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 obligations. In addition, this level	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.

		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 chapter can lead to confusion about which are intended as informational and which are intended as recommendations.	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. Introduction to IHE CAS and EURO CAS The IHE International Conformity Assessment Scheme (IHE-CAS) and the European Health Data Space Conformity

			Assessment Scheme (EHDS-CAS) both aim to establish reliable mechanisms to demonstrate compliance of electronic health record (EHR) systems with relevant interoperability specifications. While they share the broad goal of fostering trust, interoperability, and transparency, their approaches differ on a few key points when assessed against the obligations set out in the EHDS Regulation, particularly in the areas of accreditation, manufacturer responsibility, and market surveillance. Accreditation IHE-CAS relies on a traditional model of independent third-party, accredited laboratories to carry out product testing. These laboratories must comply with ISO/IEC 17025 and be audited by an entity accredited under the International Accreditation Forum (IAF). IHE International approves such labs, ensuring that conformity assessments are performed by competent third parties and that results are globally recognized and can be accepted by any public or private entity world-wide. This model offers strong technical and quality assurance. In contrast, EHDS-CAS introduces the concept of European Digital Testing Environments (DTEs) operated by Member States and placed under an EU regulation. Rather than relying on third-party ISO 17025 accredited labs, the EHDS model embeds DTEs designation by the Member States and approval by the EC under the governance structure. The European Commission will develop open-source testing software, while Member States host and operate the DTEs. This represents a shift from externalized accreditation towards a coordinated EU-led infrastructure, ensuring harmonisation and consistent application of common specifications across the Union. Manufacturer Responsibility Under IHE-CAS, manufacturers seeking conformance assessment submit their systems to accredited labs for testing and assessment, with the labs bearing responsibility for the test execution and reporting. Once validated, manufacturers can claim compliance with the relevant IHE profiles, but the manufacturers'

			ongoing responsibilities are relatively limited as these are carried by the accredited lab. EHDS-CAS places far greater responsibility on manufacturers, aligning with Articles 30, 39, and 40 of the Regulation. Before placing products on the market, manufacturers must perform a mandatory self-assessment using the test tools offered by DTEs. Moreover, they must continuously monitor compliance, re-assess products when standards evolve, and report serious incidents to national authorities. EHDS-CAS eliminates reliance on external certification providers (=accredited labs), unless the manufacturer is under a surveillance procedure (see below). This approach substantially raises the accountability of manufacturers. Market Surveillance The IHE-CAS framework does not prescribe a formal market surveillance mechanism. Oversight is indirect, with conformity signaled through certificates issued by accredited laboratories. Enforcement largely depends on purchaser requirements or contractual obligations, rather than legal sanctions. Conversely, EHDS-CAS establishes a robust, legally binding market surveillance regime, consistent with Articles 44 and 45 of the Regulation. Member States must designate market surveillance authorities empowered to prohibit, restrict, recall, or withdraw non-compliant EHR systems. These authorities can require cooperation from manufacturers, including, in case of non conformity, to submit their product to the scrutiny of an ISO 17025 accredited lab designated by the surveillance authority. They will also ensure enforcement of corrective actions within strict deadlines. If a national surveillance authority identifies systemic non-compliance, the Commission may intervene, adopt implementing decisions, including requiring withdrawal. This framework mirrors the established EU approach for medical devices and other regulated products, ensuring active monitoring, enforcement, and a transparent registry of compliant systems. Conclusion Both conformity assessment schemes

			provide valuable models for ensuring interoperability and compliance. IHE-CAS prioritises independent laboratory validation, while EHDS-CAS has manufacturer accountability and embeds oversight through Member State-led digital testing environments and market surveillance authorities. The EHDS approach, grounded in the Regulation, offers a comprehensive, legally enforceable framework that balances innovation with public trust and safety.
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."