Xt-EHR (EU4H-2022-JA-09, project number 101128085)
Targeted Stakeholder Expert Consultation on Draft Deliverables of Work Package (WP) 5 - 9

Template for comments
Deliverable: **D7.2 Medical images and reports: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems**
Version:

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EU Member State (MS) ISO 3166 two-letter country code **or "EU"** for European stakeholder organisations	**Organisation name**	**Xt-EHR target stakeholder group**	**Section/ Subsection** number	**Page** number	**Line** number	**Figure/ Table / Paragraph** number	**Category** of comment (major or minor)	**Type** of comment (general, technical or editorial)	**Comment** (justification for change)	**Proposal how to resolve comment**, proposed change	**Observation/ response to comment by WP**, information if and how comment was addressed
EU	CPME / The Norwegian Medical Association/ Royal Dutch Medical Association (RDMA)	Health care experts and providers	II. Scope and Interdependencies	xvii	251	Section II.2 "Out of Scope"	major	technical	The document explicitly lists "editing and annotation on existing image studies" as out of scope. From a clinical perspective, this exclusion poses a serious safety and interoperability concern. Annotations on medical images—such as tumor measurements on CT scans or the marking of lesion locations on ultrasound—constitute integral diagnostic information and are essential for correct interpretation and longitudinal follow-up. Their omission from the exchange framework undermines clinical completeness and may lead to loss of context or data entry errors during manual transcription, with potentially serious consequences for patient safety. For more detailed information please see also the commentary from a Radiation Oncologist from The Netherlands attached as Annex I to this response.	Add annotations on medical imagesin the scope of the deliverable. The implementation guide should ensure that all relevant annotations (e.g., measurements, markers, or delineations) are represented within the exchange format defined by the EHDS, maintaining their association with the corresponding imaging data. This will support safe, interoperable, and clinically meaningful data exchange across specialties and healthcare systems.	
EU	CPME / The Norwegian Medical Association/ RDMA	Health care experts and providers	2. Methodology	3	375-404	Methodology	minor	technical	While the methodology aligns well with HL7 FHIR, IHE, and OpenEHR frameworks, it does not yet address collaborative multidisciplinary team workflows or dynamic consent management for shared annotation and contextual review.	Extend the methodology description to include mechanisms supporting team-based collaboration, dynamic or granular consent, and patient participation in annotation and review processes.	
EU	CPME / The Norwegian Medical Association / RDMA	Health care experts and providers	4.1. Business and Functional Specifications	11-14	646	Business and functional spesifications	minor	technical	The functional use cases primarily address individual data access (patient, professional) but omit the configuration and support of digital care teams. This absence prevents the EHDS framework from reflecting real-world collaborative clinical practice, where multiple professionals and the patient jointly review and interpret imaging data.	Add use cases and functional requirements enabling team configuration, shared review, and collaborative annotation across national and cross-border settings. Ensure the technical model supports persistent, context-aware team access.	
EU	CPME / The Norwegian Medical Association	Health care experts and providers	4.1.4. Use Case Descriptions	16	768	Sharing a Medical Imaging Study and/or related Imaging Repor	minor	general	The document does not address the importance of knowing how imaging studies have been interpreted by other radiologists, particularly subspecialists at tertiary centres. Access to prior expert reports can enhance diagnostic quality and consistency across healthcare levels.	Include a statement emphasising that interoperability should enable access to prior imaging interpretations by different radiologists, including subspecialists, to support comparative review and continuity of diagnostic quality.	
EU	CPME / The Norwegian Medical Association/ RDMA	Health care experts and providers	4.1.4. Use Case Descriptions	14	747	Sharing a Medical Imaging Study and/or related Imaging Report	minor	general	Patients followed for a condition that require series of imaging over time, often have limited referral information. Radiologists may hold valuable longitudinal insight from initial work-up to later follow-up, which should be reflected in the radiological report to facilitate continuity of care.	Recommend highlighting that radiological reports should include contextual and longitudinal information, when available, to improve clarity and continuity for subsequent assessments in other countries or institutions.	
EU	CPME / The Norwegian Medical Association / RDMA	Health care experts and providers	4.1.4. Use Case Descriptions	19	799	Example 3: Decision support in a time-critical setting	minor	general	In acute medical and surgical scenarios, access to prior imaging reports is critical to rapidly identify known conditions or previous injuries affecting emergency assessment and treatment.	Expand the emergency use-case description to explicitly state the clinical value of prior imaging reports for swift and accurate acute decision-making.	
EU	CPME / The Norwegian Medical Association/ RDMA	Health care experts and providers	4.2. Semantic Specifications (code systems and value)	26	893	Semantic Specifications (code systems and value	minor	general	Excluding translation and multilingual support introduces a systemic language bias, limiting equitable access and understanding of imaging reports in multilingual environments. This contradicts the EHDS aim of equal, bias-free data exchange.	Specify a plan for multilingual value sets and controlled translation of imaging metadata and reports. Future versions should include mechanisms ensuring language-neutral interoperability for both professionals and patients.	
EU	CPME / The Norwegian Medical Association / RDMA	Health care experts and providers	4.4. Data model (datasets)	53	1453	Figure 21: Dicom Study Metadata Conceptual Model - EHDSDicom study metadata	major	technical	The technical requirements currently lack support for contextual image annotations, editing, or team-based collaboration. The reliance on static, event-based consent mechanisms may become outdated in patient-centred digital care models.	Include team annotations, dynamic consent, and context-aware data access in future releases. Evaluate consent mechanisms to ensure alignment with evolving, participatory care models.	
EU	CPME / The Norwegian Medical Association / RDMA	Health care experts and providers	4.4.6. Report Body	59	1503	Table 18	minor	technical	Additional information not present in the original referral may have been obtained verbally from the referring physician. Such contextual details can be decisive for radiological interpretation and should be reflected in the report. Annotations should also be possible in connection to the referral	Add a free text field where the radiologist can add supplementary clinical information to the referral	

Feedback CPME Gabrielle Speijer Radiation Oncologist - CatalyzIT, Oct 9, 2025

D7.2 Medical imaging studies and reports: implementation guides on EEHRxF, functional and technical requirements and specifications for EHR-systems

1. Scope and Definitions

The current exclusion of essential functionalities—such as annotation (e.g., diagnosis, regions of interest, DICOM RT structures), editing of imaging studies, and translation support—is explicitly noted as "out of scope" in this document. However, this raises significant concerns for the reliability, integrity, and long-term trust in data exchanged via the European Health Data Space (EHDS). In clinical practice, the absence of annotation and editing functionality means that critical contextual insights can be fragmented or lost, leading to real risks of misinterpretation and diminished traceability across the continuity of care. This is illustrated in the document with the MS case (p18 791), where direct image annotation is far superior to solely textual references for accurate longitudinal assessment.

Importantly, modern healthcare is delivered by multidisciplinary teams with patients as integral participants. If health data are divorced from the original care context—separating data from both clinical and patient contributors—it creates significant risks for care quality, trust, outcomes, and patient safety. The EHDS should explicitly recognize that systems must enable the data to remain closely linked to both the involved professionals and the individual patient within their authentic context of care.

For this reason, it is recommended that the working group defines a clear roadmap for the future inclusion of annotation, editing, and multilingual support. This is necessary not just for technical completeness or compliance, but for ensuring the EHDS truly supports collaborative clinical care, patient-centred decision making, and translatable outcomes across national and linguistic borders.

Access to data alone does not ensure safe, meaningful, person-centered care. Contextual clinical information—like annotated imaging reports and treatment plans—must be included in future specifications, as these are essential for continuity, accurate decision-making, and patient empowerment, especially in cross-border scenarios.

2. Methodology and Standard Alignment

The methodology in this document is closely aligned with established international frameworks, including X-eHealth, eHealth Network guidelines, HL7 FHIR, IHE profiles, and OpenEHR. Standards are consistently referenced and operationalized throughout, and functional requirements are validated for both national and cross-border scenarios. However, the review and gap analysis indicate that while harmonization is strong, the methodology does not yet fully address the technical facilitation of multidisciplinary team collaboration or dynamic consent for annotation and shared context. Further improvement should focus on supporting collaborative care teams and evolving governance models that better recognize patients as co-owners and contributors to their health data.

3. Functional requirements and use cases

The document describes the functional requirements and use cases for medical imaging studies and report exchange through EHR systems in both national and cross-border contexts. It highlights multiple actors (such as imaging study creators, repositories, consumers, and report creators), and provides technical specifications to enable data exchange, filtering, and retrieval from connected systems. However, the use cases remain focused on individual interactions, such as patient access, professional retrieval, or uploading data for a second opinion.

While the methodology does reference "patient journeys" and includes scenarios involving cross-border care, the standard being proposed does not establish any mechanism for configuring or supporting digital care teams. There are no requirements or examples for linking imaging data to a group of professionals, nor for the patient to select which clinicians or supporting specialists may view, annotate, or discuss imaging data collaboratively.

Care in practice is delivered by multidisciplinary teams with the patient as an integral participant. When care occurs internationally, it becomes essential for the digital infrastructure to enable trusted team combinations—where, for example, a patient and their treating physician can add further expert contributors, whether nationally or internationally, to help interpret data and decide on action. The current specifications do not facilitate persistent, context-rich team connections, nor do they allow for dynamic assignment of team members based on expertise and patient preference.

This structural absence in the standard means data are often separated from the clinical relationships that produce meaning, consensus, and trust. It increases the risk that shared data will not reflect real agreement or understanding among stakeholders, diminishing the integrity and clinical value of cross-border health information exchange. To support genuine collaborative care and maintain trust in digital health records, future versions of the standard should explicitly enable team configuration, shared review, and context-aware data access—across borders and care settings.

Effective care, especially across teams and borders, is only possible when actionable, trusted information is available to both professionals and patients. Insufficient context increases the risk of harm, redundancy, and mismanagement of conditions. Therefore, functional requirements should prioritize not just access but meaningful clinical context and interpretation as key outcomes.

4. Semantic Specifications

The semantic specifications as outlined in this document are designed to ensure standardized exchange of medical imaging data through selected international coding systems and valuesets (e.g., SNOMED CT, LOINC, ICD-10). However, given that translation and language support for imaging reports and metadata are explicitly excluded from both scope and technical design, a systemic bias is introduced by design.

This means that the current standard risks excluding non-dominant languages and impeding equitable access and understanding for both professionals and patients operating in multilingual contexts. By failing to support language adaptation and translation, the system is not neutral: it

favors users of the supported language(s), while others are systematically disadvantaged in terms of clinical communication, comprehension, and shared decision making.

For the EHDS to uphold the principle of equal and bias-free health information exchange across Europe, future versions of the semantic model should provide concrete mechanisms to include multilingual valuesets and controlled translation, thereby avoiding systematic inequity in clinical and patient-facing data exchange.

Maintaining a link between clinical data, use context, and the involved teams and patients is a fundamental feature for clinical accuracy and trust in shared datasets. I recommend the consultation identifies the need for a future-proof development path to support these functions in subsequent releases.

5. Technical Requirements

The technical requirements, as outlined, do not yet support the capture, storage, or display of contextual image annotations or edits. This limitation is explicitly referenced in both the scope and technical chapters, and leaves a gap for interoperability and future innovation (e.g., team annotations, multilingual data enrichment, patient-facing documentation). Considering the clinical and team-based workflows in modern care, this directly impacts patient-provider trust and shared decision making. Therefore, the consultation should advocate a clear growth and conformity model—so future releases can include such essential functionality—aligned with the practical realities of care delivery and team-based outcomes in the EHDS

A notable element is the current reliance on explicit, event-based, or emergency (break-the-glass) consent mechanisms when describing data access, annotation, and sharing scenarios. This approach has served traditional healthcare settings reasonably well. Yet, as healthcare increasingly adopts digital models and promotes patient empowerment, these one-off, static consent models risk becoming outdated. They may fail to reflect the continuous, contextual, and participatory nature of modern patient-clinician relationships and team-based care dynamics.

Emerging paradigms, such as dynamic or granular consent, offer patients and professionals the ability to manage, update, and share data preferences on an ongoing basis—empowering all stakeholders and enhancing trust in the system. While not addressed in the current document, I recommend that future development explores whether the currently described consent and access mechanisms remain fit for purpose as digital health matures. This is particularly important if the EHDS aims to support active, adaptive data stewardship and innovative, collaborative care models. Otherwise, consent may devolve into a static administrative hurdle instead of a real safeguard and enabler of personalized, team-based care.

6. Data Models

The data models for imaging reports and studies are rigorously specified, including both conceptual and logical models that facilitate interoperability, accuracy, and traceability. Major data elements (e.g., identifiers, procedures, anatomical regions, modality, metadata) are well described and mapped

to standardized terminologies. The models support structured reporting for clinical use and audit but currently lack design for richer collaborative elements such as team context, real-time annotation, or dynamic assignment of roles. Ensuring that future data models include such elements would strengthen the aims of continuity, team-based decision making, and personalization.

Conclusion

The document is cohesive, comprehensive, and methodologically robust, offering a solid baseline for harmonized imaging data exchange across Europe. The alignment with international standards is impressive; the structure is clear and actionable. However, the current scope and models remain too narrowly focused on traditional access, retrieval, and reporting, with insufficient provisions for ongoing collaborative enrichment, team involvement, contextual annotation, and equitable language support. Consider explicitly designing future requirements around these unmet needs to ensure the EHDS delivers person-centered, collaborative, and trustworthy care pathways.

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