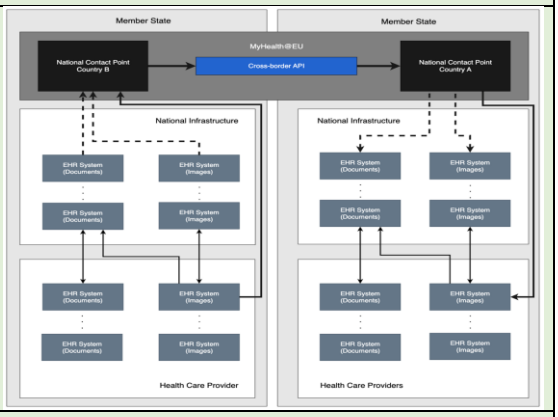
D7.2 Xt-EHR commenting form Industry X-Net

EU Member State (MS) ISO 3166 two-letter country code **or "EU"** for European stakeholder organisations	**Section/ Subsection** number	**Comment** (justification for change)	**Proposal how to resolve comment,** proposed change
Industry X-Net	4.1.3. Common Actors	**X-NET #1:**... these use cases are ...	… this use case is …
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #2:** The sentence "Quality management and validation processes are crucial for ensuring the accuracy, completeness, and clinical utility of imaging studies documentation and are based on national regulations and procedures." is out of scope and it should be remarked as such	add " are out of scope" at the end of the scentence
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #3:**The sentence "Quality management and validation processes are crucial for ensuring the accuracy, completeness, and clinical utility of imaging studies documentation and are based on national regulations and procedures." is out of scope and it should be remarked as such	add " are out of scope" at the end of the scentence
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #4:** Second sentence: "... processes are crucial for Context ensuring the accuracy, completeness, ..."" Completeness in an imaging report would need to be defined first. A report can be complete in the sense that the clinical question has been answered. However, additional findings might be withhold, because the patient	delete the word "completeness"

		doesn't want them to be addressed in the report.	
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #5:** First bullet: (of country of Affiliation) -> affiliation	country of affiliation
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #6:** The second bullet must be deleted as it is not necessarily possible for systems to know if data is incomplete. Therefore, a system has not trigger that could induce the prompting for missing data to the user.	delete second bullet in the "Variations" section
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #7:** Second bullet: The NCPs are destined for the translation. Therefore, it shouldn't be mandated, that for the uploading of information a translation service must be provided.	delete the second bullet
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #8:** Last bullet: This applies to all use cases where images are addressed. Therefore, it would be reasonable to state this requirement before the description of the use cases.	make it a general requirement statement for all use cases
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #9:** It is unclear what the addition in brackets "(read-only)" is supposed to mean	either clearify or delete "(read-only)"
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #10:** This is not realistic. The surgery has been planned with the study provided by the patient. As it is not available through the EHDS it very likely that this study will be saved into the local PACS rather than refusing to store it.	Change the scentence to " The patient's copy is uploaded to the Spanish hospital"
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #11:** The sentence is not telling what imaging studies have to do with the imaging manifests	alter "... imaging studies(imaging study manifests) ..." to ... imaging studies due to the information provided by the imaging study manifests ... "

Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #12:** Q.1.5 An imaging procedure is not a service. Keep : The date and time the imaging procedure started (e.g. study date)	Delete : Service start date
Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #13:** Q.1.7 "If one or more series elements are present in the Imaging Study, then there shall be one DICOM Study UID identifier." This is not clear what it shall mean	Put in: Globally unique identifier of an imaging study. Delete the rest.
Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #14:** Q.1.9 Is the Order Identifier worldwide or locally unique?	Specifiy the reach of the uniqueness
Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #15:** Q 2.1 The Document ID needs to be explained further, e.g. UID from the XDS context, a randomly issued id, …	
Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #16:** Q.2.4 For Author, organisation and country. There has been no description given.	Please provide a description of author, organisation, country and in which form the values shall be given (free text, codes)
Industry X-Net	4.2.3. Preferred Code Systems	**X-NET #17:** LOINC/RSNA playbook is a separate entitiy and should be listed as such	
Industry X-Net	4.3.1. Overview of the EHDS dataflow	**X-NET #18:** The figure addresses the infrastructure in details that aren't covered in the deliverables of 7.2. Therefore, it should be simplyfied. Please replace the existing fig. 3 with this one	
Industry X-Net	4.3.2. Cross-border imaging information exchange transactions	**X-NET #19:** The diagram and the corresponding text makes an assumption on the national infrastructure (being "XDS-I like"). This is not true in all MS. Plus it addresses generic document exchange aspects which are scope of D5.1.	In order to make the figure 4 more generic, remove "Healtcare Provider" on both sides of the diagram.
Industry X-Net	4.3.2. Cross-border imaging information exchange transactions	**X-NET #20:** The purpose of this figure is not clear.	In order to make the figure 5 more generic, remove "Healtcare Provider" on both sides of the diagram.
Industry X-Net	4.3.4. Requirements	**X-NET #21:** Out of scope for Xt-EHR deliverables. Should be left out from the future implementaing act and addrressed in a referneced	This section should be more explict in the way it relates to the supporting HL7 FHIR Implementation Guides and IHE Profiles. Its alignement with the non-imaging

		technical umbrella document..	cebntric Xt-EHR deliverable D5.1 should be explict. Replace lines 1110 to 1120 by the following: b) High-Level Technical Requirements This section is a placeholder that is required to ensure that the various HL7 FHIR IGs and IHE Profiles that support the high-level transaction in an exp)licit way to avoid any technical misinterpretation. As this mateiral is not of a nature suitable for direct inclusion in the correcponding EHDS implementation act due to its technical nature and the need for maintainability at the technical level without forcing burdensome updates to a regulatory document. The technical requirements in this section addresses at a high-level the functional requirements identified in the functional overview for the **Query for Available Imaging Reports and Imaging Study Manifests** transaction by reference to the FHIR Implementation Guides and IHE Profiles that specify the detailled technical solution. It is aligned with the non-imaging specific requirements specified in the D5.1 deliverable. It is organized in four elements: * the list of referenced implementation guides and profiles • the mapping of the high-level actors associated with this high-level transaction onto the actor roles identified by the underlying implementation guides and profiles • a mapping to the specific technical transaction of the underlying underlying implementation guides and profiles • any other relevant details specific to the imaging context, including constraints on aspects of the technical solution to align it with the EHDS regulations.
Industry X-Net	4.4.3. Logical Data Model – Datasets	**X-NET #22:** The logical data models do not contain information which elements are required for the different conformity levels. This makes it impossible for claim compliance for a specific level. Especially for the proposed level of semi-strucuted documents. It is stated on line 50 that confomity levels will be applied at at later stage, but this is not present when viewing the logical models.	Add to the desciption of the content of the tables (line 1480 ff) and the tables a column in which it can be defined for which conformance levels this attribute will be required. Together with information that this will be provided when the conformance levels have been defined in D8.2 (See also the comment on removing chapter 4.6 on conformity levels from this document and insteaad to reference D8.2)

Industry X-Net	4.5. Guidelines for implementers (FHIR)	**X-NET #23:** Clarifes the source of these technical specifications (e.g. standards development organizations).	Replace the entire chapter 4.5 by: 4.5 Referenced Detailed Specifications The standards development organisation specifications referenced in this document are - the FHIR Implementation Guide (IG) “HL7 Europe Imaging Study Report” https://euridice.org/imaging-report-fhir-ig/ and - the IHE Profile Manifest-Based Access to DICOM Objects (MADO) https://euridice.org/manifest-based-access-to-dicom-objects-mado/. - the API for Health Data Services Implementation Guide - https://euridice.org/api-hds-ig" These specifications have been developed under the umbrella of EURIDICE - https://euridice.org/, a joint initiative of HL7 Europe and IHE Europe.
Industry X-Net	4.6. Conformity Levels	**X-NET #24:** Conformity levels area defined in D8.2. Describing them here creates inconsistencies.	Instead reference the appropriate defintions in D8.2
Industry X-Net	4.3.3. Example Actor Groupings	**X-NET #25:** All systems in figure 6 are EHR systems. Due to the unspecific definition of EHR systems this chapter should make this point clearer. Therefore, the text and the diagram should be revised.	Replace in text "actor groupings showing the EHR system" with "actor groupings with different types of EHR systems". Replace in diagram "EHR system" with "Patient record system" Add the reason for this figure: "This example depicts the flexibility provided by the definition of high-level technical actors along with the corresponding high-level transactions. Different types of real-world EHR systems may chose to support the high-level actors that fit their role in health information exchange."
Industry X-Net	II. Scope and Interdependencies	**X-NET #26:** it remains unclear what this statement means for Pathology imaging studies in general the the possibility to uphold patient's right for getting access to the data. Are defined to be out of scope? What does this mean regarding the claim of compliance for corresponding "EHR systems"?	Make a clear statement Pathology imaging studies and the systems processing this data category being in scope or not. Replace the existing bullet with the bullet: - Digital Pathology imaging studies
Industry X-Net	II. Scope and Interdependencies	**X-NET #27:** The out of scope list doesn't state that Non-DICOM images are out of scope. However, as any of	add the bullet: - Non-DICOM objects

		the described mechanisms is relying on DICOM objects for the exchange of imaging studies it should be clearly stated.	
Industry X-Net	II. Scope and Interdependencies	**X-NET #28:** The content of the scentence has been adressed before and does not contirbute knowledge to this chapter.	delete "This document focuses on the exchange of medical imaging studies and imaging reports. However,"
Industry X-Net	1. Introduction	**X-NET #29:** Unclear scope differences between D5.1 and D7.2.	Make clear that for imaging reports only the content and structure will be defined. The mechanisms for making the reports available are defined in D5.1 (which is applicable for all document type data, like reports). This deliverable 7.2 defines only additional mechanisms which are relevant for imaging reports. And of course for imaging studies, since for these not the same mechanisms as defined in 5.1 can be used.
Industry X-Net	3.5. HL7 Medical Imaging Studies and Reports FHIR Implementation Guide	**X-NET #30:** Referencing the contributing organizations is unclear.	Please replace the first sentence with: This guide is developed under the joint leadership of HL7 Europe and IHE Europe (EURIDICE), in cooperation with the IHE Radiology Domain and HL7/DICOM Imaging Integration Working Group
Industry X-Net	3.6. OpenEHR Medical Imaging Implementation Guide	**X-NET #31:** openEHR has not contributed to the deliverables of D7.2	Consider removing this chapter here and instead add a corresponding chapter to D5.1
Industry X-Net	4.3. Technical Specifications	**X-NET #32:** The generic mechanisms for reports (documents) are covered in D5.1. It is unclear to what degree what is described here is aligned with D5.1. There is a risk of discrepancies which lead to unnecessary implementation effort and costs.	Reference D5.1 and ensure content here is aligned. Make more clear where specifics to image reports and image studies are addressed. Replace: 4.3. Technical Specifications This section provides an overview of the transactions (or transport mechanisms) used by the health professional for the discovery and retrieval of imaging studies (manifests and images) and imaging reports between Medical Imaging source EHR systems and consumer EHR systems. These transactions are 983 implemented by the EHR System Interoperability Components. It is based on existing frameworks (IHE XDS, IHE MHD, HL7 FHIR, Gazelle for testing) and outlines the 985 boundaries between the three basic domains for implementation; healthcare provider/organisation, 986 member states national domains and cross border domain. By: 4.3. Technical Specifications

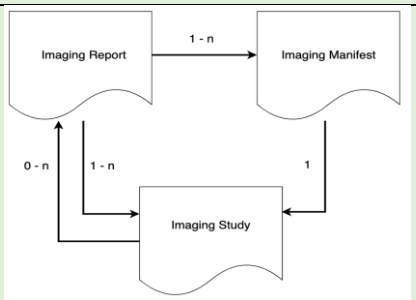
			This section provides an overview of the high-level transactions (or transport mechanisms) used by the health professional for the discovery and retrieval of imaging studies (manifests and images) and imaging reports between Medical Imaging source EHR systems and consumer EHR systems. These high-level transactions are implemented by the EHR System Interoperability Components. It is based on existing frameworks (IHE XDS, IHE MHD, HL7 FHIR, Gazelle for testing) and outlines the boundaries between the three basic domains for implementation; healthcare provider/organisation, member states national domains and cross border domain. The applicable detailled technical specifications such as FHIR Implementation Guides and IHE Profiles are referenced, in a manner aligned with the non-imaging specific requirements specified in the D5.1 deliverable.
Industry X-Net	4.1.6. Imaging Study Manifest	**X-NET #33:** Unclear why there is the need for a separate mechanism for getting information about the available images. Such a mechanismus it not necessary for the other priority data categories. e.b. EHR-Systems are directly queried for reports which fulfill specific criteria of interest.	Delete lines 864-869 Misleading here. The size of the image objects does not establish the need of being able to search for images of interest. This is also necessary for documents. Instead cover the special nature of imaging studies via the following amendment of chapter 4.1.6. Insert before line 876: 4.1.6. Imaging Study Manifest The EHDS priority data category of medical imaging studies differs from the other (document based) priority data categories in several important characteristics which require special consideration for enabling the cross border transfer of this data category: Imaging studies are large in size compared to documents. They can reach multiple gigabytes for single studies. Due to the much higher transfer and storage cost which is associated therefore with them many implementations have chosen to maintain the legally required archive of imaging studies at the healthcare provider of origin. In these implementations, imaging studies are only transferred (copied) to another healthcare provider if there is demand for specific imaging studies, e.g. because a

			patient is about to receive follow-up treatment at this new healthcare provider. Documents in contrast are in most nationwide electronic patient records stored as a copy in a central, or only a small number of federated, systems. This makes it sufficient to usually only query one system for finding all relevant documents of a patient. However, to find the relevant images the thousands of Medical Imaging Study Repositories which exist in a country would have to be queried. Compared to a document a (DICOM) imaging study is not a singular object but consists of hundreds and thousands of individual objects or multi-frame image objects, leading to potentially very large result sets in queries for imaging studies which are available for a patient. Also, healthcare providers usually do not directly make all created images available as the publishing normally follows a certain process. For example the images are first assessed for quality problems, or if a physician first needs to talk to the patient. This requires a mechanism to identify which images are to be made available, and when they are made available.. Another challenge is that the currently available standardized mechanisms for querying for medical images have predominately been designed for intra healthcare provider information exchange, e.g. DICOM C-Find or DICOM QUIDO. They do not support some of the query parameters (e.g. anatomical region) which have been identified in this document as necessary in cross-border scenarios and support many additional prameters that would expose more clinical data than necessary for filtering step . In general they not easily lend themselves to such large and distributed cross institutional and cross border access scenarios as the EHDS regulation aims to establish. Therefore, already the eHealth Network Guidelines recommended introducing a document which describes a particular imaging study and can be handled in a digital health infrastructure like all the other document types: the Imaging Study Manifest. Only after a Health

			Professional has identified in the Image Studio Manifests the images of relevance the more costly and regarding cybersecurity critical access to the images from outside the healthcare provider of origin is necessary. An imaging study manifest acts as a summary of the content of an imaging study. Attributes in the manifest providing, for example, each series description, modality type and number of images in each series, allow the Health Professional to select which parts of an imaging study are relevant for retrieval. The imaging study manifest also provides pointers to the location (PACS/VNA) for each study/series/instance (image), allowing the relevant ones to be retrieved to the Health Professional.
Industry X-Net	Abbreviations	**X-NET #34:** Acronym EOG has not been used anywhere in the document	Please remove all abbreviations from that list which have no been used in the document
Industry X-Net	Terms and Definitions	**X-NET #35:** why is health professional written in single quotes. Plus health should start with a capital H	health professional' -> Health professional
Industry X-Net	4.1.2. Role of IHE-profiles and HL7 standards	**X-NET #36:** the Imaging domain	the imaging domain
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #37:** Table 3, section Preconditions The second precondition "The medical imaging report is stored and kept updated in the Medical Imaging Report Repository." must be extend. It needs to be stated that the report is not preliminary of some kind and also signed of by an authorized person. Also it should be stated that keeping updated report is not sufficient but I will be necessary to also provide the access to the change history. Both suggestions are relevant/ essential for the clinicians. 1. A report must contain reliable information for which someone must be held accountable for (signing off). 2. If report has been altered this must be made visible in case the treatment of a patient hast been made on	Replace the second precondition by: The different signed versions of a imaging report, including addendums are stored in the Medical Imaging Report Repository

		an earlier (erroneous) version.	
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #38:** Table 3, section Preconditions The third precondition "The imaging study (or studies) referenced in the report have been completed, stored and validated." should be altered. 1. Technically a study can always be extended. The endpoint in this context is the written report. 2. There is no specific validation process for imaging studies. Therefore, remove completed and validated. The only important precondition is, that the images referenced in the report are made available = stored	Please consider changing the bullet to: The imaging study (or studies) referenced in the report have been validated and stored.
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #39:** The first bullet states "Imaging Study and report available in a structured format" Structured format is not precise and can be missleading	Imaging study and report are available complying to the EEHRxF
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #40:** The second bullet: "The diagnostic report and the referred imaging study(ies) must be online accessible." Diagnostic report must be changed to imaging report, as this is the term used throughout the document	
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #41:** The fourth bullet: "Imaging study information must be available via a server-side viewer." This bullet does not make sense. Imaging study information has nothing to do with a server-side viewer.	Change in the section Variants: "Variant B: Imaging study accessed through a URL in a web browser, where the health professional can select the appropriate content." by "Imaging Study can be viewed remotely, where the health professional can select the appropriate content" Delete the bullet in the section Precondition

Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #42:** Bullet 5 and 8 are redundant. The last bullet requires authentification and authorization. This implies that an instance managing the access rights is exisiting	Delete bullet 5 as it is addressed by bullet 8
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #43:** The variants are wrongly attributed to the Functional Process Flow step 2. The performance of the imaging study is not dependant on the consiousness status of the patient.	Either link the first bullet to step 3 and/or 6 and / or to bullets 2&3 of the Cross-border considerations
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #44:** The third bullet "GDPR requirements have to be given consideration" is too broad	Please be more specific what this bullet means, or delete it as anything that deals with Patient information has to comply with the GDPR anyway.
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #45:** Bullet 1 is not well understandable	Please rephrase
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #46:** Bullet 2 is not well explained. However, it seems that this bullet addresses organizational requirements which should handled somewhere else as this out of scope of a use case.	delete bullet Organizational errors must be handled elsewhere.
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #47:** The second bullet: "The patients in providing annotations and commentary to their existing health records in an EHR" This is highly dangerous and must only be allowed to the extend the GDPR grants rights rectifying data.	Replace the bullet by: "The patient may request rectification on their personal data of information provided in the EHR."
Industry X-Net	Annex II	**X-NET #48:** In principle the annex is useful however, out of scope and therefore misplaced in the D7.2 with the potential to cause confusion	Remove Annex II
Industry X-Net	4.1.4. Use Case Descriptions	**X-NET #49:** It should be stated that this a future use case describing high level requirements which aren't addressed in the current version of the D 7.2	
Industry X-Net	4.1.5. Search for and filtering	**X-NET #50:** At this point it would be helpful to the reader to gain some	renumber the existing sub-chapters by adding 1 -> 4.1.5.1 to 4.1.5.2 etc. then insert a new sub-chapter

	imaging studies and reports	understanding about the relation of an imaging report, the imaging manifest, the imaging study	**4.1.5.1 Relation of imaging studies and reports** For an efficient search it is important to understand the relation between the imaging studies and the imaging reports. This relation encompasses three entities - imaging studies - imaging reports - imaging manifests The following figure shows a high-level view on their relations. An imaging study is connected to exactly one imaging manifest. An imaging report always points to at least one or many imaging studies and therefore also to at least one or many imaging manifests. However, the imaging study doesn't necessarily have a representation within an imaging report.
Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #51:** Add this new fig. to the new chapter 4.1.5.1	
Industry X-Net	4.1.5. Search for and filtering imaging studies and reports	**X-NET #52:** Query parameters in the table do not match the parameters which have been defined in chapter 4.2. of the eHealth Network Guideline on imaging studies and reports. As documented in chapter 3.1. of this deliverable the eHN guideline are input to the defintions here, but no rationale for deviating from it is given.	Provide a rationale for the difference in query parameters compared on the eHN guideline. Add the following: This list of search parameters extends the initial list identified by the eHN Guideline on Imaging (Modality,Annatomical Region, Study Date). It has been extended with "technical search parameters" such as Document ID, Study Instance UID, Accession Number and Order ID, Document Technical Format) and other parameters that significantly enhance the clinician's experience (Practice Setting, Document Class, Author, organisation and country). It is important to note that these search parameters have derived from more than 15 years of deployment experience in many countries around the world. It is critical to keep the list of search parameters as small as possible, supported through short value sets to make request deterministic. The results however, should return a wider range of metadata to offer usefull information on the relevance of an imaging study.