Xt-EHR (EU4H-2022-JA-09, project number 101128085)
Targeted Stakeholder Expert Consultation on Draft Deliverables of Work Package (WP) 5 - 9

Template for comments

Deliverable: **D5.1 Technical Requirements for Electronic Health Record (EHR) systems and key system interfaces**
Version:

1	2	3	4	5	6	7	8	9	10	11	12
EU Member State (MS) ISO 3166 two-letter	**Organisation name**	**Xt-EHR target stakeholder group**	**Section/ Subsection** number	**Page** number	**Line** number	**Figure/ Table / Paragraph** number	**Category** of comment (major or minor)	**Type** of comment (general, technical	**Comment** (justification for change)	**Proposal how to resolve comment**, proposed change	**Observation/ response to comment by WP**, information if and how comment was addressed
e.g. DE	*e.g. Federal Ministry of Health*	*e.g. Health authorities and legislators*	*Section/ Subsection number*	*e.g. 14*	*e.g. 323*	*e.g. Figure 2*	*e.g. minor*	*e.g. editorial*	*e.g. Figure caption lacks introduction of acronyms*	*e.g. Introduce acronyms used in Figure 2 for reference and to avoid misinterpretation*	*e.g. agreed, acronyms introduced in D9.1_v1.0*
EU	CPME	Health care experts and providers	3.1.2 Technical Requirements	13	296		minor	editorial	Depending on the purpose, the system shall be capable of capturing, storing, intermediating, exporting, importing, converting, editing, or viewing an appropriate selection - at a minimum - from the categories of health data defined by the EHDS Regulation.	Replace 'or' by 'and'.	
			3.1.2 Technical Requirements	13	300		minor	editorial	The system shall also be able to exchange this electronic health data with other systems in a structured electronic format.	Add: 'more specific: the EEHRxF.'	
			3.2.2 Technical Requirements	15	404		major	editorial	Installation of EHR system includes both on-premises (local) and cloud based solutions.	Add: '...by using European cloud services only.'	
			4.3.1 General Requirement	29	840		minor	editorial	Where an EHR system is designed to provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European health record exchange format (EEHRxF), by means of the European interoperability software component for EHR systems.	An EHR system is designed to store and provide access to personal electronic health data…	
			5.1.1 General Requirement	38	1153		major	general	Also pay attention to user friendlyness for health professionals by not necessarily have to log in all the time.		
			4.1.2 Technical Requirements	32	725			general	EHR system should give access to all functionalities in the EHDS without further logins	One day, one-time login' to the online EHR system back-end should be the common practice, providing for automatic authentication of national components, such as electronic prescriptions, patient summaries, etc. This means that the session should remain active until the healthcare professional signs out, which does not invalidate the authentication procedure of locking and unlocking the system when a healthcare professional is required to use another terminal on the same day.	
			4.3.2 Technical Requirements	37	892			general	add additional points to 3. Recommended features/best practices	IV: Data Reconciliation and Usability: Integrating external data with any existing patient records should be supported in a seamless way for end users. V: Synchronisation with national aggregation mechanism: Support should be provided for end users to address discrepancies in national aggregation processes.	
			4.4.2 Technical Requirements	39	936			general	iii. Different coding Support: Doctors should be required to code only once for the continuity of care and the EHR system should provide for multiple primary and secondary uses, including billing and statistical reporting, to reduce data entry requirements.		
			6.1 ANNEX 1 – European Interoperability Software Component	54	1723			general	The transition to cross-institutional and international EHR interoperability creates significant opportunities while introducing new complexities in data governance. Historically, healthcare providers maintained data quality mainly through localized controls and institutional quality assurance mechanisms. However, the shift toward shared data ecosystems obscures these established quality control pathways, particularly as many jurisdictions lack the necessary infrastructure or capacity to implement equivalent safeguards at scale. A practical illustration of this challenge emerges in the EHDS patient summary requirements. When hospitals and primary care practices simultaneously contribute to a national aggregation layer that combines multiple data sources into unified EU-compliant patient summaries (D5.1/Figure 1: Interoperability components of EHR Systems), fundamental questions arise about operational protocols. While technical compliance can be achieved through various architectural solutions, the practical framework for resolving discrepancies and preserving accuracy in the clinical content at the data level often remains largely undefined. Important gaps may occur in standardizing processes for corrections of content errors, reconciling conflicting clinical data between source systems, establishing clear accountability for updates, and maintaining an audit trail of modifications across distributed datasets. These unresolved operational considerations risk undermining the clinical utility of shared health records and introduce risks despite proper technical interoperability being achieved. A fundamental challenge in shared data ecosystems is the alignment of local and nationally aggregated health data systems, which – based on current implementation experience – can create significant operational complexities.Of particular challenge under the EHDS regulatory framework will be the creation of standardized approaches for visualizing and reconciling these dual data layers in clinical interfaces. Current similar graphical presentation systems often lack compliant mechanisms to either: a) clearly and effectively distinguish between locally documented and nationally aggregated patient information, or b) provide audit-compliant reconciliation pathways when discrepancies occur This challenges EHDS requirements for accurate representation of source data and risks creating non-conformities regarding 'prevention of ambiguous health data presentation'. Without interface solutions that natively support both local clinical workflows and cross-border data exchange requirements, healthcare providers face persistent challenges in meeting the regulation's dual objectives of clinical usability and interoperable data sharing. Clear recommendation should be added, that sufficient organizational capacity and support should be provided to address those challenges.		