D8.2 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	**3.1.3**	**X-NET #1:** Allowing DTEs to operate under ISO17020/25 is unnecessary and imposing. It's unnecessary because the regulation clearly indicates that manufacturers will be solely responsible for conformity of their products to EHDS technical requirements. This is also consistent with "market surveillance", effectively removing the requirements for "accreditation" and application of ISO17020/25. It's imposing because by allowing accredited labs under ISO17020/25 to operate DTEs will create an extra burden to the EHR manufacturer, leading to increased time-to-market and increased cost, with no additional benefit on the quality side. DTEs should only provide access to and maintain access services for the test tools.	Remove the sentence starting with "These testing environments shall" and ending with "in their evaluations"
Industry X-Net	**3.1.3**	**X-NET #2**: CASCC, therefore, should NOT oversee accreditation (in an ISO17020/25 sense) as this would be effectively a very demanding task and ultimately unnecessary as the **X-NET #1** comment. CASCC, however, should oversee DTEs to ensure they meet the basic requirements for a DTE.	Remove the sentence starting with "CASCC should oversee" and ending with "across Europe." Suggested replacement: "CASCC should oversee the operations of the DTEs that have been designated by each Member State, to ensure harmonisation of testing procedures across Europe."
Industry X-Net	**4,1**	**X-NET #3**: The use of obligations, if any, would be part of the technical specifications, and should not be described in this document. In addition, the details of obligations here are overly complex. This has been recognized by WP8, which is working to simplify the use of	We propose removing chapter 4.1 entirely from this deliverable. The examples provided in the following chapters (4.2 and 4.3) are sufficient to provide an understanding of the conformity assessment.

		obligations. In addition, this level of detail is not needed in the Xt-EHR deliverable, as it is already discussed in D5.1.	
Industry X-Net	4.1.1.6.3	**X-NET #4:** Conformance should focus on interoperability, not UI (user interface) behavior or clinician workflows. Do not regulate application design (e.g., what must be displayed) or system behavior (what must be documented by clinicians and decision support, for example). Obligations should concern data exchange, not user interfaces.	If 4.1 is not removed entirely, we suggest using only “populate-if-known” for Producers and “handle” for Consumers. These are provable with automated testing and help to focus the conformance on the harmonized components.
Industry X-Net	4.1.1.1	**X-NET #5:** Local EHRs should not be treated as exchangers. Data received in the EHR from other systems can be incorporated in documents like the Patient Summary, Discharge Report, and Imaging and Diagnostic Reports that differ from what was previously sent to the EHR, which is valid given that they are interpreted and used by clinicians. It is reasonable for a provider to use both a Local EHR and an Exchanger - and in some cases this may be the same system - but they are not necessarily the same, and the requirements for Exchangers should not apply to Local EHRs. The decision about which systems to use to meet the needs of Producer, Consumer, and Exchanger for a given provider is up to the provider.	If 4.1 is not removed entirely, remove the Exchanger role from the description of Local EHRs, and add a separate system type for Exchangers.
Industry X-Net	2	**X-NET #6:** As described in lines 408-410, the best practices described in this section are intended to be included for reference and as examples, but not necessarily as recommendations for how conformity should work for EHDS. These examples are useful, but the inclusion as a major	Move these examples to an annex to ensure they are interpreted correctly as examples. We would also propose including IHE-Europe's attached document summarising the positioning of IHE CAS/EURO CAS in comparison EHDS CAS to better contextualize the examples. [ADD HERE THE WORD TEXT]

		chapter can lead to confusion about which are intended as informational and which are intended as recommendations.	
Industry X-Net		**X-NET #7:** In order to ensure that (as stated in line 747) "Member States do not impose any specific obligations for testing environments in regard to compliance with the EHDS specifications on harmonised software components" and to (as stated in line 727) "ensure harmonisation of testing procedures across Europe," the digital testing environment in each Member State must either use the software developed by the Commission as the testing tool or use a tool that is equivalent. If a Member State chooses to use its own/re-developed test tools (rather than simply making available the test tools provided by the Commission), they should be required to demonstrate the equivalency of their tests with those provided by the Commission test tool and to submit this equivalency demonstration to CASCC. Such a demonstration should prove that no tests are missing, that no additional tests have been added, and that testing procedures for manufacturers remain automated.	After this sentence: "Such digital testing environments shall comply with the common specifications for the European digital testing environment." add: "If Member States make use of testing tools other than the software developed by the Commission for these testing environments, they must demonstrate the equivalency of the testing tools with those provided by the Commission, including proof that they support automated self-certification, that no tests are missing, and that no additional tests of the harmonised components have been added, and CASCC must review and approve the equivalency."