D7.1 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	4.3.2 Data Format and Structure	X-Net #1: A variety of EHR requirements throughout the document, such as those to do with decision support, display of all lab report fields, and data quality, are outside the scope of EHDS as they are about EHR UI, behavior, or functionality outside of the interoperability and logging components.	X-Net #1: Handle conformity requirements in the implementation guide, using the methods finally agreed by WP8 (expected consultation for D8.1 and D8.2). We suggest using cardinality and "populate-if-known" and "handle" simple obligations in the implementation guide to set requirements on certain fields, rather than separate requirements involving EHR UI and functionality. This will greatly facilitate automated testing and focus the requirements on the harmonised components of the EHR.
Industry X-Net	II. Scope And interdependencies	X-Net #2: Within a Healthcare organisation a lot of applications are used. For instance, a Laboratory Information System (LIS) and an Electronic Health Record. If a healthcare provider orders some labtests, an order is sent to the LIS. The patient number is sent along to identify the patient. To minimize exchanged data not all details are sent; f.i. the Name and address are not exchanged. The LIS returns the results of the ordered tests (including the PatientNumber) to the EHR. The EHR accepts these values but doesn't store f.i. details about the calibration of the device used, etc. So if a request for lab data is sent to the Healthcare organisation, the EHR can only return the results of the (ordered) tests. Data about what type of test was used or how the device was calibrated is stored in the LIS (logfile).	X-Net #2: The EHDS handles all types of EHRs (LIS, EHR, PIS, medical devices) as 1. We need to know what kind of data has to be exchanged by the different types of EHRs and the specifications need to allow the results that can be produced by each relevant type of system rather than assuming one system can provide all relevant data. One solution is to break-down the scope of the medical results reports along two axis: - one axis related to the level of information details related to each result (A LIS manages many analyser context attributes that are not relevant for a general purpose EHR system). - a second axis related to broad categories of lab specialties and medical specialties that produces such results. If 4 OR 5 (possibly more broad categories could be defined, then the users and designers of systems could select and claim conformance for one or more category at a high or detailed level.

Industry X-Net	4.1.5 Generate a medical test result report	X-Net #3: Allowing NPU seems inconsistent with general EHDS requirements to stick to SNOMED CT, LOINC, IDMP and UCUM. Allowing multiple terminologies to be used for the same things undermines the goal of the EHDS to create interoperability. One value set should be chosen for cross-border exchange, otherwise all data consumers will be required to support both LOINC and NPU and the mapping between the two.	X-Net #3: We propose using LOINC in combination with UCUM, since it has broader use than NPU, and putting the burden of mapping on the Member States who use different value sets than the chosen cross-border one.
Industry X-Net	4.1.2 Common Actors	X-Net #4: The Order Placer, Order Filler, Automation Manager, and Order Result Tracker actors and the laboratory testing workflows between them are not in scope of what is required for EHDS: cross-border data exchange and access to results by providers and patients. While it may be possible to use the defined specifications for these workflows as well, they should not be included as expected actors in this document.	X-Net #4: Remove the Order Placer, Order Filler, Automation Manager, and Order Result Tracker actors and the Laboratory Testing Workflow diagram from this document, or clarify that they are for informational purposes and not required to use EEHRxF as part of EHDS scope.
Industry X-Net	4.1.8 Searching and receiving test reports	X-Net #5: Line 954 and the above paragraph describe query parameters to use with IHE MHD queries to locate documents. Most of the described parameters are defined in MHD, but study and specimen are not. As such, there is not defined behavior for dealing with these parameters. Less structured documents may have queryable MHD metadata, but could be missing content-level details like Study, which could cause missed data. Without an explicit rationale for including these additional content-level filters, other content-level filters might be expected for other use cases. This in turn requires defining a logic for combining content-level parameters (for example, what if in addition to a study, clients could also search on certain	X-Net #5: Start with the existing MHD parameters, be consistent with other EHDS priority data categories about how they are used, and be clear about which are in the query and which are allowed for post-request filtering. It should be rare that search or filter parameters specific to medical test results are needed. Where possible, FHIR resource searches (such as DiagnosticReport in this case) with the accompanying defined parameters should be used to accomplish this. In the rare case an additional parameter is needed, it should be defined as part of the implementation guide. We have made similar comments on Xt-EHR deliverables, such as hospital discharge report, patient summary, and it is clear that a cross-data category alignment effort is critical and should be performed during comment resolution.

		allergies or medications, all at once? What behavior should be expected?). This will create significant complexity and might produce unreliable querying patterns that result in unintentionally missed data.	
Industry X-Net	4.5.3 Data element-level conformity requirements	X-Net #6: The definition of the data-level conformity requirements needs to be the same for all priority data categories and is the responsibility of D8.2. Documenting these aspects in multiple deliverables is a source for confusion and potential inconsistencies. Also, it is essential that data element-level conformity requirements undergo stakeholder consultation, since they have the most impact to implementation.	X-Net #6: Handle conformity requirements in the implementation guide, using the methods finally agreed by WP8 (expected consultation for D8.1 and D8.2). These should be specified by the implementation guides defined by HL7 Europe and IHE Europe, and go through the consultation processes of those standards organisations to ensure there is opportunity for input from manufacturers and others in the community.
Industry X-Net	4.2.4 Comparability of results	X-Net #7: While it is stated here that mapping is needed, there is no guidance about which party should map, or how. This is needed to ensure the correct parties invest in supporting this mapping. Also, mapping between code systems is not ony "non-trivial" - in some cases, it is impossible as both systems contain concepts that do not exist in the other system. In such cases, a choice must be made between picking a more general concept for which a mapping exists to communicate (losing detail) or asking the user to provide more detail (increasing administrative burden). There is no guidance here about how to handle cases like these.	X-Net #7: Choose between the source and the receiver of the data or between the system using LOINC and the system using NPU to decide which system must map its encoding for tests. Choose whether more generic or more specific terms must be used when no exact mapping exists, document this choice, elaborate on the reasoning behind it, state the drawbacks of this choice and give guidance on how to mitigate them. Where possible, the original value should be retained.
Industry X-Net	4.1.2 Common Actors	X-Net #8: The inclusion of the Document Registry and Document Repository in the Technical Actors could imply that all member states will have these actors involved in the exchange of Laboratory Reports. Member State architecture can differ, and in some cases there might not be a separate central or	X-Net #8: Clarify that the Registry and Repository actors are dependent on Member State architecture, and may not be separate systems. The same system may serve the roles of Producer, Registry, and Repository.

		regional repository and registry; Laboratory Reports might be stored in the creating system (acting as Producer and Registry/Repository) and retrieved when needed for exchange, rather than stored centrally.	
Industry X-Net	4.1.6 Sending/Providing a report	X-Net #9: It is unclear if EHR systems are required to support ONE OF or ALL OF push/pull/notified pull, and if so, which of the technical standards required for the interoperability component of an EHR will be utilized for these transactions. For the use cases required for EHDS (patient access to data, provider access to data, cross-border exchange), only Pull is strictly necessary. While Push and Notified Pull can be useful and may be used within member states, they should not be required of EHRs for initial EHDS scope. Push and Notified Pull introduce technical complexities that are not needed to meet core EHDS goals, such as workflow trigger points, identification of receiver and routing, and authentication. Pull also aligns well with current myHealth@EU functionality.	X-Net #9: Update this bullet point to say "The EHR system SHALL make medical test results or result reports accessible through at least the standardised PULL API as described in D5.1."
Industry X-Net	4.3 Technical specifications	X-Net #10: Requirements that are defined in D5.1 and that do not have special considerations for medical test results should not be defined here. Documenting these aspects in multiple deliverables is a source of confusion and potential inconsistencies. This includes: Transport Layer Security, file formats, authentication and authorisation, and the safeguards described in 4.1.6.2.	X-Net #10: Instead of defining requirements here, refer to D5.1.
Industry X-Net	4.4.2 Logical data model (dataset)	X-Net #11: Line 239 on page xii defines veterinary medicine as out of scope, but 4.4.2.22 defines the data type "Patient Animal". This is inconsistent.	X-Net #11: Make consistent by keeping veterinary medicine out of scope, or clarify why this is needed for non-veterinary medicine.
Industry X-Net	4.1.8 Searching and receiving test reports	X-Net #12: EHDS is expected to apply HL7 FHIR. Therefore, no references to IHE XDS should be made.	X-Net #12: Keep the reference to IHE MHD here. Check that in other places where XDS is mentioned, that the document instead refers to IHE MHD, which is FHIR based.

Industry X-Net	4.1.1 Business requirements for EHR systems	X-Net #13: The section and the figure introduce "Medical Test Result" actors. But these actors are defined to process only "reports", not individual test results. However, in other places of the document a (partial) distinction is made between reports and results. E.g. Figure 2 (line 656), or chapter II.1 Scope. Sometimes "results" and "reports" seem to be used interchangeably. With the current language throughout the document it remains unclear to what degree the processing if test results instead of reports is also covered. Which makes it impossible to assess with products will have to be conformant to the requirements which are defined here.	X-Net #13: Rework the document language to be more consistent and make clear to what degree test results which are processed separate from a report are covered. We recommend that the D7.2 approach be used to identify two distinct data models: - one to "query and retrieve medical results reports" - another one to "get medical results resources" These two transactions may be useful for different applications: for example, a report might be useful for presenting a fully rendered version of a set of related tests results for interpretation with full context, while individual results in the form of Observation resources might be useful for aggregating and trending specific results.
Industry X-Net	II. Scope And interdependencies	X-Net #14: The scope of medical test results is unclear and potentially very broad, and not all types of results fit well in the data model of result reports. For example, point of care tests may not produce enough information to populate a result report.	X-Net #14: Clarify exactly which types of results are in scope and which specifications should be used to communicate them. Instead of defining what is out of scope, consider instead defining what is in scope, limiting it initially to specifically defined specialties or types of tests for which result report documents are currently produced. Establish a governance structure and process for iterating in the future to add more types of tests, allowing time to do the analysis and specification work needed to ensure the specifications are fit to the use cases.