) belonging to imaging studies cross-border. It can also apply across a group of hospitals and providers within a region or at the national

	<p>level. It provides ambulatory healthcare professionals with secure yet easy online access to patients' imaging report results, as well as to any prior diagnostic examinations from imaging departments</p> <p>Reports from the imaging examinations could be:</p> <ul style="list-style-type: none"> <li>reported to the requesting specialist</li> <li>and/or reported to another specialist (e.g., in case of referral)</li> <li>report should contain machine and human readable content</li> <li>report could contain imaging data or references to it.</li> <li>Report could contain findings of patient's examination</li> <li>Is captured in a structured way via DICOM Structured Reporting (SR)</li> </ul>
Domain	Radiology, cardiology, medical photography, pathology, and many other clinical departments
Scale	Cross-border, National/regional, within organisations
Context	Patient care benefits from the results of previous imaging reports. Knowledge that they exist as well as the ability to retrieve them is covered in this use case.
Information	The imaging report, which may not be available in some of the use cases, can be stored in HIS/RIS and/or in DICOM SR (structured report) document type.
Participants	<p>Requesting specialist or other HCP – requests the imaging report</p> <p>Owner (HCP – general practitioner or specialist) – sender(s) of the results of the imaging report</p> <p>Final recipient HCP (can be different from the one who requested the data transfer, e.g., GP asking for images to be sent to another hospital where his patient is going to be operated)</p>
Preconditions	<p>To query the existence of imaging reports requires the possibility, to search for studies of given subject, identified by unique ID in all systems connected to the eHDSI across Member States. Then, a secure and audited channel for sending medical documentation in DICOM format and using DICOM protocol is needed. For the imaging reports another pathway is to be defined. The system must be able to send the images even if the imaging report is not available for any reason (see further use cases)</p> <p>Requesting and receiving Healthcare Professional need to be connected via their Healthcare Organisation to the eHDSI/NCPeH.</p>
Functional process flow	<p><b>Requesting</b> specialist sends the request to the European MS where the patient was treated before and where image studies were made. (in the eHDSI this will mean multiple separate queries). In the ideal implementation the HCP will see the combined results from the various MS.</p> <p>As a reply, the list of available imaging studies and reports is given, containing information on:</p> <ul style="list-style-type: none"> <li>What is in the report (body region if available and protocol name)</li> <li>Where is the report (country, city, hospital), the 'location'</li> </ul> <p>From the list, specialist can select which reports are relevant to the patient care and ask for their retrieval</p> <p>This assumes not only the correct classification of imaging modality (MR, CT etc) but also what body part(s) is/are covered by the examination</p> <p>The sender(s) send the selected imaging reports to the requesting specialist</p> <p>Specialist is informed that a study has arrived and is available for viewing using local PACS system and software he is familiar with (no central browser etc) and is</p>

	able to use diagnostic software/screens for evaluation of the studies. The reports can be imported in local HIS/RIS.
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Below we describe a scenario based on UC 5.4.2

**Table 5: Example of scenario's based on UC 5.4.2**

Title	Patient gets sick on Holiday
5.4.2.1 - Patient gets sick on holiday	The Patient is on holiday abroad (country B), where she/he feels sick with the need to visit a HCP in country B. The HCP in country B needs to check if there are medical Image Reports available for the Patient that can help the HCP to understand what's wrong with the Patient. The HCP requests the list of the available Image Reports regarding that Patient to the country of affiliation (country A). Country of affiliation (Country A) returns a list showing all available imaging reports for that Patient. With the support of the patient, the HCP retrieves the selected Image Report(s)

The detailed process steps for the scenarios are described in D7.1

**Table 6: UC 5.4.3 - Imaging study sharing – detailed description**

Title	5.4.3 Imaging study sharing
Purpose	Exchange of imaging studies and insight in the workflow between healthcare institutions cross-border and peer-to-peer. In urgency cases the speed to have the images available is crucial for the patient.
Relevance	<p>This use case supports the secured sharing of imaging studies including their storage or publishing between two or more healthcare organisations <b>cross-border</b>. This use case can also apply to exchange of imaging studies across a group of hospitals and practices within one nation, region or even within one organisation.</p> <p>It provides ambulatory healthcare professionals with secure yet easy online access to patients' imaging results, as well as to any prior diagnostic examinations from imaging departments. These can be used either for comparison or to avoid duplicating imaging procedures, which would mean not only economical loss, but may cause harm to the patient because of non-necessary diagnostic irradiation exposure. In this Use Case also the tracking of the imaging study workflow is described.</p>
Domain	Radiology, cardiology, medical photography, pathology, and many other clinical departments, like optical microscopy. It can refer to any other data that is transformed into DICOM or like some people call it 'DICOMISED'. DICOMISE describes the way to change a non-DICOM object (think of a JPEG photo from holiday) to DICOM Key-Value structure.
Scale	Cross-border, National/regional, within one organisation

Context	Patient care will benefit from the results of previous examinations (imaging studies in DICOM format). The knowledge that they exist (in DICOM language Query).
Information	The basic information is the imaging study stored in DICOM format in PACS node. A reference must be made to the corresponding report belonging to the study.
Participants	Requester - Specialist or other HCP who requests the imaging study Sender - HCP (general practitioner or specialist) who sends the results of the imaging study Final recipient - HCP who receives the imaging study. The recipient can be different from the one who requested the imaging study, e.g., a GP asking for images to be sent to another hospital where his patient is going to be operated.
Preconditions	To query the existence of imaging study requires the possibility, to search for studies of given subject, identified by unique ID in all connected systems across Europe. Then, a secure and audited channel for sending medical documentation in DICOM format and using DICOM protocol is needed. For the imaging reports another pathway is to be defined. The system must be able to send the images even if the imaging report is not available for any reason (see further use cases) Requesting and receiving Healthcare Professional need to be connected via their Healthcare Organisation to the eHDSI/NCPeH.
Functional process flow	<p>The sharing must be done as fast as possible. Any delay may be life-threatening for the patient.</p> <p><b>Requesting</b> specialist in Country B sends the request to list all imaging studies available for given patient from Country A As a reply, the list is given, containing information on: What is in the study (body region if available and protocol name) Where is the study (country, city, hospital) Ideally also fast preview of the series available From the list, the specialist can select which studies/series are relevant to the patient care and ask for their retrieval This assumes not only the correct classification of imaging modality (MR, CT etc) but also what body part(s) is/are covered by the examination The sender(s) sends the imaging studies to the requesting specialist Specialist is informed that a study has successfully been sent and is available for viewing using local PACS system and software he is familiar with (no central browser etc) and is able to use diagnostic software/screens for evaluation of the studies. Final recipient has received the imaging studies <i>The sender finds the appropriate peer for the consultation or the treatment (this is out-of-scope)</i> <i>Sender contacts recipient for consultation (e.g., via phone or a teleconference).</i> <i>This communication must be reliable and reasonably safe. (This is possibly out-of-scope).</i></p>

Below we describe a couple of scenarios based on UC 5.4.3



**Table 7: Examples of scenario's based on UC 5.4.3**

5.6.1.1 Title	5.6.1.2 Stroke – acute setting
5.4.3.1 - Stroke – acute setting	A mobile CT unit is driving in a cross-border region and visits a citizen in country A who just suffered from a stroke. The mobile unit takes a CT-scan of the patient's brain and sends the images to the higher level stroke unit that resides in country B for assessment. Based on the assessment the patient goes to country B for further treatment. Important in this scenario is that the speed of the availability of the image is of utmost importance to best support patient's outcome.
5.6.1.3 Title	5.6.1.4 Intracerebral bleeding –consultation by cross-border hospital
5.4.3.2 Intracerebral bleeding – consultation by cross-border hospital.	<p>A peripheral Hospital in country A has a patient with an intracerebral bleeding; a CT scan is being performed. However, there is no neurosurgery department in the rural hospital, but it does have a cross-border agreement with a larger hospital in a neighbouring country. The healthcare professional turns to the larger hospital in country B for consultation.</p> <p>The healthcare professional in country A notifies his peer in country B that an image study will come his/her way. (PUSH/SEND). After having received the image study from Country A the neurosurgeon in Country B decides to perform a brain surgery in hospital in Country B to give the patient the best possible care and outcomes.</p> <p>The Emergency department, by applying the formally defined procedure, transfers patient's credential and the clinical documents identifiers, to the larger hospital.</p> <p>The neurosurgical team of the other hospital applies the eHDSI Cross-border "Emergency"/"Breaking the Glass" procedure to retrieve the CT scan image, to prepare the urgency surgery, together with the encounter report created by the health professional.</p>

The detailed process steps for the scenarios are described in D7.1



## 5.6.2 Priority 2

**Table 8: UC 5.4.4 – Image report sharing for patients – detailed description**

Title	5.4.4 Image report sharing for patients
Purpose	Imaging reports that will be shared with the patient or his guardian
Scope	This use case is out of scope for this project
Domain	Radiology Multidisciplinary consultation
Scale	Cross-border National/Regional Within an organisation
Context	Contrary to use case 5.4.1 which is similar to DICOM Query/retrieve model, this use case is rather “DICOM Send” procedure. It relies on interdisciplinary consultation for the benefit of patient.
Information	Imaging data, possibly also <b>non-formal</b> report of radiologist in the scenario of aneurysm rupture.
Participants	The sender of the images (mobile CT or imaging facility of smaller hospital) The recipient of the images (higher-level hospital with stroke unit or vascular surgery specialist => the patient? See name of UC?)
Preconditions	Sender needs to have reasonably fast internet connection (in case of mobile CT even mobile one). The sender and the recipient need to be connected with both fast and secure data connection. Requesting and receiving Healthcare Professional need to be connected via their Healthcare Organisation to the eHDSI/NCPeH.
Functional process flow	TBD

### (UC 5.4.5) Multidisciplinary Board Meeting – detailed description

Functional specification of this use case contains not only the exchange of the images and reports, but the harmonisation of the imaging process between the institutions. The breast cancer case was selected as an example of tumour board decision model as the description of the mammography is already well harmonised, using the BI-RADS system.

**Table 9: 5.4.5 Multidisciplinary Board Meeting**

Title	5.4.5 Multidisciplinary Board Meeting
Purpose	Sharing the results of radiological diagnostic studies, both images and reports, and insight in the workflow, between specialists from different specialisms and healthcare institutions to prepare treatment.
Scope	This use case is out of scope for this project.
Relevance	Imaging studies and reports should be shared in a multidisciplinary board meeting: in these meetings different specialists work together closely sharing

Title	5.4.5 Multidisciplinary Board Meeting
	<p>clinical decisions in care. The composition is variable, depending on the type of issue discussed.</p> <p>The availability of imaging studies and corresponding structured reports is crucial for the specialists to take the best possible decision on treatment.</p>
Domain	Radiology, cardiology, medical photography, pathology, and many other clinical departments
Scale	Cross-border, National/regional, inter-organisational
Context	<p>This Use Case has the objective of sharing imaging information beyond the boundaries of a typical, single hospital organisation. It can be used to make the information available to practitioners in different organisational entities. It builds on the use case 5.4.1, 5.4.2 and 5.4.3</p> <p>Usually before the actual MBM takes place, there is an exchange of preliminary/limited imaging studies to prepare for the MBM. During the MBM the actual imaging studies and reports are available.</p> <p>Scenario 1: A patient is suffering from lung cancer and has received surgical treatment in a hospital. After discharge from the hospital, imaging information – such as results from computer tomography – is made available to the patient’s primary care physician as well as to an office-based medical oncological specialist for follow-up treatment.</p>
Information	<p>Diagnostic Study Request</p> <p>DICOM data (typically, but not limited to, images produced by Radiology departments)</p> <p>Imaging report (typically, but not limited to, radiological report)</p>
Participants	<p>Specialist – requests the diagnostic study</p> <p>Radiologist – performs the diagnostic study, and writes the radiology report</p> <p>HCP – general practitioner or specialist – receiver(s) of the results of the diagnostic study</p>
Preconditions	<p>All preconditions for the use case 5.4.1 apply here and following should be solved as well: the imaging report should be structured and at least the core backbone should be standard. As in other medical document exchange, the reasonable level of coding system should be used along with free text additions, which should be probably kept in original language.</p> <p>Requesting and receiving Healthcare Professional need to be connected via their Healthcare Organisation to the eHDSI/NCPeH.</p>
Functional process flow	<p>GENERAL</p> <p>The need of previous studies and reports is discovered</p> <p>Query for the existing documentation</p> <p>Retrieval of the old studies and reports</p> <p>The imaging data in DICOM format is imported in local PACS</p> <p>The imaging report is imported in local HIS/RIS</p> <p>All the imported data are used for diagnosis and/or treatment decision.</p> <p>Example: BREAST CANCER USE CASE</p> <p>A patient suffering from breast cancer is considered for surgical treatment in a hospital. The data from mammography screening centre(s) outside the institution and cross-border is requested (via mechanisms described in use</p>

Title	5.4.5 Multidisciplinary Board Meeting
	<p>case 5.4.1) – the board may need multiple imaging modalities (typically mammogram(s) and MRI of the breast, as well as the pathology)</p> <p>The imaging data and reports are viewed with help of hanging protocols and timeline, this may include a non-diagnostic preview before the patient data is retrieved in HIS.</p> <p>Board decision is made and sent to the indicating specialist (this step is out-of-scope)</p>

Below we describe a scenario based on UC 5.4.5

**Table 10: Example of scenario based on UC 5.4.5**

Title	Breast cancer procedure
5.4.5	<p>A Patient is being called for mammography at her local hospital in Country A. The pictures taken show suspected areas in her breast where further investigations where needed. It was decided that she needed a breast operation for a small tumour. The Patient decided to request the procedure to be done at a hospital abroad (Country B) as this is closer to her home. Before the procedure, the surgeon abroad requests the Imaging Study on the Patient's breast in her home country (Country A) and a multidisciplinary board meeting is scheduled to ensure that the case was well understood and to prepare in the best possible way for the procedure.</p>

**Table 11: UC 5.4.6 Radiation Dose Report – detailed description**

Title	4.5.6 Radiation Dose Report
Purpose	Sharing the results of radiological diagnostic studies, both images and reports, and insight in the workflow, between healthcare institutions.
Scope	This use case is out of scope for this project.
Relevance	<p>The European Directive 2013/59/EURATOM sets out the basic safety standards for protection against the dangers arising from exposure to ionising radiation. This directive must be implemented by all EU M/S.</p> <p>There is a need for a standardised Dose Report to ease registration and exchange</p> <p>All EU countries must register the radiation data.</p>
Domain	Radiology, surgery, oncology
Scale	National/regional, inter-organisational, cross-border?
Context	This Use Case has the objective of sharing radiation dose information to comply to regulation and for patient safety reasons. It builds on the use case 5.4.2.
Information	<p>Diagnostic Study Request</p> <p>DICOM data (in this use case namely mammograms, mammographic ultrasound results and in some cases MR data)</p> <p>Imaging report</p>

Title	4.5.6 Radiation Dose Report
Participants	<p>Board secretary – requests the diagnostic study</p> <p>Radiologist – performs the diagnostic study, and writes the radiology report</p> <p>Board meeting participants (radiologist, oncologist, surgeon, ...) –receiver(s) of the results of the diagnostic study</p>
Preconditions	<p>The digitalisation of the sources of the imaging data (e.g., mammography screening centres), their connection to at least nation-wide DICOM exchange network, the possibility to share the imaging report in the same range.</p> <p>Requesting and receiving Healthcare Professional need to be connected via their Healthcare Organisation to the eHDSI/NCPeH.</p>
Functional process flow	Share radiation data which can be part of the imaging report.

## 6 Summary and Discussion

In summary, we can see that over the last number of decades, there have been many innovations in digital imaging techniques and processing which have provided new ways to assess and improve the health situation of patients. An increasing number of people are treated in more than one hospital, institution or country, for multidisciplinary, multi-centre treatment. This requires the sharing of patient medical data (including images), to ensure the effective timely treatment and deliver better patient outcomes.

Standardisation, e.g., DICOM, has been very successful in the imaging domain. But when information is to be shared in a regional, national or cross-border setting, the need for new interoperability requirements becomes evident. This X-eHealth work package has identified the following topics that require further standardisation:

- Categorisation and naming of medical documents (findability)
- Structure and data definition of imaging reports (interoperability, reusability, translatability)
- Information exchange mechanisms and infrastructure (accessibility)
- Cross-organisational imaging workflows (quality, efficiency)
- Simplify the data model with information about the coding systems we wish to use

In undertaking our analysis of the medical imaging use cases, existing standards and guidelines and categorisation we identified interoperability gaps, challenges and opportunities for standardising and enhancing the transfer of medical images. We have identified and described the functional requirements and specifications to support a structured and sustainable exchange of medical images and imaging reports among European countries.

The main opportunities for the safe and timely availability of medical images and imaging reports throughout the EU include:

- The timely availability of previous medical images coming from other countries, both in unplanned and planned care situations to provide optimal care for patients
- Possibilities for secondary use through standardisation to improve health outcomes of patients
- Standards-based software that will enable interoperability between systems and prevent vendor lock-in
- Higher quality software for user-friendly data entry and for viewing images in combination with imaging reports to prevent errors and ease registration

The main output of this document is to inform several other deliverables:

- WP6 – Definition of EEHRxF Implementable Specifications,
  - specifically Deliverable 6.2.1 – X-eHealth Implementation Guide: Diagnostic Imaging Report and Deliverable 6.2.2 – Technical Specifications for Images.
- D5.3 Laboratory Requests and Reports, D5.5 - Hospital Discharge Reports and D5.6 – Refine PS for rare diseases.
- WP7: D7.1 – X-eHealth Architecture definition to implement and deploy EEHRxF services and D7.2 X-eHealth Testing strategy and D7.3 Possible upgrades of eHDSI core and generic services.

The X-eHealth Project results will be used and further developed in new European projects and within initiatives that will emerge in future via the European Health Data Space (EHDS) such as the Joint Action on primary use.

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RSNA Rad Reporting Templates: [RadReport](#)

## 8 Annex I

### List of most relevant IHE profiles related<sup>[1]</sup> with imaging

IHE Profile	Description
XDS (Cross Enterprise Document Sharing)	XDS is an interoperability profile that facilitates the registration, distribution and access across health enterprises of patient electronic health records.  It is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprise, ranging from a private physician office to a clinic to an acute care in-patient facility and personal health record systems.
XDS-I.b (Cross - enterprise Document Sharing for Imaging.b)	XDS-I.b is an interoperability profile that extends XDS to share images, diagnostic reports and related information across a group of care sites.  It provides a solution for publishing, finding and retrieving imaging documents across a group of affiliated enterprises.
XCA (Cross-Community Access)	XCA supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/enterprises that have agreed to work together using a common set of policies for the purpose of sharing clinical information via an established mechanism.
XCA-I (Cross-Community Access for Imaging)	The XCA-I Profile extends the IT Infrastructure XCA Profile. It supports the means to query and retrieve patient relevant medical imaging data held by other communities.  XCA provides access to all medical data including diagnostic reports and imaging manifests, and provides access to the images referenced in the imaging manifests.
XDM (Cross-enterprise Document Media Interchange)	XDM provides document interchange using a common file and directory structure over several standard media. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents.
MAMMO (Mammography Image)	MAMMO ensures that the acquired digital mammography images contain all relevant information that is necessary for further image processing, application of CAD, storage, display, review and printing. This profile is absolutely necessary for generating correct digital mammography image content to ensure optimal presentation of images at a mammography review workstation.
MAWF (Mammography Acquisition Workflow)	MAWF defines how Mammography Modalities or Workstations reject images for quality reasons or correct view information in images. It furthermore describes how to document procedure and protocol changes as well as recall cases.
IRWF (Import Reconciliation Workflow)	IRWF is an integration profile that manages importing images from CDs, hardcopy, etc. and reconciling identifiers to match local values.  It establishes a flow of information that supports the efficient importation of DICOM patient data from an external enterprise. It provides specifies transactions that maintain the use of consistent patient/procedure information between the data being imported and the local enterprise, while maintaining the integrity of the original data.
SWF (Scheduled Workflow)	SWF address managing workflow process, which typically involves providing worklists, and reporting/monitoring the progress and completion of work items. Within this context, one or more content objects are generally created according to their content profile.  It establishes a seamless flow of information that supports efficient patient care workflow in a typical imaging encounter.
SWF.b (Scheduled Workflow.b)	SWF.b is an update of the original SWF profile. The key revisions are: HL7v2.5 is now required; HL7v2.3 is removed Patient Information Reconciliation (PIR) has been merged inside SWF.b Enterprise Patient Identification support is added



PIR (Patient Information Reconciliation)	PIR coordinates reconciliation of the patient record when images are acquired for unidentified (e.g. trauma), or misidentified patients.
PWF (Post-Processing Workflow)	PWF is a natural / logical extension of the Scheduled (Acquisition) Workflow Profile and provides the capabilities to sustain and optimise several tasks typically performed after image acquisition in preparation for the following image interpretation (reporting). It specifies transactions to support a seamless flow of information for typical post-processing tasks such as quality control, image reconstruction, Computer Aided Detection or 3D views generation.
NMI (Nuclear Medicine)	NMI specifies basic display capabilities that are required in nuclear medicine, and provides vendors information as to what features users expect in products that "work well" with nuclear medicine images. Portions of the profile deal with both cardiac and general nuclear medicine. Other sections of the profile ensure that nuclear medicine images can be stored and retrieved properly, and options deal with exporting result screens and viewing of tomographic (SPECT) studies.
SINR (Simple Image and Numeric Report)	SINR facilitates the creation, management, distribution, storage, and viewing of reports created in imaging facilities.  The content structure uses the DICOM Structured Report for a simple imaging report. The content structure is simple: a title, an observation context, and one or more sections, each with a heading, observation context, text, image references, and optionally coded measurements. The Report complexity is extensible, limited only to the constraints of DICOM.
DBT (Digital Breast Tomosynthesis)	DBT ensures that the acquired digital mammography and tomosynthesis images contain all relevant information that is necessary for further image processing, storage, display, review and printing. This profile is absolutely necessary for generating correct digital mammography and tomosynthesis image content to ensure optimal presentation of images at a mammography review workstation.
KIN (Key Image Note)	KIN enables a user to flag as significant one or more images in a study by referencing them in a note linked with the study ((e.g. for referring, for surgery, etc.). This note includes a title stating the purpose of the flagged images and a user comment field. These notes will be properly stored, archived and displayed as the images move among systems that support the profile.
CPI (Consistent Presentation of Images)	CPI maintains the consistency of presentation for grayscale images and their presentation state information (including user annotations, shutters, flip/rotate, display area, and zoom). It also defines a standard contrast curve, the Grayscale Standard Display Function, against which different types of display and hardcopy output devices can be calibrated.
FUS (Image Fusion)	FUS integrates systems creating, registering and displaying fused image sets and storing their results.
PDI (Portable Data for Imaging)	PDI stores image data and diagnostic reports on CDs, DVDs or USB for importing, printing or displaying in a browser.
TCE (Teaching File and Clinical Trial Export)	TCE lets users flag images and related information for automatic routing to teaching file authoring or clinical trials management systems.
ARI (Access to Radiology Information)	ARI shares images, diagnostic reports, and related information inside a single network.
WIA (Web-based Image Access)	WIA provide methods for image sharing and interactive viewing of imaging studies using RESTful services such as WADO-RS and QIDO-RS.
IOCM (Imaging Object Change Management)	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.
IID (Invoke Image Display)	IID simplifies the task of integrating non-image-aware systems like EHRs, EMRs, PHRs, RIS and other information systems with image-aware systems like PACS, VNA and Image Sharing solutions, by providing a standard mechanism to request the that imaging studies be displayed.

WIC (Web-based Image Capture)	WIC provides a simple, lightweight, mobile-friendly mechanism to encode and send DICOM encapsulated images, videos and evidence documents from the mobile device to the Image Manager so that these objects can be easily integrated into the rest of the imaging workflow.
WIA (Web-based Image Access)	WIA provide methods for image sharing and interactive viewing of imaging studies using RESTful services regardless of the backend image management infrastructure.
PIX (Patient Identifier Cross Referencing)	PIX supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains by transmitting patient identity information from an identity source to the Patient Identifier Cross-reference Manager, or providing the ability to access the list(s) of cross-referenced patient identifiers either via a query/ response or via an update notification.
ATNA (Audit Trail and Node Authentication)	ATNA establishes security measures which, together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability.

All the IHE Radiology profiles are included in the [IHE wiki https://wiki.ihe.net/index.php/Profiles - IHE Radiology Profiles](https://wiki.ihe.net/index.php/Profiles_IHE_Radiology_Profiles)

## 9 Annex II

### 9.1 FAIR Principles

#### Findable

The first step in (re)using data is to find them. Metadata and data should be easy to find for both humans and computers. Machine-readable metadata are essential for automatic discovery of datasets and services, so this is an essential component of the FAIRification process.

(Meta)data are assigned a globally unique and persistent identifier

Data are described with rich metadata (see under Reusable below)

Metadata clearly and explicitly include the identifier of the data they describe

(Meta)data are registered or indexed in a searchable resource

#### Accessible

Once the user finds the required data, she/he/they need to know how they can be accessed, possibly including authentication and authorisation.

(Meta)data are retrievable by their identifier using a standardised communications protocol

The protocol is open, free, and universally implementable

The protocol allows for an authentication and authorisation procedure, where necessary

Metadata are accessible, even when the data are no longer available

#### Interoperable

The data usually need to be integrated with other data. In addition, the data need to interoperate with applications or workflows for analysis, storage, and processing.

(Meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.

(Meta)data use vocabularies that follow FAIR principles

(Meta)data include qualified references to other (meta)data

#### Reusable

The ultimate goal of FAIR is to optimise the reuse of data. To achieve this, metadata and data should be well-described so that they can be replicated and/or combined in different settings.

- (Meta)data are richly described with a plurality of accurate and relevant attributes
- (Meta)data are released with a clear and accessible data usage license
- (Meta)data are associated with detailed provenance

(Meta)data meet domain-relevant community standards

### 9.2 Draft material to be processed later

Benefits of a uniform methodology for the categorisation of health documentation, apart from the benefits already mentioned, are:

- Automatic interoperability between XDS Affinity Domains. Metadata filtering, sorting and grouping will work in a consistent and effective way across Affinity Domains.
- Software that uses XDS metadata can be optimised and built upon standard selection options due to the standardised metadata set;
- National extensions to document metadata can become a part of the implementation guideline to cater for specific national values;

- A standard set of metadata form the basis for verifiable quality assessment of interoperability between different XDS infrastructures across Affinity Domains and across borders.

## 10 Annex III

### 10.1 Information Model

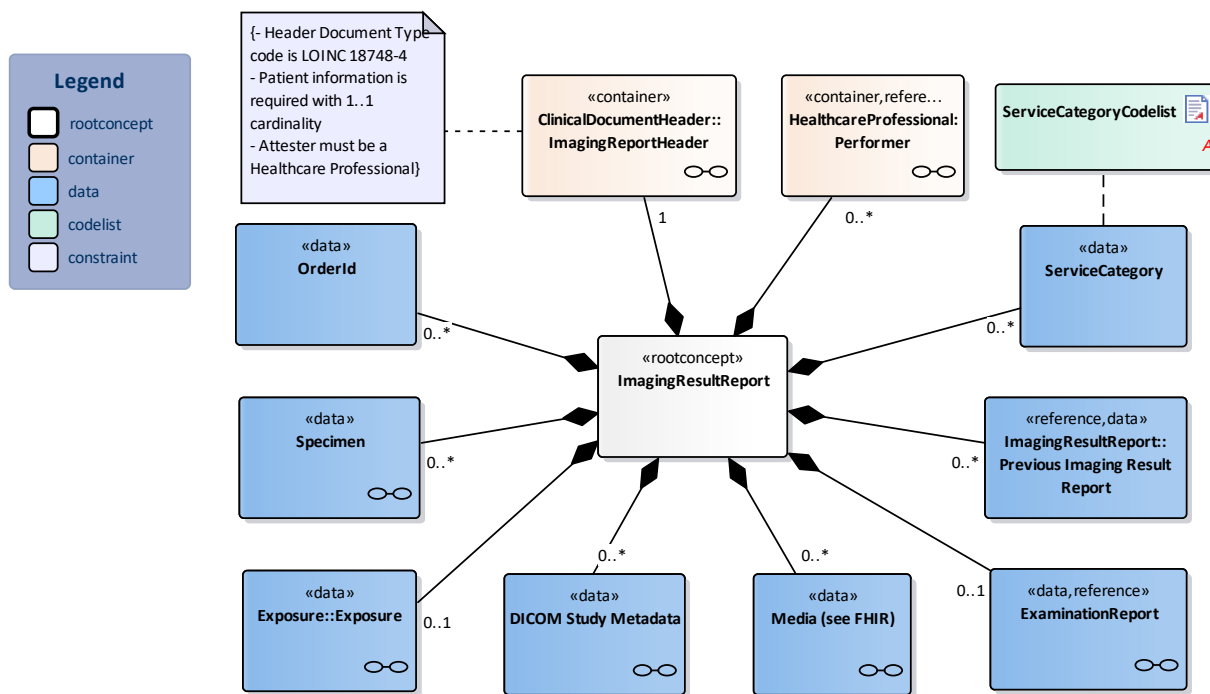


Figure 10:Information Model

Type	Concept	Cardin.	Description
rootconcept	ImagingResultReport		Imaging result report is a container that holds all report elements. Diagnostic Imaging Report (DIR) contains a consulting specialist's interpretation of image data. It conveys the interpretation to the referring (ordering) physician and is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.
container	ClinicalDocumentHeader::ImagingReportHeader	1	Container with Imaging report header information (e.g. patient, author, validator, encounter, date and time of the report etc.)
container	HealthcareProfessional::Performer	0..*	Healthcare professional that performed the examination.
Data	ServiceCategory	0..*	A code that classifies diagnostic service that created the report.
reference	ImagingResultReport::Previous Imaging Result Report	0..*	Reference to the relevant historical result report, e.g. for comparison of results or trends or to older version of the report amended by this report. Relevant report must belong to the same patient.
Data	ExaminationReport	0..1	Container with structured imaging examination report.
Data	Media (see FHIR)	0..*	Key images associated with this report.

Type	Concept	Cardin.	Description
Data	DICOM Study Metadata	0..*	A container with selected/relevant data elements of the DICOM Study.
Data	Encounter	0..1	A reference to an encounter when imaging examination was ordered.
Data	OrderId	0..*	Identifier assigned to this order instance by the orderer and/or the receiver and/or order fulfiller.
Data	Specimen	0..*	Details about the specimens on which this diagnostic report is based. Element would be used when the subject of the report is a specimen taken from the patient, e.g. tumour sample.
Document	ServiceCategoryCodeList		

## 10.2 DICOM study

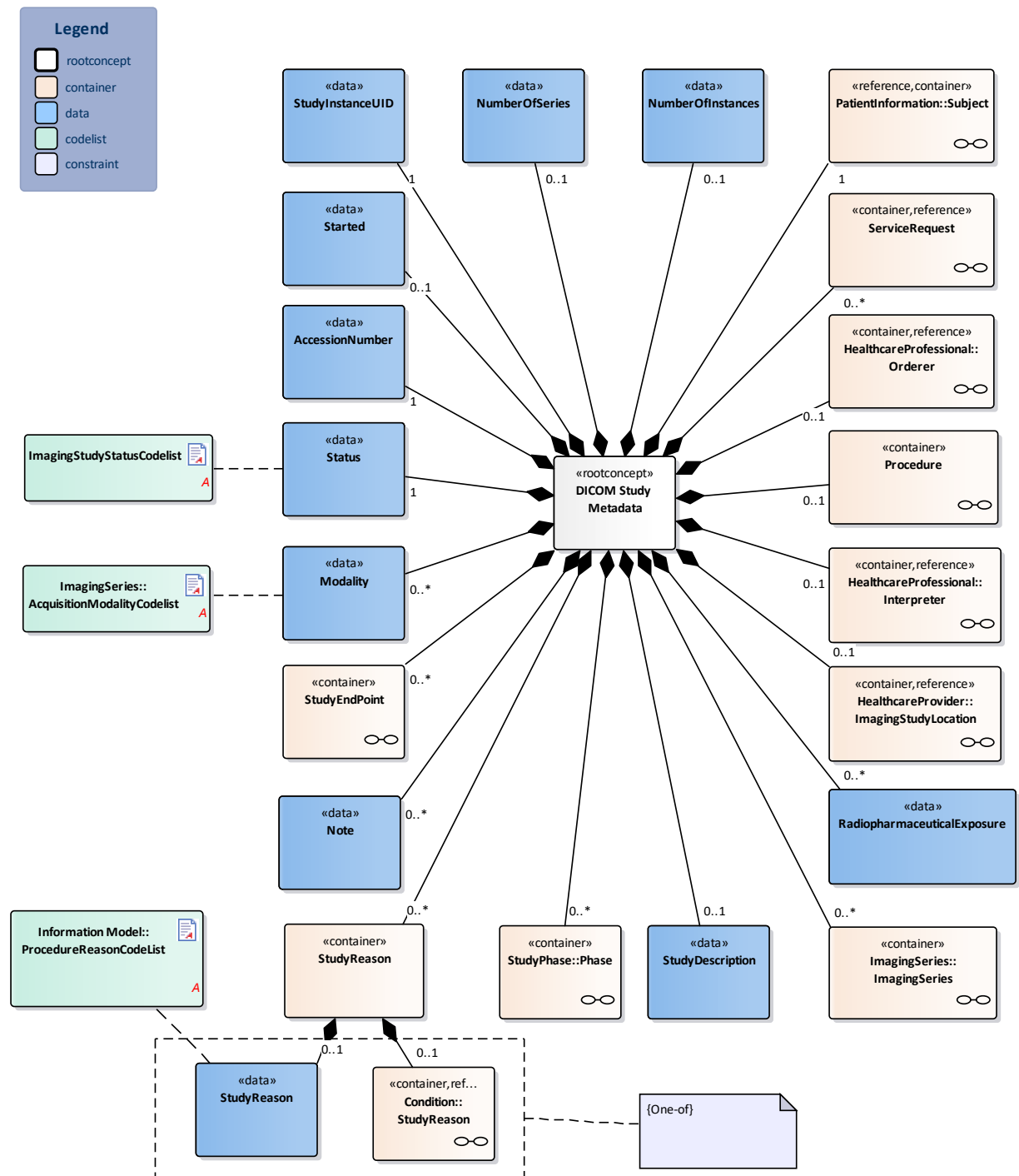


Figure 11: DICOM study

Type	Concept	Cardin.	Description
rootconcept	DICOM Study Metadata		Root concept of the DICOM Study. It is a representation of the content produced in a DICOM study. A study comprises a set of series, each of which includes a set of Service-Object Pair Instances (SOP Instances -

Type	Concept	Cardin.	Description
			images or other data) acquired or produced in a common context. A series is of only one modality (e.g. X-ray, CT, MR, ultrasound), but a study may have multiple series of different modalities.
Data	StudyInstanceUID	1	Globally unique identifier of the study. If one or more series elements are present in the ImagingStudy, then there shall be one DICOM Study UID identifier.
Data	NumberOfSeries	0..1	Number of Series in the Study. This value given may be larger than the number of series elements this Resource contains due to resource availability, security, or other factors. This element should be present if any series elements are present.
Data	NumberOfInstances	0..1	Number of Service-Object Pairs (SOP) Instances in Study. This value given may be larger than the number of instance elements this resource contains due to resource availability, security, or other factors. This element should be present if any instance elements are present.
reference	PatientInformation::Subject	1	The subject, typically a patient, of the imaging study.
container	ServiceRequest	0..*	Diagnostic request that resulted in this imaging study being performed.
container	HealthcareProfessional::Orderer	0..1	The requesting/referring physician.
container	Procedure	0..1	Container with information on the procedure which this ImagingStudy was part of.
container	HealthcareProfessional::Interpreter	0..1	Healthcare professional who read the study and interpreted the images or other content.
container	HealthcareProvider::ImagingStudyLocation	0..1	The principal physical location where the ImagingStudy was performed.
Data	RadiopharmaceuticalExposure	0..*	The radiation exposure caused by inner use of radio-pharmaceuticals expressed as value in standard SI units [Bq].
Data	StudyDescription	0..1	The Imaging Manager description of the study. Institution-generated description or classification of the Study (component) performed.
container	StudyReason	0..*	Why was study performed.
Data	StudyReason	0..1	Description of clinical condition indicating why the ImagingStudy was requested. This may be a coded entity or may simply be present as text.
container	Condition::StudyReason	0..1	Indicates problem/condition which existence justifies this Study.
Data	Note	0..*	User-defined comment.
container	StudyEndpoint	0..*	The network service providing access (e.g., query, view, or retrieval) for the study.
Data	Modality	0..*	A list of all the series.modality (DICOM element) values that are actual acquisition modalities.
Data	Status	1	The current state of the DICOM Imaging Study.
Data	AccessionNumber	1	An identifier of the Imaging Service Request (DICOM element).



Type	Concept	Car-din.	Description
Data	Started	0..1	Date and time when the study was started.

ImagingStudyStatusCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Registered	registered	hl7:ImagingStudyStat us	2.16.840.1.113883.4.642.4. 991	The existence of the imaging study is registered, but there is nothing yet available.
Available	available	hl7:ImagingStudyStat us	2.16.840.1.113883.4.642.4. 991	At least one instance has been associated with this imaging study.
Cancelled	cancelled	hl7:ImagingStudyStat us	2.16.840.1.113883.4.642.4. 991	The imaging study is unavailable because the imaging study was not started or not completed (also sometimes called "aborted").
Entered in Error	entered-in-error	hl7:ImagingStudyStat us	2.16.840.1.113883.4.642.4. 991	The imaging study has been withdrawn following a previous final release. This electronic record should never have existed, though it is possible that real-world decisions were based on it. (If real-world activity has occurred, the status should be "cancelled" rather than "entered-in-error".).
Unknown	unknown	hl7:ImagingStudyStat us	2.16.840.1.113883.4.642.4. 991	The system does not know which of the status values currently applies for this request.

## 10.3 ImagingSeries

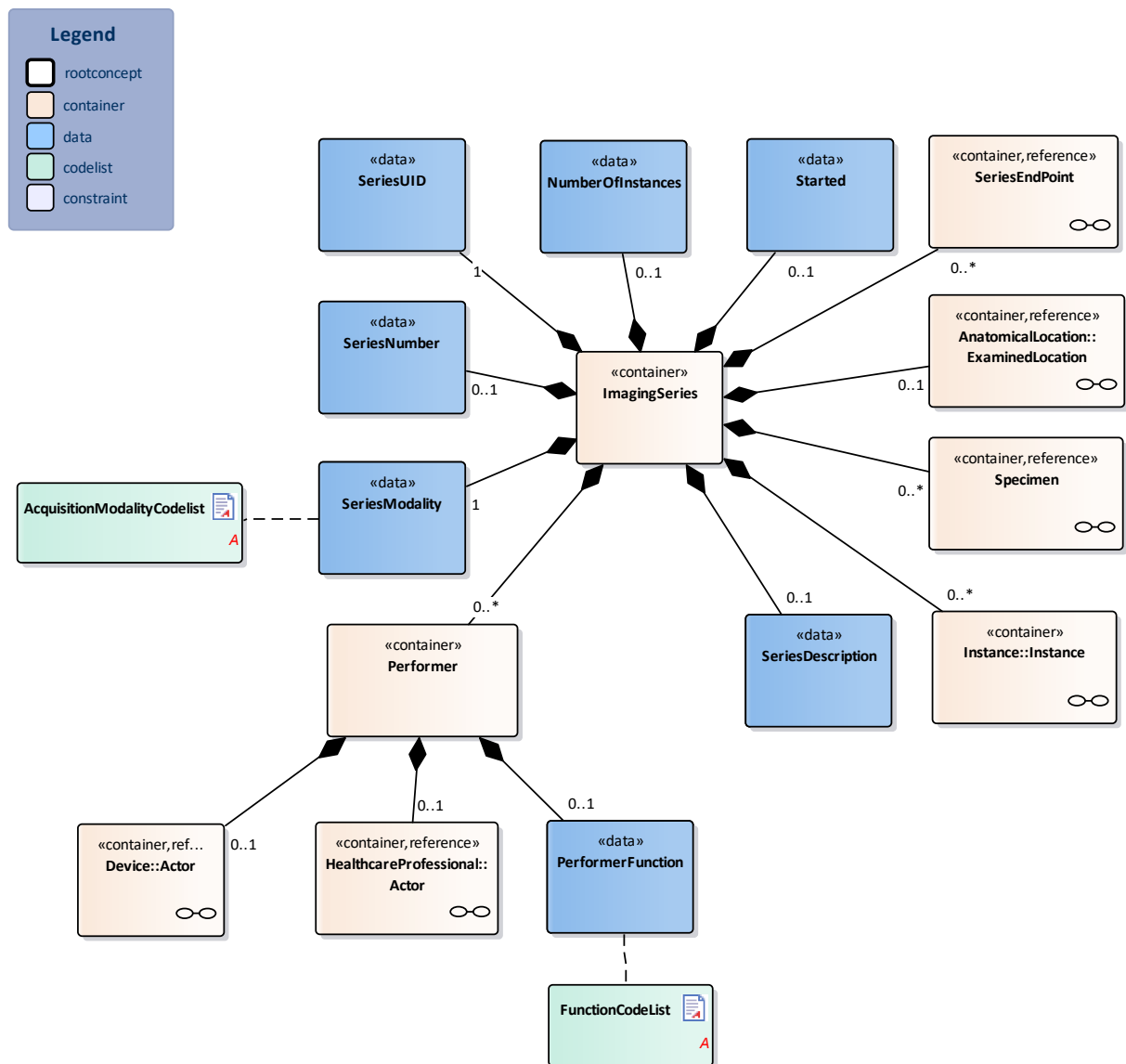


Figure 12:Series

Type	Concept	Card	Description
container	ImagingSeries		A container of the ImagingSeries concept. Each study has one or more series of images or other content.
Data	SeriesUID	1	The DICOM Series Instance UID for the series.
Data	NumberOfInstances	0..1	Number of Series Related Instances.
Data	Started	0..1	Date and time where the series was started.
container	SeriesEndPoint	0..*	Series access endpoint.
container	AnatomicalLocation::ExaminedLocation	0..1	The anatomic structures examined.

Type	Concept	Card	Description
container	Specimen	0..*	The specimen imaged, e.g., for whole slide imaging of a biopsy.
Data	SeriesDescription	0..1	A description of the series.
container	Performer	0..*	Indicates who or what performed the series and how they were involved. The performer is recorded at the series level, since each series in a study may be performed by a different performer, at different times, and using different devices. A series may be performed by multiple performers.
container	Device::Actor	0..1	Device used to perform a series.
container	HealthcareProfessional::Actor	0..1	A performer of the series.
Data	PerformerFunction	0..1	Distinguishes the type of involvement of the performer in the series.
Data	SeriesModality	1	Acquisition modality used by this series.
Data	SeriesNumber	0..1	The numeric identifier of this series in the study.

AcquisitionModalityCodeList			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
All values		DICOM Acquisition Modality	1.2.840.10008.6.1.19	<a href="http://dicom.nema.org/medical/dicom/current/output/chtml/part16/sect_CID_29.html">http://dicom.nema.org/medical/dicom/current/output/chtml/part16/sect_CID_29.html</a> html and <a href="http://dicom.nema.org/dicom/2013/output/chtml/part03/sect_A.8.html">http://dicom.nema.org/dicom/2013/output/chtml/part03/sect_A.8.html</a> (secondary capture – e.g.. a screenshot – may be modality independent, therefore are labelled as „SC“ – for the simplification Screenshot may be taken as another „modality“ together with the list in section CID 29.  XC should be used for general optical photography (https://www.hl7.org/fhir/DSTU1/imaging-modality.html)

FunctionCodeList			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
consultant	CON	hl7:v3_ParticipationType	2.16.840.1.113883.5.90	
verifier	VRF	hl7:v3_ParticipationType	2.16.840.1.113883.5.90	
performer	PRF	hl7:v3_ParticipationType	2.16.840.1.113883.5.90	
secondary performer	SPRF	hl7:v3_ParticipationType	2.16.840.1.113883.5.90	

FunctionCodelist		OID:		
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
referrer	REF	hl7:v3_ParticipationType	2.16.840.1.113883.5.90	

## 10.4 Instance

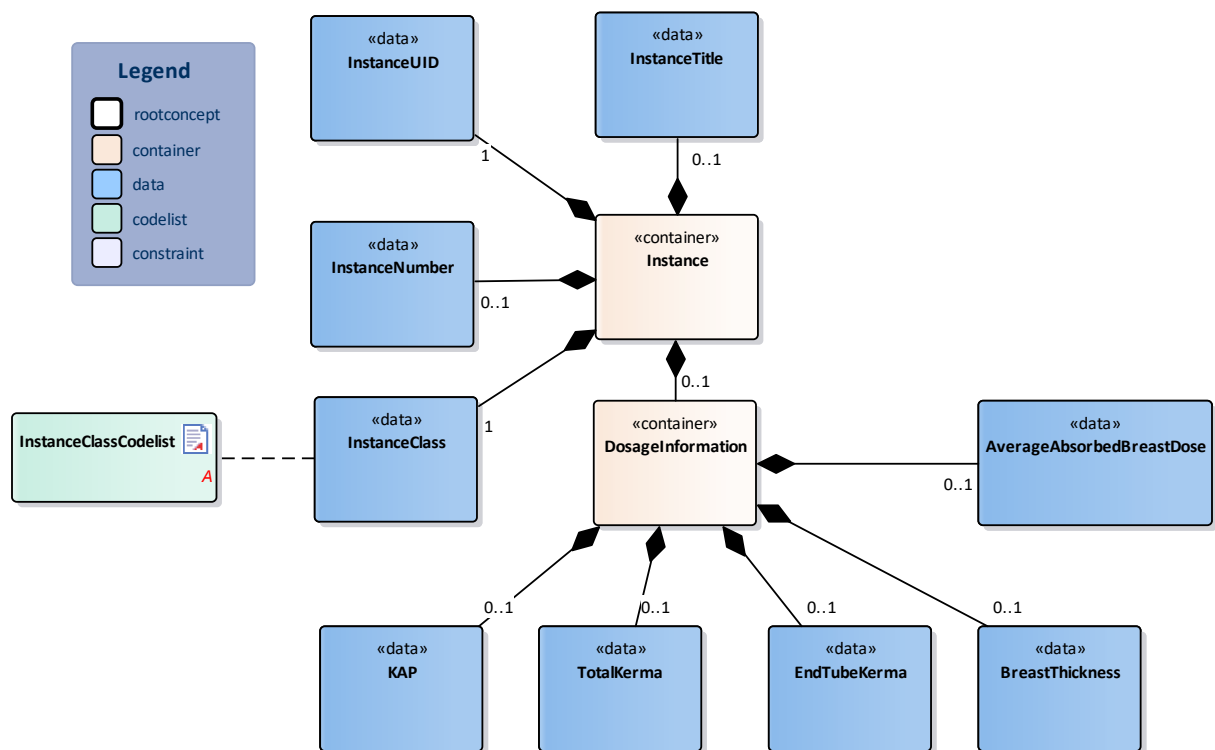


Figure 13:Instance

Type	Concept	Card	Description
container	Instance		Service-Object Pair (SOP) instance within the series, e.g. an image, or presentation state.
data	InstanceUID	1	The DICOM SOP Instance UID for this image or other DICOM content.
data	InstanceTitle	0..1	The description of the instance.
data	InstanceClass	1	DICOM instance type.
data	InstanceNumber	0..1	The number of instance in the series.
container	DosageInformation	0..1	

Type	Concept	Card	Description
data	AverageAbsorbedBreastDose	0..1	Average absorbed breast dose.
data	BreastThickness	0..1	Thickness of breast for the calculation of Average absorbed breast dose.
data	EndTubeKerma	0..1	Kerma at the end of tube (dental X-ray).
data	KAP	0..1	Kerma area product
data	TotalKerma	0..1	Total Kerma.

FunctionCodeList		OID:		
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
All codes		<a href="http://dicom.nema.org/medical/dicom/current/output/chtml/part04/sect_B.5.html#table_B.5-1">http://dicom.nema.org/medical/dicom/current/output/chtml/part04/sect_B.5.html#table_B.5-1</a>		

## 10.5 StudyPhase

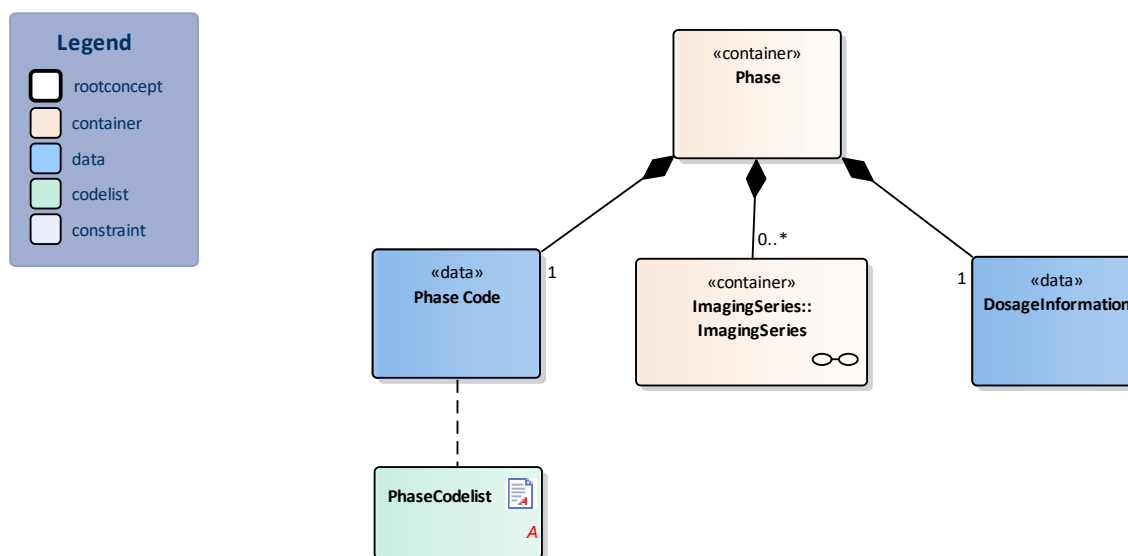


Figure 14: StudyPhase

Type	Concept	Card	Description
container	Phase		Study phase captures information about radiation exposure during imaging examination.
data	Phase Code	1	Study phase, e.g., without contrast, arterial phase, venous phase, delayed phase. Only some types of studies have phases.

Type	Concept	Card	Description
data	DosageInformation	1	DLP (dose length product) - Computerized Tomography (CT) related.
container	ImagingSeries	0..*	A container of the ImagingSeries concept. Each study has one or more series of images or other content.

PhaseCodelist			OID:
Display name	Code	Coding Syst. Name	Coding System OID
Without contrast			
Arterial phase			
Late arterial phase			
Venous phase			
Portal phase			
Delayed phase			
Late enhancement phase			

This is an example value set. The complete value set shall be completed during implementation.

## 10.6 ExaminationReport

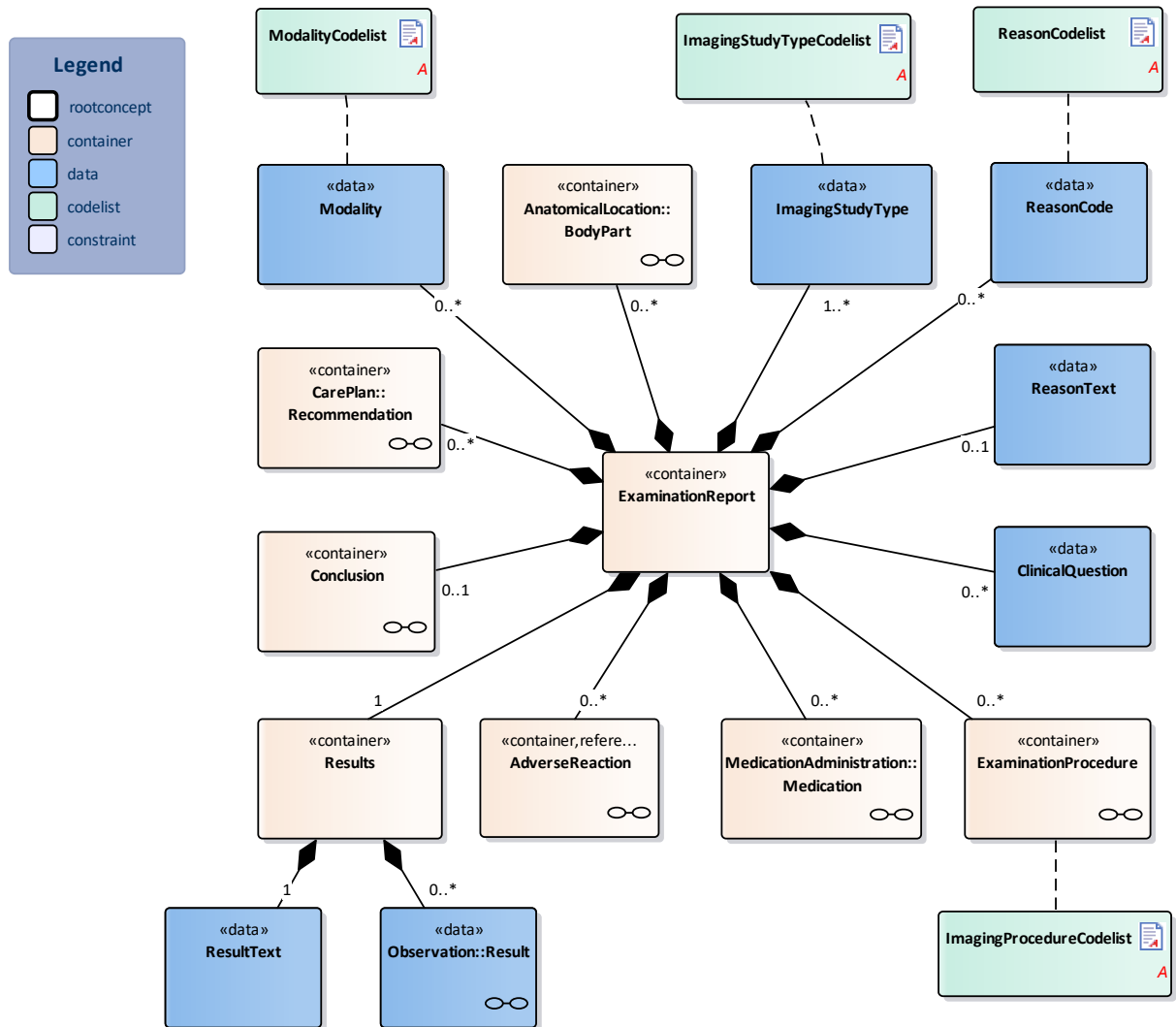


Figure 15:ExaminationReport

Type	Concept	Card	Description
container	ExaminationReport		Container with structured imaging examination report.
container	AdverseReaction	0..*	Adverse reactions related to examination, modelled as AllergyIntolerance information model.
container	AnatomicalLocation::BodyPart	0..*	BodyPart that had been examined.
container	CarePlan::Recommendation	0..*	This section includes the study interpreter's recommendations for follow-up studies or procedures.
data	ClinicalQuestion	0..*	A clinical question that needs to be answered by the examination. Example: "Suspected Lung tumour."
container	Conclusion	0..1	Conclusion includes the most important diagnoses or other clinical conclusions that can be made from imaging observations and/or other clinical information. This section may include global assessments, such as BIRADS Categories or the equivalent.
reference	ExaminationOrder	0..1	Identifier of the imaging order.
container	ExaminationProcedure	0..*	Imaging procedures performed expressed by a code and/or text entry.

Type	Concept	Card	Description
data	ImagingStudyType	1..*	Type of the imaging study performed.
container	MedicationAdministration::Medication	0..*	Drug administered as a contrast agent or other type of medication administered in relation to examination.
data	Modality	0..*	An imaging modality that performed the imaging study.
data	ReasonCode	0..*	A coded reason of the imaging examination order.
data	ReasonText	0..1	Description of clinical condition indicating why imaging examination was ordered. Example: "Cough lasting for 3 months"
container	Results	1	Report section with narrative part and optionally also coded result entries.
data	ResultText	1	Narrative report of the examination results or findings.
data	Observation::Result	0..*	Result observations related to imaging examination.

ImagingProcedureCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Concepts to be selected from <363679005   Imaging (procedure)   hierarchy		SNOMED CT		

ImagingStudyTypeCodelist		OID:		
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
All values		LOINC Imaging Document Codes	1.3.6.1.4.1.12009.10.2.5	<a href="https://loinc.org/oids/1.3.6.1.4.1.12009.10.2.5/">https://loinc.org/oids/1.3.6.1.4.1.12009.10.2.5/</a>
Examples:				
US for pregnancy	11525-3	LOINC	1.3.6.1.4.1.12009.10.2.5	
MR Spine study	18756-7	LOINC	1.3.6.1.4.1.12009.10.2.5	

ModalityCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	Description	
Autorefraction	AR	DICOM PS 3.3-2011 Section C.7.3.1.1.1		
Content Assessment Results	ASMT			
Audio	AU			
Bone Densitometry (ultrasound)	BDUS			
Biomagnetic imaging	BI			
Bone Densitometry (X-Ray)	BMD			
Computed Radiography	CR			
Computed Tomography	CT			



ModalityCodeList	OID:		
Concept Name	Concept Code	CodeSys. Name	Description
Diaphanography	DG		
Document	DOC		
Digital Radiography	DX		
Electrocardiography	ECG		
Cardiac Electrophysiology	EPS		
Endoscopy	ES		
Fiducials	FID		
General Microscopy	GM		
Hard Copy	HC		
Hemodynamic Waveform	HD		
Intra-Oral Radiography	IO		
Intraocular Lens Data	IOL		
Intravascular Optical Coherence Tomography	IVOCT		
Intravascular Ultrasound	IVUS		
Keratometry	KER		
Key Object Selection	KO		
Lensometry	LEN		
Laser surface scan	LS		
Mammography	MG		
Magnetic Resonance	MR		
Nuclear Medicine	NM		
Ophthalmic Axial Measurements	OAM		
Optical Coherence Tomography (non-Ophthalmic)	OCT		
Ophthalmic Photography	OP		
Ophthalmic Mapping	OPM		
Ophthalmic Tomography	OPT		
Ophthalmic Visual Field	OPV		
Optical Surface Scan	OSS		
Other	OT		
Plan	PLAN		
Presentation State	PR		
Positron emission tomography (PET)	PT		
Panoramic X-Ray	PX		
Registration	REG		
Respiratory Waveform	RESP		
Radio Fluoroscopy	RF		
Radiographic imaging (conventional film/screen)	RG		
Radiotherapy Dose	RTDOSE		
Radiotherapy Image	RTIMAGE		
Radiotherapy Plan	RTPLAN		
RT Treatment Record	RTRECORD		
Radiotherapy Structure Set	RTSTRUCT		

ModalityCodelist		OID:	
Concept Name	Concept Code	CodeSys. Name	Description
Real World Value Map	RWV		
Segmentation	SEG		
Slide Microscopy	SM		
Stereometric Relationship	SMR		
SR Document	SR		
Subjective Refraction	SRF		
Automated Slide Stainer	STAIN		
Thermography	TG		
Ultrasound	US		
Visual Acuity	VA		
X-Ray Angiography	XA		
External-camera Photography	XC		

ReasonCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Concepts to be selected from 243796009   Situation with explicit context (situation)   hierarchy		SNOMED CT		

## 10.7 Exposure

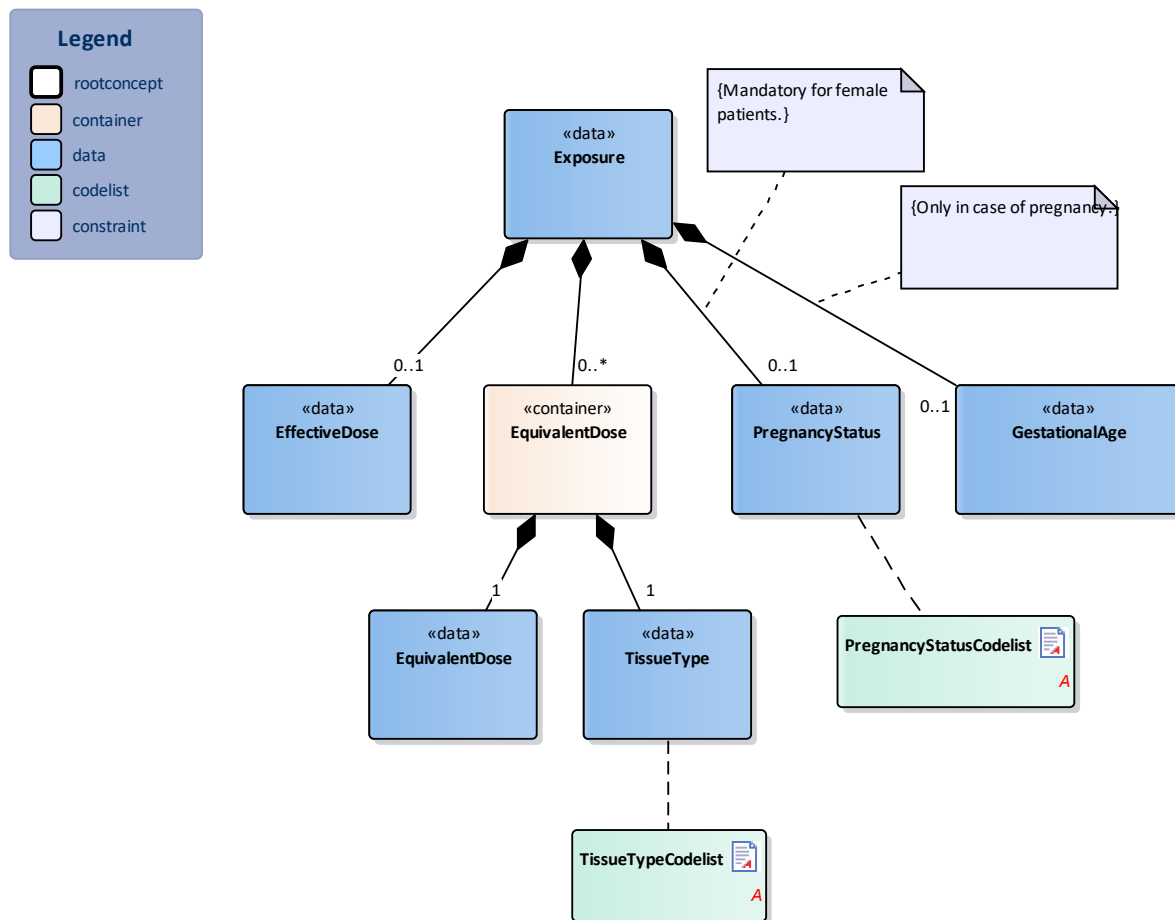


Figure 16:Exposure

Type	Concept	Card	Description
container	Exposure		A container with information about radiation exposure of the patient during Imaging investigation.
data	EffectiveDose	0..1	Sum of equivalent doses to all organs, from external and/or internal exposures, each adjusted to account for the sensitivity of the organ to radiation. [mSv]
data	PregnancyStatus	0..1	Pregnancy status when the imaging examination was performed. E.g., pregnant, not pregnant, unknown.
data	GestationalAge	0..1	Duration of the pregnancy on the day on which the patient was asked or at the delivery. The duration can be given in days (d) or weeks (wk).
container	EquivalentDose	0..*	A package including information of all equivalent dose attributes.
data	EquivalentDose	1	Equivalent dose is a measure of the radiation dose to tissue where an attempt has been made to allow for the different relative biological effects of different types of ionizing radiation. Equivalent dose is based on the absorbed dose per organ, adjusted to account for the effectiveness of the type of radiation [mSv].
data	TissueType	1	Type of the tissue for which do dosage was enumerated.

Type	Concept	Card	Description

PregnancyStatusCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Pregnant	77386006	SNOMED CT		
Not pregnant	60001007			
Unknown	261665006			

TissueTypeCodelist		OID:		
Concept Name	Concept Code	CodeSystem	CodeSystem OID	Description
Stomach	69695003	SNOMED CT		
Colon	71854001			
Lung	39607008			
Red bone marrow	75330005			
Brest	76752008			
Adrenal structure	23451007			
extra thoracic region				
gallbladder	28231008			
heart	80891009			
kidney	64033007			
lymph nodes	59441001			
muscle	91727004			
oral mucosa	113277000			
pancreas	15776009			
small intestine	30315005			
spleen	78961009			
thymus	9875009			
uterus/cervix	110633001			
prostate	41216001			
gonads	43174007			
urinary bladder	89837001			
oesophagus	32849002			
liver	10200004			
thyroid	69748006			
bone surface	425647002			
skin	39937001			
brain	12738006			
salivary glands	385294005			

See also:

<https://radiopaedia.org/articles/tissue-weighting-factor>

## 11 Annex IV

Contrary to the well-defined DICOM specifications, the structured report has been defined in several ways, by CDA/HL7, FHIR and a DICOM supplement 20. Moreover, the Austrian ELGA Project for Radiology defined the following data fields that could be used as an European starting point:

- Patient
- Visit
- Order
- Anamnesis
- Indication
- Patient status/..
- Current examination
- Earlier examination(s)
- Earlier examination results
- Complication(s)
- Findings
- Summary
- Diagnosis
- Conclusion
- Recommendation
- Addendum
- Contact person for questions
- Signed by
- Additional information

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