eHealth Network

Guideline on

the electronic exchange of health data
under Cross-Border Directive 2011/24/EU

Medical imaging studies and reports

Release 1.0, Nov 2023

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

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1. USE CASE DESCRIPTION

Medical imaging studies and medical imaging reports

The availability and exchange of imaging studies and imaging reports is a relevant part of the European eHealth services, contributing to the application of patients' rights in cross-border healthcare per Directive 2011/24/EU of 9 March 2011. Imaging studies and imaging reports are explicitly noted in Paragraph 11(d) of Commission Recommendation of 6 February 2019 on a European Electronic Health Record exchange format (EEHRxF).

Five use cases are proposed, of which use case 1 is in scope for the first version of this Guideline. Technical specifications to support the implementation of the use cases described in the Guideline will be developed separately.

Use case 1: Request and retrieval of imaging studies and imaging reports by a health professional involved in providing care for a patient

Priority: 1

Title	**Drafts for the guideline**
Purpose	Imaging studies and reports are made available in a cross-border context to a requesting health professional: ● When a previously performed imaging study or report is needed to support clinical decision making. ● In case of emergency or to support consultation or for continuity of care. As information sharing is not limited to the cross-border use case, Member States could also use these guidelines for national and regional level interoperability to ensure consistency as well as avoid fragmentation and duplication of efforts.

Relevance	The availability of previously performed imaging studies and reports may help to: ● Provide better support for health professionals in care-related decision making (and avoid treatment errors). ● Avoid unnecessary imaging procedures and duplication, gaining time and reducing costs. ● Prevent unnecessary harm to the patient because of medical irradiation, in line with Council Directive 2013/59/Euratom. ● Provide a possibility to compare results. ● Provide the possibility to re-evaluate previous medical imaging by an expert
Domain	Imaging studies are commonly produced by specialties such as radiology, surgery, nuclear medicine, cardiology, medical photography, pathology, neurology (ultrasound), internal medicine, gynaecology, obstetrics, dental medicine, urology, however no clinical speciality is excluded. Consumers: any authorised healthcare provider. The guideline intends to extend the use of medical imaging to a broader context.
Scale	Cross-border, national/regional, between organisations. The focus is on the cross-border exchange, but the guideline may also be used in other contexts.

Context	1. The availability of both imaging reports and imaging studies is relevant for the continuity of care. Imaging reports and corresponding imaging studies are usually presented together, using a unique ID that links them. End users should be able to have access to the imaging report and/or the corresponding imaging study. 2. A list of available imaging studies may contain many list items (sometimes hundreds). In order to quickly access the desired information for the task at hand, the end user must be able to select and combine different search parameters. This requires a predefined set of metadata elements that can be used for grouping, sorting and filtering the list of available information. 3. These metadata elements should enable different criteria for searching and filtering. 4. The access to the images of an imaging study may be offered either by: (1) moving the image data to the requester so that it has the possibility to perform, with its own imaging software, the viewing as well as advanced processing of these native images or (2) requesting the launch of a server-side or remote viewer offered by the source of the imaging study so that the requester may simply use an off-the-shelf browser.
Information	These guidelines provide information specifications on the following: ● Imaging study manifest ● Imaging report ● Metadata on imaging studies and reports used for search and retrieval The metadata enables the creation and presentation of a list of available imaging studies and reports, sortable on time, purpose, body part, modality, provenance or other (combinations of) attributes. They are also used to connect/link individual imaging studies to their accompanying imaging reports.
Participants	1. Health professional(s) in the patient's country of origin/affiliation (country A) 2. Health professional in the country of visit/treatment (country B) 3. Citizen/Patient

Preconditions	There should be sufficient bandwidth for transmitting the images across the networks. Metadata enabling the presentation, filtering, grouping and ordering of imaging studies and imaging reports should be available according to the requirements presented in Article 10: Data. Imaging studies should be linked to (an) imaging report using at least one common identifier when they are associated. A means to identify a set of relevant/significant images within the imaging study should be available for fast review of imaging studies and the ability to retrieve/display first these images.

Functional process steps	1. The *Patient* from Country A consults a *Health Professional* in the country of treatment (Country B). 2. The *Health Professional* (in Country B) is identified, authenticated and authorised. 3. The *Health Professional* (in Country B) provides information to the patient on how personal health data in the *imaging studies and reports* will be collected and processed in Country B. 4. The Patient is identified (in Country B) and the patient identity is confirmed by the country of affiliation (Country A). 5. The *Health Professional* in Country B queries Country A for a list of imaging studies and imaging reports of that patient, providing, if needed, additional query parameters, such as time period, modality, study procedure, body part, or procedure code. 6. Country A provides a list of the available *imaging studies and/or reports* to Country B. 7. The *Health Professional* selects (including filtering, ordering, grouping) and requests the relevant *imaging studies and/or reports* from Country A. 8. Country A provides the requested *imaging studies and/or reports* to Country B. In case there are multiple versions of studies/reports, the latest versions are provided. 9. The *Health Professional* (in Country B) is presented with the requested *imaging studies and/or reports* through a user interface provided by a local information system, a dedicated viewer, a portal or an alternative technical solution. The *Health Professional* may also be enabled to download the requested *imaging studies and/or reports* to the system used locally for later use if allowed by the national law and relevant data protection arrangements. 10. The *Health Professional* (in Country B) uses the *imaging studies and/or reports* to provide healthcare service. Depending on national law in Country B, the retrieved information might be stored, e.g. for the purposes of keeping track of health data used for any clinical decisions. The storage time is regulated in this case by national law in Country B.

Table 1: Description of use case 1: Request and retrieval of imaging studies and imaging reports by a health professional involved in providing care for a patient

Use case 2: Request and retrieval of imaging studies and imaging reports by a patient

Imaging studies, imaging reports and possibly requests thereof are made available to be accessed by the patient.

To be decided upon in a later version of the Guideline.

Priority: 2

Use case 3: Provision of imaging studies to a health professional providing care for a patient

A specific set of imaging studies (and/or imaging reports) are sent from Country A to Country B to provide aid in treating a patient (notably in second opinion or emergency scenarios). More information about the use case is available in D5.4 Chapter 5 of the X-eHealth. A notification about the relevant information is sent to Country B, followed by a request of the indicated information.

To be decided upon in a later version of the Guideline.

Priority: 3

Use case 4: Ordering of an imaging study evaluation and retrieval of an imaging report

Second opinion, consultation for rare diseases.

To be decided upon in a later version of the Guideline.

Priority: 3

Use case 5: Return imaging related information to Country A in order to populate the patient record.

A specific set of imaging reports and/or imaging studies, resulting from the care received by a patient in Country B, is sent to Country A in order to populate the patient's medical record.

To be decided upon in a later version of the Guideline.

Priority: 2

2. GUIDELINES FOR MEDICAL IMAGING STUDIES AND MEDICAL IMAGING REPORTS

The Member States in the eHealth Network have adopted these supplementary clauses to the eHealth Network General Guidelines for the electronic exchange of health data under Cross-Border Directive 2011/24/EU to support the exchange of medical imaging studies and medical imaging reports data. There being no specific additional requirements, reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter I - General Considerations

Article 1: Objectives and scope

Imaging studies and imaging reports cover 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 as well as external structures, e.g. in dermatology. It provides insight into the location, size, structure, perfusion, 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. They enable health professionals (increasingly assisted by image processing algorithms) to find the right diagnosis, guide therapeutic decisions and aid in surgical and non-surgical procedures.

These guidelines are addressed to the Member States and apply to the implementation of cross-border exchange of interoperable imaging studies and imaging reports in order to support safe and efficient provisioning of care services in another Member State. These guidelines, although not directly applicable, may inform the national development and the implementation of imaging studies and imaging reports exchange in order to increase the consistency in the decisions made at the national level, which are strictly out of the scope of these guidelines.

Systems implemented using these guidelines could reduce duplication of imaging studies, reduce time until the start of therapy and thus enhance patient safety. This means patients do not have to go through repetitive testing and imaging procedures such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) scans. The availability of previously taken imaging studies and related imaging reports could improve treatment outcomes. The availability of imaging studies and imaging reports could also be useful in consultations between health professionals regarding their patients, especially in case of difficult situations or in a cross-border context.

In scope:

- Use case 1 (priority 1): Imaging studies and imaging reports produced in Country A (country of affiliation) and retrieved by a health professional in Country B (country of treatment).
- All DICOM objects requested in Country B and made available by Country A, for example, used in radiology, ultrasound, nuclear medicine, cardiology, endoscopy, mammography or dentistry.
- Imaging reports.

Out of scope in this version of the guideline:

- Use cases 2-5 (priority 2-3)
- Radiation dose management (Only the initial elements are included in this release, and further work is needed)
- Hanging protocols management
- Ordering and workflow
- Editing and annotation on existing image studies
- Translation of texts within DICOM objects
- Reimbursement of medical services

Article 2: Terms and definitions

For the purpose of these guidelines, the definitions included in Directive 2011/24/EU, in the eHealth Network General Guidelines, and the following definitions shall apply:

Definitions:

Term	Definition
Accession number	This is an identifier, managed by the RIS at the local level, which usually uniquely identifies an imaging procedure request, and links it to imaging study(ies) and related imaging report(s). As it is prefixed by the registration authority it is a globally unique ID, usable both nationally and cross-border.
DICOM	Digital Imaging and Communications in Medicine (DICOM) is the global standard for medical images developed by American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA). It offers a standardised representation of imaging studies, together with related contextual information. It encompasses a uniform methodology for the capture, storage and distribution of imaging studies anywhere in the world.

Health professional	A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment, as defined in Directive 2011/24/EU
HL7	Health Level 7
ICD-10	International Statistical Classification of Diseases and Related Health Problems 10th Revision
IHE	Integrating the Healthcare Enterprise
Imaging report	An imaging report reflects the observations and interpretations of one or more imaging studies. 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, exposure information, conclusion and advice.
Imaging study	An imaging study comprises a set of objects, including images and other objects, that were made for a specific purpose and usually in response to a request from a healthcare provider. The Imaging Study does not include the Imaging Report as defined in this guideline.
Instance	An instance is the smallest component of the imaging study , 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.
Key image	An image within the imaging study that is flagged to reflect its significance in order to facilitate a prioritised retrieval and display of these images.
LOINC	Logical Observation Identifiers Names and Codes
Imaging study manifest	A document listing the key information about the content of an imaging study. It acts as a summary for the actual imaging study that is large (typically megabyte or gigabyte size) and complex (hundreds of data elements). It includes location pointers to its image content and organises this information according to the well-established model of an imaging study made of one or more series and each series made of instances or images.
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.

Metadata	Information that is given to describe or help you use other information. Metadata are information parameters that provide contextual information about the actual information within a document (or other information container). Examples are: date of event and/or publication, size in bytes, technical format, template, standard version, document version, author specialty, functional category et cetera.
Modality	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).
NCPeH	National Contact Point for eHealth An organisational and technical gateway for the provision of Cross-Border eHealth Information Services under the responsibility of a Member State (as defined in Commission Implementing Decision 2019/1765)
PACS	Picture Archiving and Communication System. A PACS consists of three major components: a secure network for the transmission of imaging and patient information, workstations for interpreting and reviewing images, and archives for the storage and retrieval of images and reports. Combined with web technology, a PACS has the ability to deliver timely and efficient access to images, interpretations, and related data. A PACS is usually linked to a Hospital Information System.
Patient	A natural person who seeks to receive or receives healthcare in a Member State (as defined in Directive 2011/24/EU)
RADLEX	Lexicon of radiological Information. RADLEX has been largely integrated within LOINC.
Series	Each DICOM study contains one or more series. A series is defined as a set of one or more DICOM instances that were generated by the one equipment (modality) at one encounter/session with the patient. A single imaging study can contain a series of the same or different types of modalities. For example, within a single study, there may be a Positron Emission Tomography (PET) series, a CT series, and a plain X-ray image.
SNOMED-CT	Systematised Nomenclature of Medicine -- Clinical Terms SNOMED CT consists of coded concepts that are linked and logically related. This feature allows the meaning of information recorded in clinical information systems, health data & analytics platforms and interoperability solutions to be processed by a computer

Study Instance UID	The globally unique identifier of an a imaging study.
RIS	Radiology Information System. The main functions of a RIS are the patient scheduling, resource management, examination performance tracking, reporting, results distribution, and procedure billing. Typically, it is integrated in the HIS and the PACS.

Article 3: Intended use

Whether in emergency situations or in planned care, imaging studies are being used extensively. 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 theragnostic). **Therapeutic** interventions or image guided procedures include radiological, neuro-radiographic, radiological, cardiological and radiotherapeutic interventions. Imaging quality based on high quality standards is key in contributing to proper diagnosis.

Patients are often treated by more than one medical or interventional speciality and/or in more than one healthcare organisation. Imaging studies, imaging reports and associated metadata should be shared between professionals on different levels: within an organisation, between organisations, regionally/nationally and across country borders.

For the proper assessment of the progress of a disease or condition over time, access to imaging studies that were previously made (in the country of affiliation) is needed. As imaging technologies are used for many purposes, the number of available imaging studies can sometimes grow to hundreds. In order to quickly select the most relevant studies, the health professional should be presented with a list of available imaging studies and imaging reports , with the possibility to interactively filter, sort or group them, based upon a set of metadata parameters.

1. The provisions in the "eHealth Network guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - General guidelines" apply.
2. Imaging studies and imaging reports should complement information provided through other services, such as through the Patient Summary.
3. Imaging studies and imaging reports should be presented to the health professional in an understandable way, namely regarding language, structure and vocabularies.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 5: Identification, authentication and authorisation

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 6: Patient safety

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 8: Quality standards and validation

In the current version of the guideline, only exchange of final imaging reports is supported.

Article 9: Education, training and awareness

When imaging studies and imaging reports are exchanged cross-border, it is relevant to raise health professionals' awareness of different types of procedures and methodologies used in different Member States, as they may impact the understanding of the presented material. Interoperability between workflows can be achieved by implementing relevant standards such as those specified by IHE.

Chapter IV - Semantic Considerations

Semantic interoperability is the ability of computer systems to exchange data with unambiguous, shared meaning. It is a requirement to enable machine computable logic, inferencing, knowledge discovery, and data federation between information systems. This is accomplished by adding data about the data (metadata), agreeing on shared data and information models, and linking each data element to a controlled, shared vocabulary. It is these shared data models and vocabularies, and their associated links to an ontology, which provide the foundation and capability of machine interpretation, inference, and logic.

While the journey of semantic interoperability varies across Member States, the chapters below discuss the most common elements in the medical imaging domain.

Article 10: Data

Selection list and filtering parameters

In Step 5 of the Functional process of the use case 1, a list of available imaging studies and imaging reports is mentioned. The purpose of this list is to support health professionals to discover the most relevant information for a specific context. The following guidelines should be considered.

The reasons for these process steps (the presentation of a list of available imaging studies and reports) are the following:

The **number** of available imaging studies of a patient may be large and their purposes may be diverse. Step 5 describes a transaction where the NCPeH of Country B requests, and the NCPeH of Country A returns a structured list of available documents of a certain patient. This list consists of a number of contextual parameters for each document that can be used for a user-friendly and interactive presentation of the available studies in an intuitive and recognisable way. The parameters can be used for different presentation modes, such as a table with columns that can be sorted, tabs per study type, grouped lists, filtering possibilities et cetera. The list request can be simple (requesting all available documents) or parameterised, using the metadata to select the most relevant documents.

The **size** of an imaging study can be substantial, from megabytes up to gigabytes. The size of the imaging studies is prohibiting a full download of all available imaging studies. It is therefore necessary to take the expected download time into account and allow the requester to choose to access imaging studies and imaging reports most likely relevant.

In order to find and select the right information, a list of available imaging studies manifests and imaging reports is needed. This list contains a predefined set of contextual information parameters (metadata) that can be used by the end user to interactively make this selection. The list can be used by an application that facilitates this selection. The technical details on how this is offered are beyond the scope of this guideline.

In addition to the provision of a list, extra possibilities to quickly find whether an imaging study may be relevant for closer inspection and downloading could be:

- the provision of snapshots or thumbnails
- the presence of a set of key images that are flagged within the imaging study
- references from within the imaging report to launch a server-side application in Country A that allows for lightweight viewing of the imaging study, without having to move the images to Country B.

In the above requirements we have distinguished three levels of interactions (see Section 3 Chapter V for the transactions performed between NCPeH):

1. The initial query request with an associated predefined set of contextual information parameters (metadata) that can be used by the end user to interactively make an initial request with the proper filtering to expect in return a shorter and more relevant list of matching studies or reports. The metadata used for this query is defined below under the subtitle “Filtering and returned Report and Studies Metadata (generic or imaging specific)”.
2. The user-friendly, intuitive and reliable selection of among the elements of this initial list with more information on each matching study manifests or reports to quickly select among them the desired ones and request their download. The information used as a basis for this selection is called “Imaging study Manifest Data Set" and is defined in section 4.2.
3. In the case of imaging studies, with access to the entire imaging study manifest, the download of the imaging study or selected images may be triggered by selecting either or both the Imaging Study UID and the Series Instance UID.

Filtering and returned Report and Studies Metadata (generic or imaging specific)

The following parameters have been identified as the most relevant for the initial query among the available studies. These parameters should be included on the list of medical imaging reports and studies presented to the health professional so that the identification of the relevant report is possible.

1. The document class (imaging and/or report)
2. Modality - the type of imaging capture hardware
3. Procedure date (study date) - the date and time the imaging study started
4. Anatomical region (short list of body parts or body systems)
5. Imaging procedure
6. Study Instance UID
7. Accession number
8. Order identifier

Metadata parameters that are returned (in addition to the above) and relevant for retrieval and further inspection purposes:

1. The ID or reference needed for the retrieval of the document (Imaging Study Manifest instance UID or Report Unique ID).
2. The technical format of the documents. This can be used to see whether the file can be opened.
3. The author, organisation and country of the Report or Imaging study.

The full dataset for medical imaging reports is included in Section 4.1. The dataset for the medical imaging manifest is located in Section 4.2.

Article 11: Terminology

Member States wishing to engage in cross-border communication are encouraged to use for that communication the preferred code systems as described in the datasets in Section 4.

Article 12: Controlled Lists (Value set Catalogues)

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter V - Technical Considerations

Article 13: Technical requirements

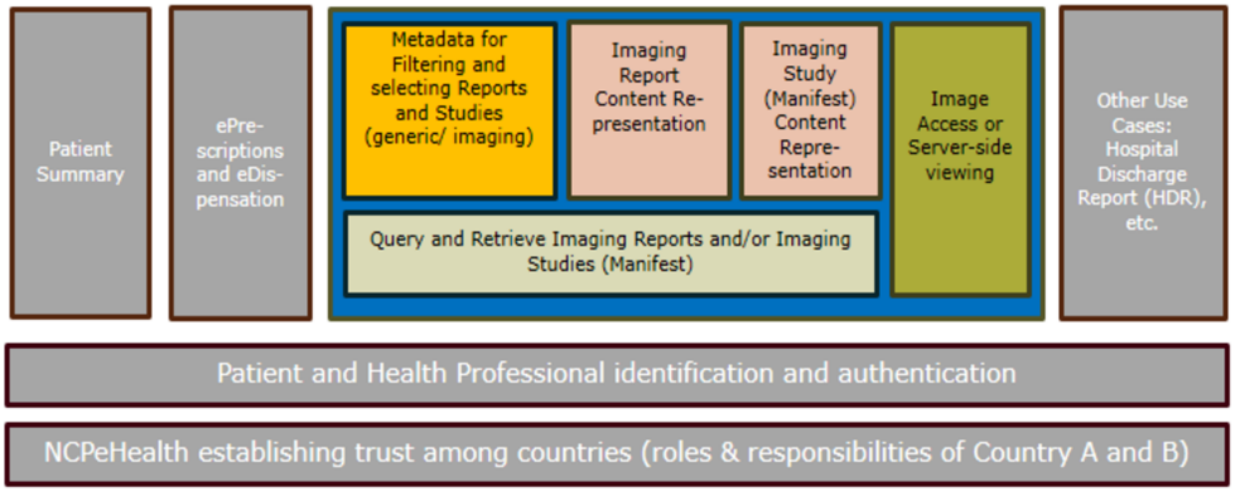
When analysing the technical requirements for use case 1 (see Section 1 USE CASE DESCRIPTION - use case 1), these need to be placed in the context of already deployed use cases such as those used in MyHealth@EU for the access to Patient Summaries, ePrescriptions and eDispensation. In addition, a number of requirements that are necessary to offer a common foundation across multiple use cases including imaging need to be addressed in a common way. They include identification and authentication of health professionals and patients, as well as the means to establish trust among communication countries and are already specified in the eHealth Network General Guidelines (Article 5).

To be able to exchange imaging reports and imaging studies, the needed business functionalities specific to imaging should be designed to operate within this overall context which is depicted in the figure below.

Note: The colours in the above diagram only aim to distinguish between different business requirements providing the context and the focus placed on Imaging Reports and Imaging Study Access.

Business requirements specific to the exchange of imaging reports and imaging studies between NCPeHs, as scoped in use case 1, are further described in the remainder of this section, organised into the following building blocks:

- Query and retrieve imaging reports and/or imaging studies (manifest pointing at the medical images).
- Filtering and selecting imaging reports and imaging studies based on generic and imaging specific metadata. Requirements for such metadata are analysed in Article 10 of Section 2.
- Imaging report content representation. Requirements for the content of an imaging report are addressed in Section 4.1.
- Imaging study manifest (pointing at the medical images). Requirements for the content of an imaging study manifest are addressed in Section 4.2.
- Access to images or remote (server-side) viewing of images.



Note: the colours in the above diagram only aim to distinguish the different nature of building blocks such as those supporting query and retrieve transactions, metadata for query filtering, document content exchanged and transactions to access to images).

The orchestration of these building blocks in a workflow between the NCPeHs of Country B and Country A is described in Section 3, Chapter V. These are building upon the general functionalities of MyHealth@EU, such as patient identification, consent, authentication, translation, mapping, networking capabilities (as described in general guidelines and implementation guides of MyHealth@EU).

The imaging related building blocks introduced in this section have to be specified in technical details including references to international standards and profiles, sufficient to achieve interoperable NCPeHs. This is beyond the scope of this guideline.

Article 14: Security

Member States shall ensure that they are fully compliant with the cross-border Security Policy.

Article 15: Testing and audit

Considering the size of exchanged information, notably images, testing should consider bandwidth issues.

Testing efforts should address the correct linkage between imaging studies and imaging reports.

3. SUPPORTING INFORMATION

This section provides supporting information and explanatory text to aid understanding of the guidelines, and the rationale behind the proposals. It therefore follows the same structure as the eHealth Network General Guidelines. This chapter can be taken as inspiration for any initiative aiming at implementing interoperable imaging studies and imaging reports.

The main goal of this chapter is to disseminate common practices for initiatives implementing the exchange of medical images and medical imaging reports.

The material in this chapter has built on work from the X-eHealth project.

Chapter I - General Considerations

Article 1: Objectives and scope

These guidelines were prepared on the basis of the X-eHealth project deliverable D5.4.

Article 2: Definitions

There is no specific support information.

Article 3: Concept and intended use

There is no specific support information.

For the intended use, an integrated approach towards the selection and presentation of the available medical information of a patient will be presented in the General Guidelines.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

There is no specific support information.

Article 5: Authorisation, authentication and identification

There is no specific support information.

Article 6: Patient safety

There is no specific support information.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

Following the Refined eHealth European Interoperability Framework (ReEIF) interoperability levels, the following enablers can be mentioned for the implementation of the guideline:

Legal and regulatory level:

- European/International programs or governance supporting legal initiatives
- European/International legal framework
- The appropriate trust frameworks between all relevant parties

Policy level:

- Funding of relevant projects at EU and national level
- Coordinated approach to the implementation of the guideline and the standards referenced therein
- Endorsement and strong support by the eHN
- Strong involvement and support of the health professionals

Care process level:

- Appropriate change management within Member States to align national care processes with the defined cross-border use cases

Information and application levels:

- Alignment of the applicable systems used in the Member States' national infrastructures to conform to the data sets defined in the guideline

Infrastructure level:

- Development of connectors between relevant systems such as PACS, VNA, NCPeH
- In distributed environments, possibly the development of indexing functionalities to efficiently locate the necessary objects (imaging studies and reports)

Article 8: Quality standards and validation

There is no specific support information.

Article 9: Education, training and awareness

There is no specific support information.

Chapter IV - Semantic Considerations

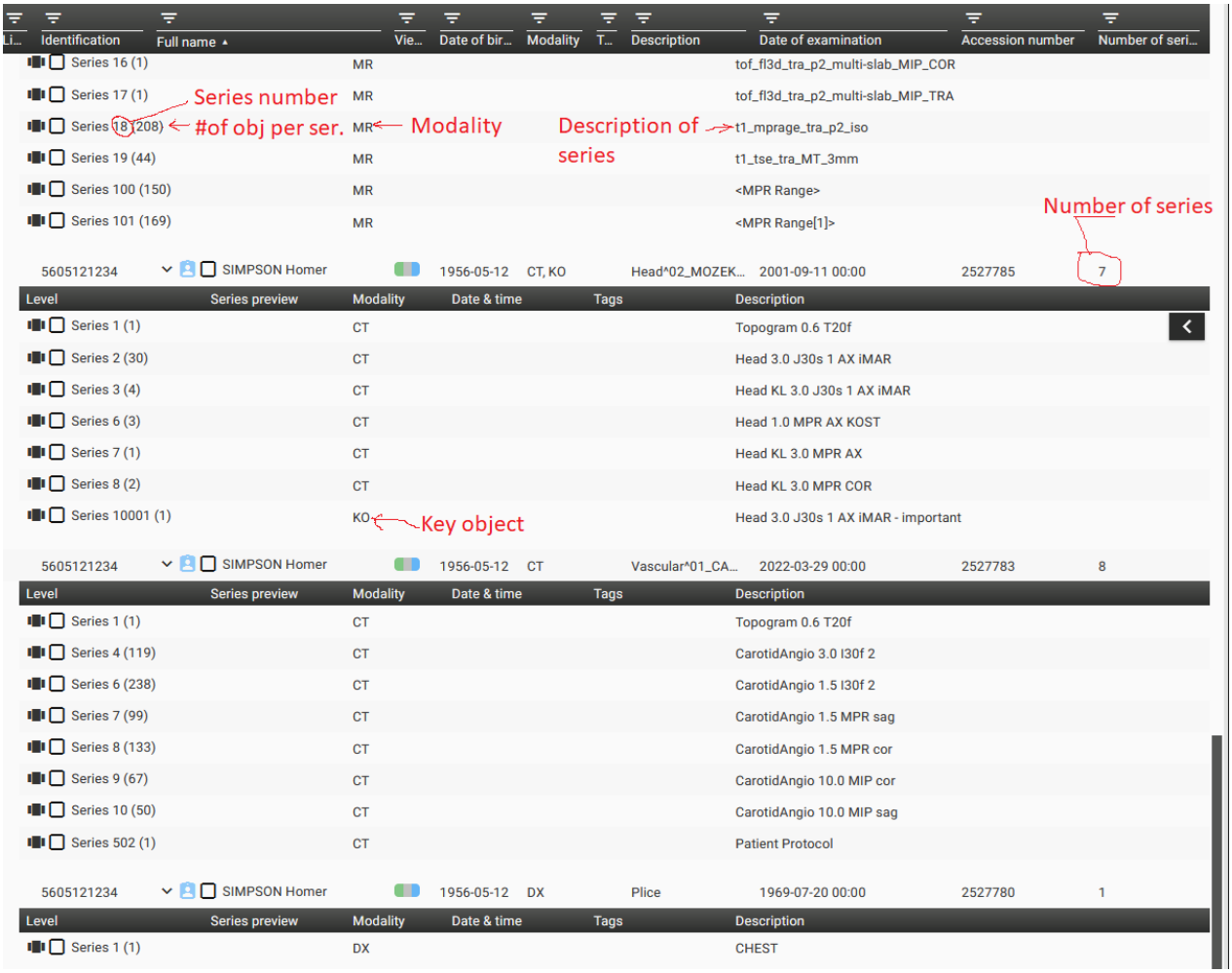
Article 10: Data

The data elements for this guideline can be found in Section 4.

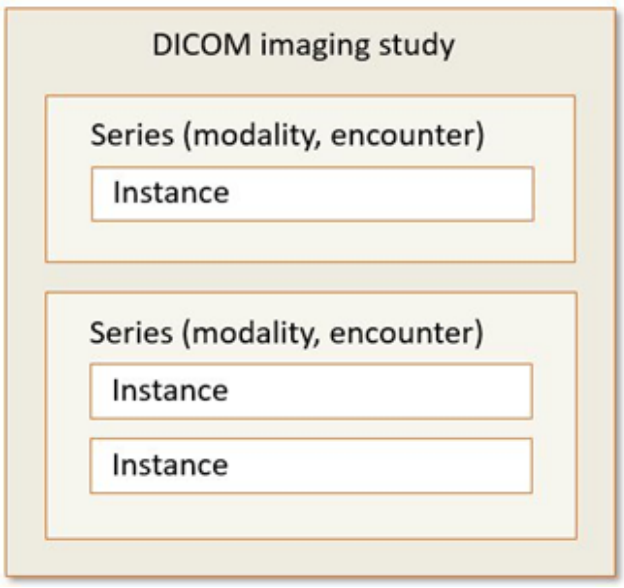
Metadata elements should enable different methods for searching. Some options are:

- a "tabbed" presentation mode, where the tabs divide the different imaging studies according to their modality, speciality or other factors
- a table list with several columns that are configurable by the end user, with the possibility to change the order of each of the columns
- a timeline, where the available imaging studies are shown in chronological order
- the possibility to enter a search text that results in imaging studies whose metadata contain the search term. It is advised to involve PACS vendors in this discussion.

Examples of view of the above-mentioned metadata in a GUI with the possibility to download study/serie(s):



Schematic overview of imaging study structure:



Article 11: Terminology

An agreement between Regenstrief Institute (owners of LOINC) and SNOMED International was signed in fall of 2022. As a result of the agreement all LOINC concepts will be included in SNOMED CT as a SNOMED CT extension keeping LOINC identifiers.

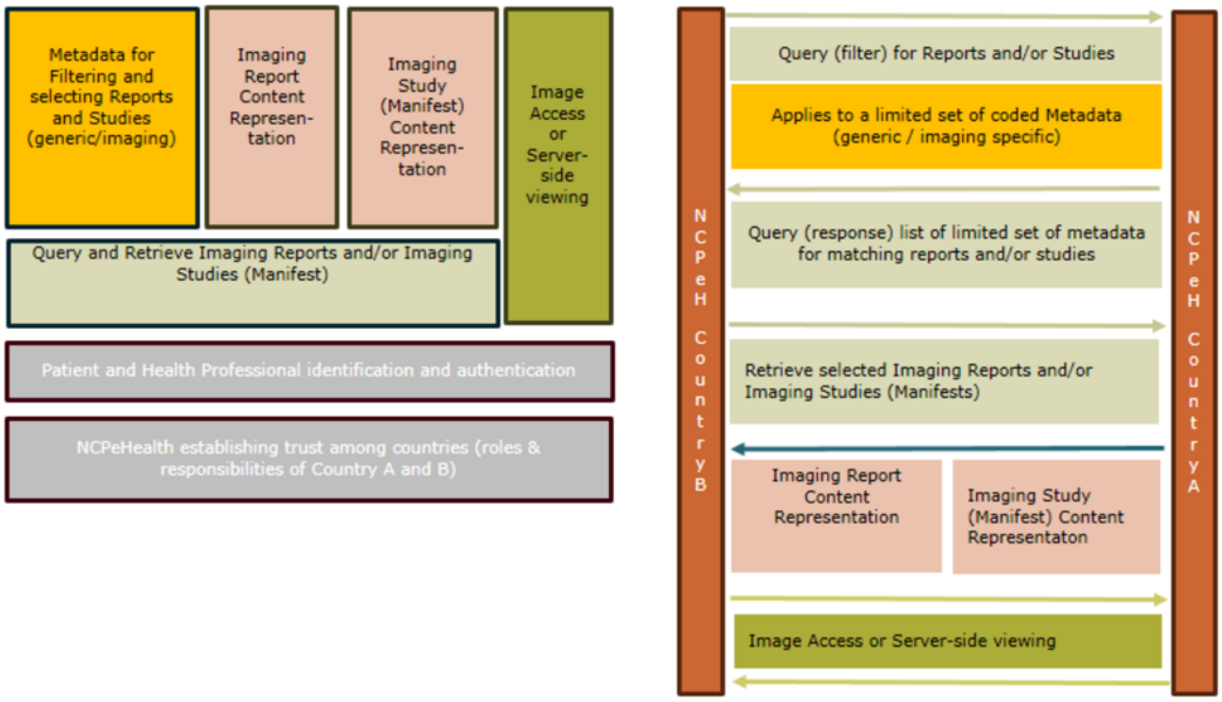
Article 12: Controlled Lists (Value set Catalogue)

There is no specific support information.

Chapter V - Technical Considerations

Article 13: Technical requirements

In the following figure, the building blocks identified in Section 2, Chapter V (on the left side of the figure) have been assigned to transactions (right side of the figure) between the NCPeHs of Country B (country of treatment) and the NCPeH of Country A (country of affiliation). These transactions are presented from the perspective of the cross-border exchange of imaging studies and imaging reports, for illustrative purposes.



Note: The colours in the above diagram only aim to distinguish the different nature of building blocks such as those supporting query and retrieve transactions, metadata for query filtering, document content exchanged and transactions to access to images).

The transfer of images of an imaging study (green transactions) may be performed back to the Country B NCPeH serving the requester so that the requester may use its own imaging software for viewing as well as for the advanced processing of the native images. It may also be possible to launch a server-side viewer offered by the source of the imaging studies within the infrastructure served by the NCPeH of Country A. Such a remote viewer needs to be basic so that it is usable without language dependencies (or use basic English). Such server-side viewing has the advantage of using off-the-shelf browser tools by the requester, thus making the access to that imaging study through an URL embedded in the text of the imaging report.

In case dedicated secure networks are used between NCPeHs and their bandwidth is insufficient for the transfer of imaging studies, the recommendation is to consider using the secure dedicated network for the query and transmission of imaging reports and imaging study metadata, and to add alternative network solutions with sufficient bandwidth for the transmission of the images of medical imaging studies.

To optimise the use of available bandwidth while maintaining an adequate image quality, and a reasonable access time to images, the NCPeH of Country A needs to have enough information from the requester to apply an appropriate compression technique and algorithm. The means to flag specific images as key images and the ability to access specifically will also make a better use of the available bandwidth.

Article 14: Security

There is no specific support information.

Article 15: Testing and audit

There is no specific support information.

4. Data sets

The data sets indicated in the following tables are considered relevant for patient safety and the provision of an adequate level of care both at the cross-border and national levels.

It is up to each implementation project to decide on the conformity and cardinality (i.e. data elements required or optional and the number of repetitions), unless specifically stated.

Implementation projects need to make a final decision on mandatory and/or required (null allowed) elements.

Health insurance and payment information are included in the dataset as an option to support any use case scenarios where this information may play an important role.

Note: some of the code systems or value sets are indicated using the SNOMED CT Expression Constraint Language (ECL) notation.

4.1. Medical imaging report data set

Medical imaging report header

Field		Field description	Preferred Code System (*), (**)
A.1 Report header data elements			
A.1.1 Identification of the patient/subject			
A.1.1.1	Family name/surname	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.	

Field		Field description	Preferred Code System (*), (**)
A.1.1.2	Given name	The given name/first name of the patient (also known as a forename or first name). This field can contain more than one element.	
A.1.1.3	Date of birth	The date of birth of the patient [ISO TS 22220]. As the age of the patient might be important for the correct interpretation of the test result values, a complete date of birth should be provided.	ISO 8601
A.1.1.4	Personal identifier	An identifier of the patient that is unique within a defined scope. Example: Example: National ID (citizen card / eID), health number, passport, etc. Multiple identifiers could be provided.	
A.1.1.5	Gender	This field must contain a recognised valid value for "administrative gender". If different, "physiological gender" should be communicated elsewhere in the relevant clinical information section.	HL7 Administrative Gender
A.1.2 Patient/subject related contact information			
A.1.2.1	Address	Mailing and home or office addresses. The addresses are always sequences of address parts (e.g., street address line, country, ZIP code, city) even if postal address formats may vary depending on the country. An address may or may not include a specific use code; if this attribute is not present it is assumed to be the default address useful for any purpose.	ISO 3166 for Country Code
A.1.2.2	Telecom	Telecommunication contact information (addresses) associated with a person, such as phone number, email, or messaging service. Multiple telecommunication addresses might be provided.	

Field		Field description	Preferred Code System (*), (**)
A.1.3 Health insurance and payment information			
A.1.3.1	Health insurance information	Health insurance information is not always required, however, in some jurisdictions, the insurance number is also used as the patient identifier. It is necessary not just for identification but also forms access to funding for care.	
A.1.3.1.1	Health insurance provider code	Unique health insurance company identification code.	
A.1.3.1.2	Health insurance provider name	The full, official name of the healthcare insurance provider.	
A.1.3.1.3	Health insurance policy number	Number or code under which the insured person is registered at the insurance provider.	
A.1.4 Information recipient (intended recipient or recipients of the report, e.g., GP, another specialist), if applicable			
A.1.4.1	Recipient identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number. In case when the recipient is not a health professional, e.g., a patient, an appropriate personal identifier should be used.	
A.1.4.2	Recipient name	Person name [the structure of the name will be the same as for the patient (given name, family name / surname)].	
A.1.4.3	Recipient organisation	The healthcare provider organisation information.	

Field		Field description	Preferred Code System (*), (**)
A.1.4.4	Address	Mailing and home or office addresses. The addresses are always sequences of address parts (e.g., street address line, country, ZIP code, city) even if postal address formats may vary depending on the country. An address may or may not include a specific use code; if this attribute is not present it is assumed to be the default address useful for any purpose.	
A.1.4.5	Country	Country of the recipient as part of the address.	ISO 3166
A.1.4.6	Telecom	Telecommunication contact information (addresses) associated to a person, such as phone number, email, or messaging service. Multiple telecommunication addresses might be provided.	
A.1.5 Author (by whom the imaging report or a subset of its results was authored). Multiple authors could be provided.			
A.1.5.1	Author identifier	The health professional or authoring device identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.1.5.2	Author name	Person or device name.	
A.1.5.3	Author organisation	The healthcare provider organisation information.	
A.1.5.4	Authoring date and time	Date and time the document was last modified.	ISO 8601
A.1.6 Legal authenticator (The person taking responsibility for the medical content of the document)			

Field		Field description	Preferred Code System (*), (**)
A.1.6.1	Legal authenticator identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.1.6.2	Legal authenticator name	Person name.	
A.1.6.3	Legal authenticator organisation	The healthcare provider organisation information.	
A.1.6.4	Authentication date and time	Date and time the document was authorised.	ISO 8601
A.1.7 Result validator			
A.1.7.1	Result validator identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.1.7.2	Result validator name	Person name.	
A.1.7.3	Result validator organisation	The healthcare provider organisation information.	
A.1.7.4	Validation date and time	Date and time when the document was validated.	ISO 8601
A.1.8 Document metadata			
A.1.8.0	Document ID	Unique identifier of the document	

Field		Field description	Preferred Code System (*), (**)
A.1.8.1	Document type	A coded type of the document. Fixed value "Diagnostic Imaging report"	LOINC
A.1.8.2	Document status	The status of the imaging result report. E.g., preliminary (in case of an emergency situation), final.	hl7:DiagnosticReportStatus
A.1.8.3	Report date and time	Date and time of the result report creation.	ISO 8601
A.1.8.4	Document title	Document title, e.g., "Diagnostic Imaging Report"	
A.1.8.5	Imaging procedure	Imaging study procedure(s) performed. This element is relevant for the interactive selection of the available studies.	LOINC SNOMED CT
A.1.8.6	Report custodian	Organisation that is in charge of maintaining the imaging report.	
A.1.8.7	Confidentiality	Level of confidentiality of the document. Implicit value is normal.	hl7:Confidentiality
A.1.8.8	Language	Language in which the document is written.	ISO 639
A.1.8.9	Version	Version of the document.	
A.1.8.10	Study Instance UID	Unique global identifier(s) that identifies an imaging study upon which the imaging report is based. An identifier that links an imaging report to one or more imaging studies. This element is relevant for the interactive selection of the available studies.	OID

Field		Field description	Preferred Code System (*), (**)
A.1.8.11	Accession number	This is an identifier, managed by the RIS at the local level, which usually uniquely identifies an imaging procedure request, and links it to imaging study(ies) and related imaging report(s). As it is prefixed by the registration authority it is a globally unique ID, usable both nationally and cross-border.	

Medical imaging report body

Field		Field description	Preferred Code System (*), (**)
A.2 Order information Note: an imaging report could respond to multiple orders.			
A.2.1	Order ID	A unique identifier of the imaging study order.	
A.2.2	Order date and time	Date and time of the order placement.	ISO 8601
A.2.3	Order placer professional identifier	The health professional identification number. Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.2.4	Order placer name	Person name.	

Field		Field description	Preferred Code System (*), (**)
A.2.5	Order placer specialty	Medical specialty of the requester (e.g. Oncology, Neurosurgery, Dermatology, Gastroenterology)	SNOMED CT
A.2.6	Order placer contact details	Contact details of order placer (address and telecom details).	
A.2.7	Order placer organisation	Order placer organisation information.	
A.3 Order reason Note: an imaging report could respond to multiple reasons			
A.3.1	Reason	Description of a clinical condition indicating why imaging examination was ordered. The reason could be expressed in coded or textual form. The reason represents the primary condition or finding leading up to a request for an imaging investigation. Example: "Cough lasting for 3 months"	SNOMED CT
A.3.2	Problem / diagnosis / condition	Health conditions affecting the health of the patient are important to be known for a health professional in relation to the imaging encounter. Clinical conditions of the subject are relevant for the interpretation of the results.	ICD-10* SNOMED CT Orphanet
A.3.3	Clinical question	Specification of clinical question (goal of the investigation) to be answered by the imaging investigation.	
A.4 Specimen information Note: a specimen (not attached to a body) can be used for diagnostic, forensic and medical research purposes.			

Field		Field description	Preferred Code System (*), (**)
A.4.1	Specimen identifier	An identifier of the specimen which is unique within in a defined scope. Example: identifier assigned by ordering system. Multiple identifiers can be used.	
A.4.2	Material	Specimen material (e.g. "Specimen from breast obtained by biopsy").	SNOMED CT
A.4.3	Collection period	Collection date time or period.	ISO 8601
A.4.4	Anatomic location	Anatomic location (body location, laterality) where the material is collected (e.g. "Elbow, left").	SNOMED CT ICD-O-3
A.4.5	Morphology	Morphological abnormalities of the anatomical location where the material is taken, for example wound, ulcer.	SNOMED CT
A.4.6	Source Device	If the material is not collected directly from the patient but comes from a patient-related object, e.g. a catheter	SNOMED CT EMDN
A.4.7	Collection procedure/method	If relevant for the results, the method of obtaining the specimen.	SNOMED CT
A.4.8	Received date	Date and time that the material is handed over at imaging department or workplace performing imaging study.	ISO 8601
A.5 Examination Report			
A.5.1	Imaging procedure description Note: this part records the technical details of the performed procedures and may include information about protocol, imaging phases, imaging device, anatomical location, performer, place, date and time of performance.		

Field		Field description	Preferred Code System (*), (**)
A.5.1.1	Modality	Imaging modality (or modalities) expresses the type of device used during imaging procedure. This element is relevant for the interactive selection of the available studies.	DICOM Modality
A.5.1.2	Procedure date	Date and time of the procedure or interval of its performance.	ISO 8601
A.5.1.3	Procedure text	Detailed textual description of the procedure.	
A.5.1.4	Procedure code	Code representing the procedure.	SNOMED CT
A.5.1.5	Procedure name	Full name of the procedure according to the used procedure coding standard.	
A.5.1.6	Anatomical focus (Part of the body focused during the procedure)		
A.5.1.6.1	Body location	Localisation on/in the body (part of the body focused during the procedure). The element could be repeated to provide information at multiple levels (bigger body location, smaller body location). This element is relevant for the interactive selection of the available studies.	SNOMED CT ICD-O-3
A.5.1.6.2	Laterality	Body side of the body location, if needed to distinguish from a similar location on the other side of the body.	SNOMED CT
A.5.1.7	Device ID	Normalised identifier of the acquisition modality equipment instance such as UDI according to REGULATION (EU) 2017/745.	

Field		Field description	Preferred Code System (*), (**)
A.5.1.8	Performer	Identifies the performer of the procedure.	
A.5.1.8.1	Performer Id	Performer identifier unique within a given context (namespace). Either an internal identifier assigned by a healthcare provider institution or (preferably) a national health professional ID such as the license or registration number.	
A.5.1.8.2	Performer Name	Person name.	
A.5.1.8.3	Performer Organisation	The healthcare provider organisation information.	
A.5.1.9	Additional procedure details	Additional information pertaining imaging procedure, such as imaging phase. e.g., without contrast, arterial phase, venous phase, delayed phase. Only some types of studies have phases.	SNOMED CT
A.5.2	Medication (Medication section includes information about medication administered during the medical imaging examination (contrast, sedation, stress agents), etc.)		
A.5.2.1	Brand name	Brand name of biological medicinal product or when justified by the health professional (ref. Commission Directive 2012/52/EU)	
A.5.2.2	Code	Product Code	IDMP
A.5.2.3	Active ingredient list	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: "paracetamol"	ATC* (IDMP identifier, when available)
A.5.2.4	Strength	The content of the active ingredient expressed quantifiably per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dosage form. Example: 500 mg per tablet	UCUM, EDQM Standard Terms

Field		Field description	Preferred Code System (*), (**)
A.5.2.5	Pharmaceutical dose form	The form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablet, syrup)	EDQM Standard Terms
A.5.2.6	Route of administration	Path by which the pharmaceutical product is taken into or makes contact with the body.	EDQM Standard Terms
A.5.2.7	Date and time	Date and time of medication	ISO 8601
A.5.3	Adverse reaction (Adverse reactions manifested during imaging investigation.)		
A.5.3.1	Allergy description	Textual description of the allergy or intolerance	
A.5.3.2	Type of propensity	This element describes whether this condition refers to an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance)	SNOMED CT
A.5.3.3	Allergy manifestation	Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction)	SNOMED CT
A.5.3.4	Severity	Severity of the clinical manifestation of the allergic reaction.	SNOMED CT
A.5.3.5	Criticality	Potential risk for future life-threatening adverse reactions when exposed to a substance known to cause an adverse reaction.	SNOMED CT
A.5.3.6	Onset date	Date of the observation of the reaction	ISO 8601
A.5.3.7	Certainty	Assertion about the certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Diagnostic and/or clinical evidence of the condition.	SNOMED CT

Field		Field description	Preferred Code System (*), (**)
A.5.3.8	Agent or Allergen	A specific allergen or other agent/substance (drug, food, chemical agent, etc.) to which the patient has an adverse reaction propensity.	SNOMED CT (for non-drug allergy) or ATC (for drug allergy) (IDMP, when available)
A.5.4	Results Note: The results summarise the findings and observations by the health professional following the imaging study. Note: this part includes textual as well as structured results or findings of the imaging investigation).		
A.5.4.1	Date	Date and time of the observation	ISO 8601
A.5.4.2	Result text	Comments and narrative representation of the observation results and findings.	
A.5.4.3	Observation details (report could contain multiple observations, e.g. dimensions, density etc.)		
A.5.4.3.1	Observation code	Code representing the observation.	SNOMED CT
A.5.4.3.2	Observation name	Full name of the observation according to the used observation coding standard.	
A.5.4.3.3	Observation method	Observation method (measurement principle) to obtain the result.	SNOMED CT
A.5.4.3.4	Observation result	Results of the observation including text, numeric and coded results of the measurement and measurement uncertainty. The content of the observation result will vary according to the type of observation. Examples: diameter, density, and number of nodes.	SNOMED CT (for ordinal or nominal scale results and result interpretation) UCUM (for units)

Field		Field description	Preferred Code System (*), (**)
A.5.5	Conclusion A concise and clinically contextualised summary including interpretation/impression of the diagnostic report		
A.5.5.1	Impression	Narrative description of the clinical conclusion (impression).	
A.5.5.2	Coded conclusions (Coded clinical conclusions (impressions) expressed as conditions or observations).		
A.5.5.2.1	Condition or finding	Condition or finding from imaging investigation.	ICD-10*= SNOMED CT Orphacode
A.5.5.2.2	Staging or grading	Assessment of the condition expressed using common staging or grading (typically TNM but also other) or coded observations (Bi-Rads, Li-Rads etc.).	E.g. TNM Bi-Rads Li-Rads
A.5.6	Recommendation (This section may include recommendations for additional imaging tests or other actions)		
A.5.6.1	Description	Narrative description of the recommended activities including additional tests, medication etc.	
A.5.6.2	Care plan	Narrative containing the plan including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient. In the future it is expected that the care plan could be provided in a structured and coded format.	
A.6 Key images associated with this report			
A.6.1	View	The name of the imaging view e.g. Lateral or Antero-posterior (AP).	
A.6.2	Body location	Anatomic location (body location, laterality) where the material is collected, e.g. Elbow, left	SNOMED CT

Field		Field description	Preferred Code System (*), (**)
A.6.3	Media type	Classification of media as image, video, or audio.	hl7:media-type
A.6.4	Modality	The type of acquisition equipment/process. This element is relevant for the interactive selection of the available studies.	DICOM Modality
A.6.5	Device	The device used to perform an imaging study	SNOMED CT EMDN
A.6.6	Format	Height, width, and number of frames of the image in pixels (photo/video).	UCUM
A.6.7	Duration	The duration of the recording in seconds - for audio and video.	UCUM
A.6.8	Performer	Identifies the performer of the imaging acquisition process. Performer may include: performer identifier, performer name, performer type, performer medical speciality, performer organisation, and performer contact details.	
A.6.9	Comment	A comment about the image. Typically, this is used to provide an explanation for why the image is included, or to draw the viewer's attention to important features.	
A.6.10	Content	The actual Media, such as selected key image data inline or a reference. Consider FHIR Attachment resource.	
A.7 Comparison study			
A.7.1	Comparison Study	Documentation (reference) of a prior Imaging Report to which the current images were compared.	
A.8 Presented form			

Field		Field description	Preferred Code System (*), (**)
A.8.1	Attachment	Entire report as issued. Rich text representation of the entire result as issued by the diagnostic service. Multiple formats are allowed but they SHALL be semantically equivalent.	

(*) In a foreseeable future, the suggested preferred vocabularies might be superseded or complemented, as mentioned in Guidelines Article 11(2).

(**) The Preferred code system(s) has been selected based on adequacy to convey the information using the methodology of the Subgroup on Semantics. When more alternative international code systems are available, all are listed when it is assumed to be unlikely that agreement can be reached short term. Mapping between code systems could be proposed for specific use cases.

4.2. Imaging study manifest data set

The data set defines the contents of the key information about the imaging study as conveyed by the imaging study manifest data set. The imaging study manifest contains key information about the imaging study that is referenced, including the “pointers” that allow access to the series of images.

It is important to note that the metadata used in expressing the filters associated with the querying for a list of imaging studies and/or imaging reports are defined in Section 2 Article 10: Selection List and filtering Parameters. These parameters are expressed as coded values from standardised value sets to ensure a robust search for a list of relevant imaging studies. Such metadata filtering parameters are associated with imaging studies, but may not be present in the content of the imaging study manifest.

Field	Field description
B.1 Imaging study Manifest Dataset	

Field		Field description
B.1.1	Study instance UID	Globally unique identifier of the study. If one or more series elements are present in the Imaging Study, then there shall be one DICOM Study UID identifier. This element is relevant for the interactive selection of the available studies.
B.1.2	Description	The Imaging Manager description of the study. Institution-generated description or classification of the Study (component) performed. This element is relevant for the interactive selection of the available studies, preferably in English.
B.1.3	Study custodian	Organisation name, address, and contact information.
B.1.4	**List of Series** Note: The number of series in an imaging study is derived by counting the number of items in the list of series.	
B.1.4.1	Series Description	For each imaging Study Series includes descriptive information about the series (e.g. phase). This element is relevant for the interactive selection of the available studies.
B.1.4.2	Series Unique Identifier	A globally Unique ID for the series. All images belonging to such a series will bear this element. This element is relevant for the interactive selection of a specific series within an available study.
B.1.4.3	Modality	The acquisition modality (acquire on a patient) or technical modality (computer generated instance such as a presentation state) associated with the images of the series.

Field		Field description
B.1.4.4	Radiation dose information	Kerma area product (KAP), Total KAP, Kerma at the end of tube (dental X-ray), Thickness of breast for the calculation of Average absorbed breast dose. Further work is needed to refine this definition of dose data in the imaging study manifest. The presence of the dose management reports within the imaging study as standardized by DICOM may be an alternative to consider in later revision of this guideline.
B.1.4.5	Other series information	Imaging Series information such as series number.
B.1.4.6	Series endpoint	An endpoint describes the technical details of a location that can be connected to for the delivery/retrieval of imaging information. Sufficient information is required to ensure that a connection can be made securely, and appropriate data transmitted as defined by the endpoint owner. These may be locally hosted services, regional services, or national services.
B.1.4.7	List of Instances in the series Note: The number of instances in a series is derived by counting the number of instances in the present list.	
B.1.4.7.1	Instance Globally Unique Identifier	Unique Identifier for the image instance
B.1.4.7.2	Instance Class Globally Unique Identifier	Unique identifier for the class of image instance
B.1.4.7.3	Instance Number	Integer assigned to an image by the acquisition modality.

5. REFERENCES AND EXAMPLES

5.1 Standards and Profiles

DICOM standard: https://www.dicomstandard.org/

DICOM Part 20: https://dicom.nema.org/dicom/2013/output/chtml/part20/sect_A.3.html

HL7 FHIR standard: https://hl7.org/fhir/

IHE Radiology Profiles https://www.ihe.net/resources/technical_frameworks/#radiology

5.2 Existing EHN guidelines

Common Semantic Strategy: The Release 1 of the eHealth Network guidelines on medical imaging studies and reports was prepared in full alignment with the goals, roadmap and governance proposed in the Common Semantic Strategy for health in EU, adopted by the eHealth Network in Nov 2019.

The General Guidelines - Guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU

Link: https://health.ec.europa.eu/system/files/2022-06/ehealth_health-data_electronic-exchange_general-guidelines_en.pdf

The eHN Guideline on Patient Summary (Release 3.3)

Link: https://health.ec.europa.eu/system/files/2023-10/ehn_guidelines_patientsummary_en.pdf

The eHN Laboratory Result Guidelines (Release 1.1)

Link: https://health.ec.europa.eu/system/files/2023-07/ehealth_ehn-lab-results-guideline_en.pdf

5.3 European Health Data Space & European Electronic Health Record exchange format

The Medical Imaging Guidelines concept originates from the Recommendation on a European Electronic Health Record exchange format (EEHRxF) and is being taken forward by the European Health Data Space regulation proposal.

Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197