D5.1 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	General comments	**X-Net#1:** The specification does not differentiate enough between different EHR systems and API's. Which results in requirements are placed on EHR systems that do not make sense for the specific EHR system and are incredibly expensive to implement without any additional benefit. This makes the document in its current form unacceptable. Proper review is only possible when such differentation has been performed.	Rewrite of the document to be more specific about requirements for different EHR system types and use cases. Use cases must include cross-border national HR, patient access, wellness applications and information exchange between different type of EHR systems within healthcare providers. The document should identify the different EHR system types and label each requirement to what EHR system it refers to. The requirements should include what information types a EHR system of a certain type is required to implement. Note the EHR system types should be specific enough to cover the variety of systems deployed in hospitals (e.g. PACS, RIS, LIS, HIS, ...).
Industry X-Net	General comments	**X-Net#2:** The document specifies many requirements for which the base in the EHDS regulation is unclear.	Ensure to reference the appropriate EHDS articles when specifying mandatory requirements. Referencing the articles generically in table 1 is insufficient.
Industry X-Net	General comments	**X-Net#3:** The majority of the specified requirements is on the business logic of EHR systems and the developemt process for these systems. There are only very few requirements for the harmonized components. This is inapproprate. Also specifiying the business logic and development process of EHR systems has no base in the EHDS regulation. In addition it creates problems for EHR systems which are also SaMD/MD for which such aspects are covered by other regulation.	Remove the EHR system requirements and focus on the requirements for the harmonized components and specify only requirements for EHR systems which are necessary in the context of the EHDS regulation and do not overlap with other regulation.
Industry X-Net	General comments	**X-Net#4:** The document is expected to specify high-level requirements which give guidance to the detailed technical standards which are prepared by the SDOs (like HL7 and IHE) but fails in large parts in this.	Define functional requirements of the interoperability component (provide patient search, document search, resource search, secure access), and assign the SDO's (IHE EU, HL7 EU) with the responsibility to define the techincal implementation of the interoperability standards in the FHIR format, as has been done with the logical models, but including actors and transactions as well - to meet the functional requirements defined by 5.1. These groups have an established track record of achieving collaboration and success in interoperability.

Industry X-Net	General comments	**X-Net#5:** There are many "Recommended Features/Best Practices" in the document. They could probably help less mature vendors to understand what normally needs to be done to fulfill some of the EHDS requirements. But having these recommendations in the document creates the risk that the EC picks them up as mandatory requirements in the implementing cast and/or that auditors specifically look for the things listed there. So they could become "kind of mandatory" and require more mature vendors to carefully analyse and map for even potentially adapt their processes.	Remove the recommended features/best practices.
Industry X-Net	General comments	**X-Net#6:** There is no clear distinction between EHR vendor vs. care provider responsibilities. Some of the requirements requirements are configured at the health-system level and not at the EHR level and therefore shouldn't be requirements for EHRs: Ex: "Line 1186 - Periodic Review of Roles: Conduct regular audits of user roles and privileges to remove outdated or unnecessary accounts. Since this document is about technical requirements for EHR systems requirements for care providers are misplaced in the document	Remove requirements for care providers.
Industry X-Net	General comments	**X-Net#7:** Often terms are used for which the exact meaning is unclear.	Add a "definitions" chapter.
Industry X-Net	5.2 Comprehensive Logging of Access Events	**X-Net#8:** The logging scope is not made clear in the document. This needs to be defined to determine which activities in an EHR systems need to be logged, how the purpose of access can be determined, and which technical mechanisms are appropiate to transport the log data to the health data access service(s). Logging everything and providing it everywhere will results in 10000's of records to be generated and shared each day of a hospitalization. This will be very expensive to implement and users will drown in the information.	The logging scope should be made explicit. It is proposed to define the scope of an EHR system to log data exchanged through the interoperability component at the level of the priority data category from a security and privacy disclosure point of view. Other goals such as performance measurement, clinical workflow tracking (access to a specific piece of data in a patient record, e.g. An Allergy from an Patient Summary), system errors management are out of scope.
Industry X-Net	5.2 Comprehensive Logging of Access Events	**X-Net#9:** The logging architecture (PUSH of AuditEvent) has the potential to create a flood of information which adds a burden to system performance and user experience. What logging information is useful depends on the purpose of the retrieval. A general overview has very different requirements than a detailed investigation due to a suspected security/privacy violations.	Once the comment **X-Net#9** scope is agreed, the push of events becomes reasonable.
Industry X-Net	5.3.1 General Requirement	**X-Net#10:** Capturing purpose of use for logging (Line 558-562): Requiring users to enter a purpose of use is burdensome, slows down important clinical workflows, and would lead to inkonsistent recording of access	A fixed set of access purposes needs to be specified which can be set automatically by the EHR systems based on the context which which the data is accessed.

		purposes which are not of much use persones assessing the access logs.	
Industry X-Net	6 ANNEXES	**X-Net#11**: Annex has very valuable contents , it addresses three key points:1- using business actors for defining interactions (agree), 2- gives some architectural ideas how the various pieces (cross-border infrastructure, national infrastructure, EHR systems of care providers etc.) may fit together - which, define core requirements for all priority areas 3- and defines a template to be used for the specification of interoperability in priority area as specific extensions to the core requirments.	Reorganize this deliverable: - include architectual concepts, part 1, (after some rework because the correct concept has some problems, see comment **X-Net#1** above) and the actors based specification requirement as a requirement on implementation specificaton/profiles in the body of the deliverable. - Move template (part 3) to a separate document, or into a distinct annex with its scope expressed clear, for internal use among Xt-EHR WP.- Include in the body of document, the base requirements from the requirements for the individual interfaces (e.g. the common search for document-based queries). The use of red color text is not sufficiently clear to indicate that the imaging related requirements were only examples and be clear that priority data categories specific requirments should move to the corresponding Xt-EHR deliverable.