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

Delivera **D8.1 Classification and functional profiles of EHR systems guidelines**

Version: v9

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EU Memb er	**Organisation name**	**Xt-EHR target stakeholder group**	**Section/ Subsection** number	**Page** number	**Line** number	**Figure/ Table / Paragraph**	**Category** of comment (major or	**Type** of comment (general,	**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 - Standing Committee of European Doctors	**Health care experts and providers**	1 Introduction				major	general	There should be some practical value of this document provides for healthcare professionals, aside from stating that the EHDS should not create additional administrative burden for them. The document seems to overlap in certain areas with previously published documents, being lengthy and sometimes not very concrete. Article 12 of the EHDS regulation should be refferred to reflect the user-friendly manner of presenting personal electronic health data in EHRs to allow easy of use by health professionals.	Insert a sentence recognising that: "The primary function of the electronic health record (EHR) is to support clinical practice and the requirements of the European Health Data Space (EHDS) must not compromise this purpose; Usability measures must be adopted to evaluate effectiveness, efficiency and healthcare professional satisfaction when using an EHR system; Only 'user-friendly', fully functional systems should be allowed on the market and essential 'user-friendly' features should be included in EHR systems without additional costs." All functionalities/applications must be fully integrated in EHRs. The financing of implementation and updating must be covered by national health authorities. Paralell solutions outside EHRs will create unnecessary administrative burdens, lack of time with patients and are thus not acceptable in a situation with limited human and financial resources.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	1 Introduction	2	Jan-35		major	general	While D8.1 consistently and deliberately limits EHDS interoperability obligations to system-level technical capabilities throughout the main body of the document, this principle is not stated explicitly in the Executive Summary. In practice, clinicians, healthcare managers, and public purchasers often rely primarily—or exclusively—on the Executive Summary when interpreting the intent and implications of the deliverable. Implementation experience demonstrates a material risk that, in the absence of such an explicit clarification, interoperability requirements may be misinterpreted during procurement and deployment as requirements on clinical documentation practices or workflows, particularly in organisations with limited technical or legal procurement capacity. Explicitly reflecting the document's safeguards against transfer of compliance burden to clinical users at Executive Summary level would substantially strengthen correct interpretation, without expanding the scope or altering the normative structure of D8.1.	Add an explicit clarification to the Executive Summary or the Introduction, for example: Interoperability conformance under the EHDS is defined exclusively as a property of system-level technical capabilities and observable data exchange behaviour. This deliverable does not regulate clinical workflows, clinical documentation practices, or professional conduct. EHDS interoperability compliance SHALL NOT be achieved by imposing additional documentation, structured data entry, or workflow requirements on health professionals. Conformity assessment verifies whether systems are technically capable of exchanging data in accordance with the applicable Interoperability Profiles, independently of how data is produced within the system. Where structured data are not available, existing human-readable narrative representations constitute a valid and sufficient means of interoperability compliance. Mandatory data elements and cardinalities apply solely at the level of exchanged instances. They do not imply requirements for clinical data completeness, real-time documentation, or the creation of artificial or placeholder values. Where mandatory information is not available, systems are expected to refrain from constructing or exchanging the corresponding profile instance, without restricting lawful access to available health data through other appropriate means.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	3.7.1 Example 1 – General Practitioner system	18	536		minor	technical	While the example effectively illustrates system classification and applicable profiles, there is a potential risk that references to producer obligations (e.g. "populate structured data elements") could be misinterpreted as requirements on clinicians' documentation practices. Given that examples are often used operationally in procurement and implementation contexts, an explicit clarification would reduce this risk.	Add a short clarifying sentence stating that producer obligations refer exclusively to system capabilities for exposing structured data where available within declared scope, and do not imply requirements for clinicians to modify documentation practices or ensure data completeness.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	4.1 Conformance Baseline for Interoperability Profiles	20	589-615		major	technical	While D8.1 appropriately limits its scope to system-level interoperability and explicitly avoids regulating clinical workflows or documentation practices, there remains a material risk that certification requirements could in practice be operationalised by vendors through increased documentation constraints imposed on clinicians. Although this risk is implicitly mitigated throughout the document, an explicit clarification would strengthen the robustness of the conformity framework and reduce the likelihood of misinterpretation in procurement, implementation, and certification contexts. In particular, there is a need to clearly distinguish verifiable system capabilities from clinical documentation practices used to generate data.	Add an explicit clarification to Section 4.1 or alternatively in Section 4.6, for example: "EHDS interoperability conformance SHALL be demonstrated exclusively through observable system capabilities for data exchange. Compliance SHALL NOT be achieved by imposing additional real-time clinical documentation, structured data entry, or changes to clinicians' documentation practices. Producer and Consumer obligations require the ability to exchange structured data and existing human-readable narrative content where available, but do not justify requirements for health professionals to generate new documentation solely for interoperability or certification purposes. EHDS interoperability compliance SHALL be achieved through system capabilities for exchanging existing data and SHALL NOT require health professionals to re-enter, re-document, or restructure clinical information that already exists within the system."	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	5.2 Rationale for focusing on interoperability profiles	29	910-930		minor	general	Clear and appropriate overall scope limitation (positive). The rationale for limiting the scope of D8.1 to interoperability profiles, and explicitly avoiding full functional EHR profiling, is clearly articulated and well aligned with the legal scope of the EHDS Regulation. In particular, the explicit recognition that applying comprehensive functional profiles would risk introducing non-mandated requirements is a strong and appropriate clarification.	No change proposed. This section provides an important and well-formulated clarification that should be preserved as written	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	6.2 Metadata Interoperability Profiles	32	980-992		minor	technical	The metadata profiles appropriately focus on ensuring provenance, authorship, and traceability of exchanged data, independently of clinical content. However, given the diversity of national patient identification schemes across Member States, additional clarification that mandatory identification metadata does not imply the use of any specific national identifier (e.g. national personal identification numbers) could further support consistent implementation and avoid unnecessary constraints.	Consider adding a clarifying note stating that mandatory identification metadata refers to unambiguous identification within the exchange context and does not mandate the use of specific national identifiers.	

EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	7.1 Narrative fallback requirement (document-level profiles)	36	1129-1137		minor	technical	While the narrative fallback requirement is clearly framed as a system-level interoperability and safety mechanism, there remains a potential risk of misinterpretation whereby narrative generation could be perceived as a clinical documentation obligation. Given the otherwise strong and consistent separation between system capability and clinical practice throughout D8.1, a brief reinforcing clarification would further reduce the risk of misapplication in procurement or implementation contexts.	Add a short clarifying sentence, for example: “The generation of a narrative representation is a system capability and does not imply any additional clinical documentation or manual authoring requirements for health professionals.”	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	9 Conclusions and Next Steps	252	1795-1837		minor	general	The clarity and internal consistency of D8.1 in limiting EHDS obligations to system-level interoperability capabilities is appreciated. However, implementation experience suggests a risk that interoperability compliance may in practice be translated into additional documentation or workflow burdens for clinical users through procurement processes and vendor interpretation, particularly in organisations with limited procurement capacity. This risk lies outside the normative scope of D8.1 but may significantly affect real-world implementation.	Consider developing a separate, clearly non-normative procurement and implementation guidance, distinct from D8.1, aimed at healthcare providers and public purchasers. Such guidance could support correct interpretation of EHDS interoperability obligations, highlight common misinterpretations, and help prevent unintended transfer of compliance burden to clinical practice.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	4.2 Role of Cardinalities in EHDS Interoperability Profiles	21-22	638-659		minor	technical	Explicit protection against clinical documentation burden (positive). The clarification that mandatory cardinalities apply exclusively at instance level for technical conformance assessment, and do not introduce obligations on clinical data entry or clinical workflows, is precise, necessary, and highly valuable. This formulation significantly reduces the risk of misinterpretation leading to unintended clinical documentation burden.	No change proposed. This clarification is important and well formulated. However, its practical effect depends on corresponding alignment of the data-level profile tables in Chapter 7, which currently risk undermining this principle in certification and implementation contexts.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	7 Interoperability Profile Specifications	38-250	multiple	All data-level profile tables	major	general	While the data-level profile tables in Chapter 7 are intended to define testable interoperability capabilities, the current level of structural fragmentation and granularity of clinical information into a large number of predefined elements represents a significant concern. Even where population of individual elements is formally optional, the existence and detailed specification of these fields is not neutral. In practice, such structures exert strong normative pressure on system design, user interfaces, procurement criteria, and implementation strategies. This risks shifting system design towards field completion and structural exhaustiveness rather than supporting clinical reasoning, narrative documentation, and the inherent uncertainty of medical practice. Increased structural granularity does not reduce clinical uncertainty, even if it creates an appearance of precision on paper. Patients do not present as standards, clinical problems are not discrete or stable, and documentation must remain flexible enough to reflect evolving judgement and context. Fragmented, field-driven models risk promoting false precision, reducing tolerance for uncertainty, and indirectly increasing documentation burden on clinicians, despite explicit textual statements that clinical workflows are out of scope. Given that D8.1 underpins certification and labelling under the EHDS, these structural design choices will inevitably be reinforced through testing regimes, vendor implementation strategies, and procurement decisions. Once embedded at certification level, such models become difficult to reverse, particularly for smaller vendors and weaker procurement environments.	Clarify explicitly that the tabular structures in Chapter 7 define interoperability capabilities only and do not constitute an intended, expected, or recommended clinical data model. It should be stated unambiguously that: -the inclusion of an element SHALL NOT be interpreted as an expectation that systems routinely capture, structure, expose, or prompt for that element in clinical workflows; and -systems may legitimately support narrative-first or hybrid representations where this better reflects clinical practice and uncertainty.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	7 Interoperability Profile Specifications	38-251	multiple	All data-level profile tables	major	general	The tabular profiles in Chapter 7 are explicitly intended to underpin test artefacts, conformity assessment, and certification under the EHDS. However, the presentation of these tables does not acknowledge that several of the underlying technical specifications developed in WP 6 and WP 7 remain under active discussion and revision, including substantial clinical feedback regarding scope, granularity, and feasibility. Earlier work packages have begun to move away from overly fragmented and fine-grained data models. In contrast, Chapter 7 appears to reintroduce these models in a consolidated, authoritative, and normative-looking form, without indicating that they are provisional or subject to revision. This creates a real risk of regression and undermines coherence across the Xt-EHR work programme. Locking detailed table structures at this stage risks pre-empting unresolved design decisions and constraining future alignment with clinical practice. Given the downstream role of D8.1 in certification and labelling, this premature stabilisation is not acceptable. Interoperability must not become an end in itself. It is, and must remain, a means to support better clinical practice and improved patient outcomes. Technical structures must follow clinically validated requirements, not precede them.	State explicitly that the tabular structures in Chapter 7 are dependent on, and subordinate to, the finalised technical specifications developed in WP 6 and WP 7. In particular, it should be made clear that: the Chapter 7 tables are not stable or final until the relevant technical specifications are finalised and clinically validated; and these tables must be reviewed and updated accordingly before being used as a basis for test artefacts, certification scenarios, or conformity assessment. The Joint Action should explicitly commit to revising Chapter 7 to ensure alignment with the final technical specifications, clinical practice, and support for narrative-first and hybrid data representations.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	3 System Classification for EHDS Interoperability	14	377-381		minor	general	The explicit statement that system classification is used “solely as a technical structuring mechanism” is an important and well-chosen clarification. This wording clearly limits classification to interoperability scoping and should not be interpreted as a basis for governing clinical workflows or documentation practices.	No change proposed. The emphasis on “solely” is important and should be preserved. However, its practical effect depends on corresponding alignment of the data-level profile tables in Chapter 7, which currently risk undermining this principle in certification and implementation contexts.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	3.5 Scoped conformance	17	497-507				The scoped conformance model is clearly defined and provides an effective mechanism to ensure proportional application of EHDS interoperability obligations. The explicit statement that systems are assessed only for declared scope, roles, and supported data categories is particularly important for heterogeneous and modular system landscapes.	No change proposed. The section is clear and internally consistent. However, its practical effect depends on corresponding alignment of the data-level profile tables in Chapter 7, which currently risk undermining this principle in certification and implementation contexts.	
EU	The Norwegian Medical Association / CPME - Standing Committee of European Doctors	Health care experts and providers	7 Interoperability Profile Specifications				major	general	The standards must demand the need of system’s vendors to continuously update their systems as medicine evolves. Standards cannot remain static; they must be regularly revised and require corresponding system updates. System architectures must therefore support frequent, seamless updates—comparable to routine updates of mobile applications.	Standards must be regularly updated, versioned, and explicitly require vendors to implement mandated changes within defined time limits as a condition for maintaining certification and conformance. Once a system is approved, ongoing compliance must depend on timely implementation of current or supported standard versions—following the same logic as certified mobile applications that require regular updates to remain functional and approved. The costs for this must be covered by national heath authorities and not healthcare providers/personnel.	