Template for comments

Deliverable: **D5.2 Technical Requirements for European Electronic Health Record Exchange Format (EEHRxF) metadata**

Version:

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EU Member State (MS) ISO 3166 two-letter country code **or "EU"** for European stakeholder organisations	**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 or editorial)	**Comment** (justification for change)	**Proposal how to resolve comment**, proposed change	**Observation/ response to comment by WP**, information if and how comment was addressed
EU	CPME	Health care experts and providers	7.1 Governance and Lifecycle Management	46	1244			general	D5.2/7.1 While the proposal frequently emphasizes the importance of robust mechanisms for involving business users in understanding EHR logical models and broad community participation, most healthcare professionals today remain excluded from decision-making processes. A significant barrier is the knowledge gap that largely prevents comprehension of current model presentation formats - even when less technical alternatives like UML are proposed. This technical barrier is often addressed by technically skilled healthcare workers who, nevertheless, require clearer communication resources to effectively engage with the broader clinical community. This is particularly critical for ensuring representativeness, as only through widespread inclusion of non-technical staff can we obtain optimal feedback from end-users. Current knowledge presentation formats can be improved. Especially for extending clinical topics planned for the future, tailored communication materials need to be developed. The implementation of standardized frameworks for inclusive medical professional representation – with verifiable participation mechanisms and clear entry points for non-technical HCPs – is essential to fulfill EHDS obligations.		
	CPME	health care experts and providers	5.3 Quality Monitoring and Validation	31	876			general	While inherent and system-dependent dimensions provide a technical foundation, context-aware quality assessment is indispensable for clinical applicability. Usability measures must be adopted to evaluate efficiency, effectiveness and healthcare professional satisfaction when introducing EHDS functionalities in EHR systems.		
EU											
EU	CPME		7 Data Governance Requirements	46	1244			general	Clinical data models reside in complex environments and their creation requires a thoughtful knowledge engineering effort to specify these elements so that the recommendation is useful, actionable, and targeted to the right person at the right time and with the right presentation. To achieve the most effective knowledge exchange and validation between these diverse expert groups, a multi-layered knowledge representation framework should be implemented. Such a framework would facilitate structured, hierarchical, and accessible communication, enabling seamless collaboration and alignment across disciplines. With time, the EHDS will enable standardized approaches adapted to future needs, including the implementation of mutiple standards based on clinical requirements. To maximize inclusiveness, the system should incorporate submission mechanisms accepting non-technical proposals. This aligns with the EHDS mandate for accessible participation frameworks, while maintaining rigorous standardization through backend validation of non-technical submissions against established standards.		
EU	CPME	healthcare experts and providers						General	The requirements must be usable and user friendly to avoid excessive time spent from clinicians; must be based on existing needs for collab among clinicians; the requirements need to be flexible enough to facilitate for different cultures, organisation, task distributions and financing systems across member states; the requirements must be flexible to allow continously medically innovation, and also local improvement of processes , ie not locked into a technical standard; the requirements must be possible to update and change without loosing older data ie backwards compatible; the requirements must be sustainable for the EHR-industry.		