D5.2 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	5.4 Data Quality Governance and Responsibilities	**X-Net#1**: In this chapter, it's not clear what the specific governance processes that need to be managed, nor who is responsible for exercising each one of these governance processes on the metadata.	
Industry X-Net	General Comments	**X-Net#2:**This leaves open where the metadata quality rules are defined.	The less variation there are injected by national extentions, the better (political goal of EHDS) Metadata quality goal needs to be defined on EU level.
Industry X-Net	General Comments	**X-Net#3:** Doesn't make sense that every EHR systems makes this quality checks	What does metadata quality mean? Real time validation is also a problem.
Industry X-Net	6.3.1 EDHS Data Set (base class)	**X-Net#4:** 5.2: All metadata elements should not have to exist (e.g. in a header) for each transaction - metadata elements need to be mapped to existing FHIR elements and transactions, but the mapping depends heavily on on the specific exchange for each priority category (In MHD exchange of IPS, it's in DocumentReference, but in MPD exchange, it's in MedicationRequest) or the specific use case (Search for an audit of who has seen this document). Overall Document-Level search parameters need to be minimally shared elements (patient, document type), the more specific and usable elements depends on the priority data category (e.g. in Lab, "give me all Lab Results for blood glucose"). Example 2: Transactionally, it does not	The metadata elements should be mapped to existing FHIR resources, transactions, and use cases by HL7 EU and IHE in specific implementation guides, as has been done for the priority categories. The metadata requirements should be harmonized with the interoperabilty/logging component specifications in 5.1. The Document search parameters (both shared across data categories and specific to data categories) should explictly documented in relationship to the Document Reference Resource in an explict "data set". This point is mentionned a couple times in the document, but never addressed. The section focus cannot be achieved as

		make sense that all metadata should accompany each transaction - this should be determined by the use case: For example, AuditEvent accompanying every document in a header (“here’s a document, here’s who’s seen it so far”) adds bloat to clinical exchange and is quickly incomplete. Metadata for audit use cases and clinical use cases should be separated - the audit need is better met by an ad-hoc AuditEvent search interaction “which entities have received this document”.	currently suggested by tagging specific elements as search parameters
Industry X-Net	4.1 Foundation	**X-Net#5:** The implementation guides concept may be part of metadata, but the guides themselves need to be outside of the metadta specifications.	Change "implementation guides" by "reference by implementation guides"
Industry X-Net	General Comments	**X-Net#6:** 8.2.4 Search Parameters 1391 Search parameters are also defined on a logical layer as business requirements as well as on the technical layer as implementation guidance. 1393 In logical models, key elements for searching are marked respectively. 1394 When creating FHIR profiles for data exchange, the parameters defined on a logical layer must be added to the specification if they are not already in the core FHIR specification. 1396 In HL7 FHIR standard searchability is defined using a specific resource SearchParameter. Being a structured, machine-readable type of metadata, SearchParameters can be automatically processed by systems, making the adoption of consistent search possible across Member States. For example, Composition resource, which is the backbone for document exchange, includes over 20 search parameters in the FHIR core specification (see the list).	To be in line with the staememnt made in section 4.2, line 498 that we strongly back: "While **the initial emphasis is on document-based data exchange**, the metadata framework is intentionally designed to support a broader set of data exchange architectures". The following update is necessary: 1393 In logical models, key elements for searching are marked respectively. In particular, document level search are explicitly addressed in the logical data model to ensure consistency across data categories. In line 1396, the reference to Composition Resource should not be in the scope of this document: 1396 In HL7 FHIR standard searchability is defined using a specific resource SearchParameter. Being a structured, machine-readable type of metadata, SearchParameters can be automatically processed by systems, making the adoption of consistent search possible across Member States.
Industry X-Net	General Comments	**X-Net#7:** Throughout the document, it is mentionned that document type, will be used to identify the data category coveyed by the document (line 347, section 1, section 4 line 450; . This is a misuse of document type (although unfortunately current). Both CDA and	It is proposed to retrun document type to its original intent, and leave each data category document the selction of a value set of all related document types in LOINC. Of course this value set may evolve and grow.

		FHIR binds document trype to the LOINC value set. It has more than 12000 types of doicument identified. The document type is intended to be a clinically precise type of document as understood by health professionals. Each data category covers in general more than one hundred document types. This level of precision is needed for HP to decide if a document resulting from a broad search is relevant or not. This error was made with the CDA based documents, but should not be carried forward.	The X-Net industry Team is ready to work with Xt-EHR to define an alterntive mechanism based on Categories and Practice Settings where the document was created.