The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Open questions on the implementation of primary use in the European Health Data Space

Aligning technology and data with clinical workflows

This document aims to compile the concerns expressed by CPME in the context of the European Joint Action Xt-EHR - Extended EHR@EU Data Space for Primary Use.[1] The content is therefore related to the topics of consultation with stakeholders and reflects CPME's requests for emphasis and clarity.

This document is intended to support the technical discussions with the European Commission on matters related to the implementation of the European Health Data Space Regulation (EHDS),[2] and in view of the operational decisions to be taken by the MyHealth@EU steering group, as foreseen in Article 95 of the EHDS. This document can also support CPME members at national level, helping to bridge national realities and needs with the EU objectives and requirements for primary use purposes.

General principles

- **Build on national infrastructure that already works.** All aspects of EHDS implementation should build on effective national systems, standards and infrastructure. Member States with mature systems should be able to meet EHDS requirements without unnecessary rebuilding or duplication. Wherever possible, the necessary adaptations should be made through shared national infrastructure, minimising the need for individual practices and other healthcare providers to redesign their systems and workflows.

[1] The Joint Action Xt-EHR - Extended EHR@EU Data Space for Primary Use was coordinated by the National eHealth Authority – NeHA (Cyprus) and co-funded by the European Union, <https://www.xt-ehr.eu/>, accessed 17 September 2026.
[2] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance), OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

- **Technology and data requirements must not dictate clinical workflows** – clinical practice is dependent on local variance, patient context, culture, organisational regulations, funding, among other aspects. When information models rigidly enforce clinical workflows, they introduce unintended inefficiencies, wasting time for clinicians.
- **Interoperability requirements should not change clinical documentation practices or increase structured data entry** – ensure that interoperable technical capabilities of electronic health record (EHR) systems are not considered as clinical documentation requirements which ought to be captured by doctors and other healthcare professionals. The presence of predefined fields encourages field-driven system design at the expense of clinical reasoning, narrative documentation, and the unavoidable uncertainty of medical work. Increased structural granularity does not reduce clinical uncertainty, even if it creates the appearance of precision. It is necessary to ensure that the presence of an interoperability element must not be interpreted as implying routine data capture or clinical workflow requirements. Interoperable technical capabilities should be clinically validated, before being used for test artefacts, certification scenarios, or conformity assessments.
- **Avoid unintended task shifting** – EHDS implementation should be assessed for unintended shifts of tasks and responsibilities between healthcare professionals, organisations and level of care. Technical requirements should not implicitly transfer administrative, data reconciliation or documentation responsibilities to clinicians without an explicit assessment of clinical necessity, workload and accountability.
- **Ensure meaningful clinical involvement throughout implementation** – doctors and other healthcare professionals should be meaningfully involved throughout the design, testing, implementation, evaluation and revision of EHDS specifications. Clinical involvement should not be limited to consultation on completed technical solutions. Appropriate clinical informatics expertise should be included in technical governance structures to bridge clinical practice and technical standardisation.
- **Prevent digital exclusion** – implementation of EHDS patient access rights must ensure that patients who lack digital skills, digital identification, suitable devices or the ability to use digital services are not disadvantaged. Equivalent non-digital or assisted access routes should remain available where necessary.
- **Reduce electronic documentation burden** – ensure the right balance between structured and unstructured data in the EHR file. Mandatory structured fields, and data models that require clinicians to enter or reconcile information manually, increase documentation burden, pull time away from patients and may reduce clinical usability.

Interoperability must primarily be achieved through reuse of data already generated for clinical care, not through new documentation requirements.

- **Prevent the loss of clinical narrative and judgment** – fragmenting clinical information into many structured fields is poorly suited for medical practice, as patients and medical conditions do not necessarily fit precisely into predefined categories, over-structuring risks displacing free-text clinical reasoning, in particular in general practice/family medicine and psychiatry.
- **Appropriate communication of test results** - The implementing rules should preserve the possibility of a short, clinically justified delay in making certain results electronically available, where necessary to allow the treating physician to communicate and explain the findings to the patient first, in particular serious test results.
- **Enable innovation by being prescriptive on what matters** – the implementation of the EHDS must not create a de facto oligopoly in which only the largest vendors have the financial, technical and regulatory capacity to comply. The implementation requirements should be proportionate, technology-neutral and limited to what is strictly necessary to achieve interoperability, security and patient safety. Excessively detailed or prescriptive requirements may create barriers to entry, favour the largest and most established electronic health record (EHR) vendors, and reduce competition and innovation unintentionally. Small EHR vendors, app developers and other innovative providers must have a realistic opportunity to develop and certify interoperable solutions.

A. European Electronic Health Record Exchange Format – usability elements for European doctors

1. Clinical usability must come first

EHR systems must function primarily as practical working tools for clinicians, and not to collect electronic health data for other stakeholders. Systems that are too complex, slow, or misaligned with clinical workflows undermine care quality and bring additional risks to patient safety.

We strongly recommend focusing on the ability to exchange relevant information, rather than imposing uniform documentation requirements across all actors.

2. **Automation over manual data entry**

EHR data should be auto-populated and synchronised with health-related registries and databases, including eDispensation and ePrescription systems, to avoid manually re-entering the same data by clinicians. Manual entry can be unreliable, time-consuming, and a source of errors.

3. **Distinguish missing information from confirmed absence**

The normal state of a human being is no medication and no procedures. EHR systems must clearly distinguish between information that is unavailable, not assessed, reported absent and clinically confirmed absent. An empty field must not automatically be interpreted or displayed as "none". Where information has not been documented, systems should preserve that uncertainty without imposing unnecessary documentation requirements on clinicians.

4. **Avoid cluttering the record with outdated procedures.**

The term "medical or care procedures" is broad in medicine, and this section risks becoming overloaded with unnecessary or irrelevant entries. While some procedures may be clinically important at the time they are performed, many become insignificant over time. Listing every procedure throughout a patient's life may lead to a cluttered, unmanageable record that reduces clinical value.

5. **Move from dropdown menus to free text with AI-assisted coding and significance ranking**

Dropdown menus can cause inefficiencies by forcing clinicians to check whether the procedure they performed is included in the predefined list. This takes time and may lead to omissions or imprecise entries. Instead, the input field should support free text or standardised coding, allowing for efficient and accurate documentation.

AI tools can assist by automatically coding free text entries and organising them into categories, such as "recent procedures" and "forever" clinically significant procedures. Significance can be identified through coding logic, enabling the system to highlight major interventions (e.g., surgeries) while de-emphasising minor or outdated procedures in summary views. It should be possible to enter year only to allow documentation of historical procedures even when the exact date is unknown.

6. **Preserve narrative free text as the preferable format, with structured fields auto-populated from it**

The general narrative field is the primary, sometimes sole, essential documentation element necessary for the healthcare professional. If specified fields are needed, they should be populated automatically using AI from the narrative field or through the patient summary. Structured fields and overly complex electronic data registration should not replace clinical judgment and narrative reasoning.

7. **Preserve clinical meaning during AI processing**

AI-assisted coding, summarisation and extraction of structured data must preserve the clinical meaning of the source documentation, including negation, diagnostic uncertainty, temporal context and information provenance. EHR systems must preserve the chronological sequence of symptoms, observations, investigations, clinical assessments and interventions, distinguishing when events occurred from when they were documented. They must also retain how diagnostic hypotheses and levels of certainty evolved as new information became available.

Systems must not convert suspected conditions into confirmed diagnoses, historical findings into current problems, or retrospectively established diagnoses into facts apparently known at an earlier stage. Relevant documentation should remain accessible, and AI-derived entries should be identifiable, reviewable and correctable, with validation requirements proportionate to their clinical consequences.

B. European Electronic Health Record Exchange Format – content and data-model design

8. **Require active substance and international codes identification**

The medication summary is the most critical component of patient summaries. Ensuring continuity of medication is essential when patients move between healthcare regions or across national borders. The medication list also provides valuable indirect clinical information, for example, the presence of insulin indicates that the patient has diabetes.

Given the wide variation in brand names and manufacturers across countries, it is crucial that ePrescriptions include the name of the active substance and the appropriate international codes. This helps avoid misunderstandings and reduces time spent identifying medication purposes or equivalents in other countries.

9. Synchronise medication data automatically

The medication list in the patient summary must not rely on manual data entry. Manual input inevitably results in outdated or inaccurate lists due to incomplete updates from the various prescribers involved in patient care. It leads to duplication, errors related to dose adjustments, and confusion about discontinued treatments. To ensure reliability, the medication list should be automatically synchronised with each country's ePrescription infrastructure. Once the EHDS ePrescription component is in place, it must support API-based integration between the EU model and national systems, enabling automatic population and real-time updates of the medication summary in the patient summary.

10. Avoid note bloat and information overload

Many deliverables of the Joint Action Xt-EHR propose overly granular, fragmented data models with excessive mandatory fields for patient summaries and discharge reports. This leads to note bloat, redundancy, alert fatigue, and reports that are too long to be read in practice, losing clinical findings. For example, a discharge report with 139 data entry fields risks burying critical information in noise, making reports less likely to be read, increasing the risk of missing clinical findings — the opposite of their intended safety function.

With regards to alert fatigue and redundancy of data entries in the system, it must be ensured that the "alerts" model does not require entering the same information in multiple places (e.g., once as a problem and then again as an alert), which is both inefficient and prone to inconsistency.

The "informativeness" approach, defined as the category that "directly concerns the usefulness of information for clinical purposes", started to be methodologically tested by clinicians,[3] and should be further explored.

11. Wellness app data needs strict guardrails

Wellness and fitness apps data should not freely flow into the EHR file due to poor data quality, lack of standardised protocols, lack of algorithm transparency, and alert-fatigue concerns. As these data are not clinical, they could saturate the EHR file and create medico-legal exposure for doctors if integrated without clinical gatekeeping. Data from certified digital apps, which use standardised protocols and are transparent about the

[3] KP Fadahunsi, O'Connor S, Akinlua JT, Wark PA, Gallagher J, Carroll C, Car J, Majeed A, O'Donoghue J, "Information Quality Frameworks for Digital Health Technologies: Systematic Review", J Med Internet Res 2021;23(5):e23479, doi:10.2196/23479; and KP Fadahunsi, Wark PA, Mastellos N, Neves AL, Gallagher J, Majeed A, Car J, "A Novel Framework to Assess Clinical Information in Digital Health Technologies: Cross-Sectional Survey Study", JMIR Med Inform 2025;13:e58125, doi: 10.2196/58125.

algorithms employed, should only be added to the EHR with agreement of the treating physician.

12. Preserve multidisciplinary annotations and clinical context in medical imaging exchange

Modern healthcare is delivered by multidisciplinary teams with patients as integral participants. The EHDS implementation guide should ensure that all relevant annotations from a multidisciplinary team (e.g., tumour measurements, markers, or delineations) are represented within the European electronic health record exchange format (EEHRxF), maintaining their association with the corresponding imaging data. They are part of the integral diagnostic information, and their loss during exchange could cause misinterpretation.

Health data cannot be separated from the original care context, as it creates significant risks for care quality, trust, outcomes, and patient safety. Access to data alone does not ensure safe, meaningful, and person-centred care. Contextual clinical information must be included in future specifications, as this is essential for continuity, accurate decision-making, and patient empowerment, especially in cross-border scenarios. In addition, translation and multilingual support cannot be excluded from imaging semantics, as it would introduce systemic bias against non-dominant-language users, contradicting EHDS's equity aims.

For this reason, it is recommended that future inclusion of local annotation, editing, and multilingual support should be shared across border in the local language of the examiner. This is necessary not just for technical completeness or compliance, but to ensure the EHDS truly supports collaborative clinical care, patient-centred decision making, and translatable outcomes across national and linguistic borders.

C. Data quality, provenance and accountability in shared records

13. Avoid data washing in the EHR

Systems receiving or interpreting exchanged data must not infer, impute or fill in missing data elements; these must be displayed explicitly as "no information available".

14. Caution on including patient self-monitored data

Patient self-monitored data should only be included in the shared EHR if jointly agreed with the relevant healthcare professional.

15. Ensure data reconciliation and clinical governance in aggregated/shared records

European doctors raise concerns about reconciling locally documented data with nationally aggregated data, audit trails, and accountability for corrections — technical interoperability does not guarantee clinical data governance. It needs to be clear if a healthcare professional-only section will continue to be possible at national/local level.

During the negotiation of the EHDS Regulation, the intention of the legislation was not to interfere with this extended version of the EHR at national level, only to define the minimum categories to be shared across borders. How will the EHDS model respond with sections that exist at local level but not in the EHDS model? Will sensitive information be exchanged in wrong fields? Please note that also in a discharge report, there may be messages that only healthcare professionals should be aware of, particularly in case of further treatment. Consider again cases of mental health issues.

16. Protect health data of vulnerable groups in the EHR system, in particular children

Digital access settings can expose sensitive information to parents or guardians. While few children require confidentiality from their parents, the consequences of lost confidentiality can be catastrophic. Clear rules on access to children's data are required, in particular for teens. The default setting in EHR systems should be to deny digital access (default deny), with the option to grant it after a risk and vulnerability assessment focusing on the needs of vulnerable children (risk-based exceptions).

Parental access to children's electronic health records should strike a balance between parental responsibilities and the child's best interests, evolving autonomy and right to confidentiality, in accordance with national legislation.

Very sensitive data which can lead to stigmatisation and discrimination, and third-party data (e.g., infectious disease contacts, pregnancy history in some contexts, abortion procedures, etc.) should be excluded from patient summaries and discharge reports. For example, infectious contacts are only relevant in diseases where contact tracing is necessary, meaning situations in which the infectious contact also requires follow-up, such as testing, quarantine, or similar measures. This information concerns third-parties and should be processed through a dedicated system for contact tracing.

17. Responsibility for information in shared records

The technical availability of information in a shared EHR does not, in itself, establish that a healthcare professional has reviewed, validated or accepted responsibility for that

information. This becomes particularly relevant when large amounts of historical information become accessible across different organisations and countries.

Responsibilities for creating, updating, reconciling and using shared information should be explicitly allocated, as different actors emerge (e.g. healthcare professionals, patients, developers and institutions). Assessment of a healthcare professional's responsibility should take account of their clinical role, the relevance and visibility of the information, its provenance and reliability, and the reasonable opportunity to review it in the circumstances of care.

18. Partial studies and selected key images

The EDHS frameworks will allow healthcare professionals to access either a complete imaging study, part of a study, or only selected key images. It should be made very clear to the user when only a subset of the original examination has been viewed. Selected key images or a partial study should not inadvertently be interpreted as equivalent to reviewing the complete diagnostic examination.

19. Auditing AI-derived information in EHR systems

An EHR system which incorporates AI must ensure that there is a clear distinction between an AI output and the healthcare professional's own judgement. The interface should clearly demonstrate to healthcare professionals when AI has been used and what role it played. An AI-generated output cannot become part of a recommendation or medical record without this explicit attribution. For example, if AI-generated measurements, segmentations or annotations become part of an imaging study or report, their provenance should remain visible during exchange, including whether they were subsequently reviewed or validated by a healthcare professional. If doctors are to remain responsible for the medical decision, they need to be able to assess the AI output, question it and, if necessary, override it.

20. Control and accountability for AI actions in EHR systems

AI systems that can modify records, transmit information or initiate clinical or administrative actions must operate within explicitly authorised tasks and permissions. Autonomous actions with clinical or confidentiality consequences should be subject to appropriate human authorisation, with a clear distinction and record-keeping (logs) of the proposed action and an executed action. Accountability should reflect the responsibilities and effective control of developers, vendors, deploying organisations and healthcare professionals. Systems should support safe interruption of automated actions and

correction or reversal where feasible. Clinicians cannot reasonably be held responsible for technical processes or background actions that they cannot inspect, control or prevent.

D. Governance and long-term sustainability

21. Technical standards must evolve with medicine

Healthcare will continuously evolve and change. European doctors cannot know the needs or opportunities of tomorrow, and practical requirements will differ across clinical areas. Technical standards must therefore support the continuous development of healthcare systems and enable innovation. At the same time, interoperability frameworks should be designed to allow modular implementation and incremental adoption. This will make it possible for smaller vendors and innovators to contribute with valuable solutions without having to meet unnecessary requirements unrelated to their specific use cases.

CPME welcomes regular updates of the technical standards based on clinician's changing needs, with defined processes for prioritising these needs. Technical standards must be versioned and backwards compatible, and being explicitly required to vendors to implement mandated changes within defined time limits as a condition for maintaining certification and conformance. Once a system is approved, ongoing compliance must depend on timely implementation of current or supported standard versions.

As currently there is no structured framework for maintaining living standards or fostering continuous enhancement, CPME welcomes the development of a specific framework where groups of doctors and developers collaboratively improve and implement the technical standards, preventing them from becoming obsolete.

22. No shifting of financial burden to doctors and healthcare providers

Doctors and healthcare providers cannot bear costs of continuous system updates, interface changes, or added functionalities. National health authorities or vendors must cover these.

23. Introduce appropriate safeguards for telemedicine

Telemedicine should be clinically, not commercially, driven. Providers must be properly registered, regulated, and indemnified. Face-to-face care remains the "gold standard."[4]

[4] See CPME policy on telemedicine, March 2021, <https://www.cpme.eu/api/documents/adopted/2021/3/CPME_AD_Board_20032021_012.FINAL_.CPME_.Policy.on_.Telemedicine.pdf>, accessed 25 September 2026.

Annex I: Open implementation questions

This section addresses implementation questions which have been raised by CPME across the Joint Action Xt-EHR deliverables.[5] They highlight points where guidance and technical specifications were ambiguous, contradictory, or left practical mechanics undefined. Where content developed in the Joint Action Xt-EHR deliverables is not reflected in the draft tertiary legislation, the European Commission should provide an explanation why it was omitted and how and by whom those issues will be addressed.

CPME stresses the importance of EU and Member State regulators to coordinate with national implementors and users on the distinct aspects of implementation, ensuring that appropriate discussions are held at national level with relevant stakeholders. In particular, national medical associations. Doctors and other healthcare professionals should be meaningfully involved throughout the design, testing, implementation, evaluation and revision of the EHDS specifications. Clinical involvement should not be limited to consultation on completed technical solutions. Appropriate clinical informatics expertise should be included in technical governance structures to bridge clinical practice and technical standardisation.

D5.1 – Technical requirements for EHRs, logging and interfaces

- **Data reconciliation**: When multiple sources (hospitals, primary care) are presented together into a unified patient summary, how are conflicting clinical data reconciled? Who has accountability for corrections, and how is an audit trail maintained across distributed datasets?
- **Local vs. aggregated data display**: How should clinical interfaces visually distinguish locally documented from nationally aggregated information, and what does an audit-compliant reconciliation pathway look like?
- **AI outputs** - Are AI outputs indication part of the EHDS logical model? If local models have AI outputs, does the EHDS model make a clear distinction between what is the doctor analysis and what is the AI output/result?
- **Login and authentication model**: Will the EHR system be able to give access to all priority categories of personal electronic health data (e.g. ePrescriptions, patient summaries, etc.) preserving the “one day, one-time login"? 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. How will shared workstations be accommodated?

[5] The Joint Action Xt-EHR - Extended EHR@EU Data Space for Primary Use was coordinated by the National eHealth Authority – NeHA (Cyprus) and co-funded by the European Union, <https://www.xt-ehr.eu/>, accessed 17 September 2026.

D5.2 – Technical requirements on EEHRxF Metadata

- **Governance mechanism**: How, concretely, will non-technical healthcare professionals meaningfully participate in reviewing/validating clinical data models presented in UML or similar formats they cannot read?
- **Standard flexibility**: How will the framework accommodate multiple, evolving national standards while still ensuring EU-wide interoperability?

D6.1 – Patient Summary

- **Alerts architecture** (unresolved across multiple deliverables): Is the alerts model a flag on existing data, or an independent list?
- **Minors' access rights**: What legal/technical mechanism defines guardian access limits, and at what organisational level (department/unit) should access decisions be made?
- **Empty/default field behaviour**: How the "none" default data field, interacts with mandatory-field validation logic in FHIR IPS conformance testing? Can this be specified clearly?

D7.2 – Medical images and reports

- **Annotation scope**: Since annotation/editing is explicitly "out of scope," how will annotated diagnostic content (e.g., tumour measurements) be preserved and exchanged? Will there be a roadmap, or is this a permanent gap?
- **Team-based access**: There is no mechanism for configuring digital care teams or determining which clinicians can view, annotate, discuss imaging collaboratively. How should persistent, context-aware team access be implemented?
- **Consent model**: Is static, event-based consent still fit for purpose, or does the framework need to move to dynamic, granular consent - and if so, how?
- **Multilingual support**: How will multilingual value sets and translation of imaging metadata/reports actually be implemented, given they are currently excluded from scope?
- **ECG and other organ function tests:** Where are these going to be included?
- **Population-based screening programmes** – For breast cancer population-based screening programmes, screening radiologists should, where clinically appropriate and authorised, be able to access relevant prior hospital-based imaging studies and reports. Comparison with previous imaging is an essential part of mammographic interpretation. Conversely, patients should also have the same rights of access and download of mammograms and related reports generated within population-based screening programmes, as they have for imaging performed in hospitals or other healthcare settings. How to ensure that imaging acquired within organised population-based screening programmes, such as breast cancer screening mammography, is fully included within the EHDS imaging framework, including access to relevant prior hospital-based imaging for screening professionals and access to screening images and reports for patients?

D7.3 – Discharge reports

- **Data provenance/compilation**: It is unclear how the EHR is meant to compile a discharge report. From where does each of the 139 fields actually source its data (manual entry, other modules, registries)?
- **Element sourcing ambiguity**: Multiple specific fields (Alerts, Admission Evaluation, Past Problems, Family History, Physical Examination) refer source data elements (e.g., EHDS Observations, EHDS Condition) that do not contain a matching named field - where should this data come from?
- **Repeated-measurement handling**: If vital signs/observations are recorded multiple times during an admission, should all entries or only selected ones be included in the discharge report? And who decides the selection criteria?
- **Diagnostic categorisation purpose**: What is the clinical value of categorising diagnoses as "treating" vs. "recognised"?

D8.1 – Classification and functional profiles of EHR systems guidelines

- **Core unresolved tension**: Can cardinality/mandatory-field requirements at the "interoperability profile" level truly be kept separate from clinical documentation requirements - or will vendors and regulators inevitably translate them into clinical workflow requirements? Despite textual disclaimers, this might not be resolved when implementing the EHDS.
- **Update/versioning obligations**: No mechanism specified for how technical standards will be kept updated as medicine evolves, or how compliance will be maintained over time as versions change.

D8.3 – Wellness application labelling guidelines

- **Two-way communication scope**: The deliverable does not distinguish between "personal health environment" apps (which may warrant two-way exchange) and generic wellness/fitness apps (which should not) - this categorical boundary is undefined.
- **"Using data within a wellness app"**: What does this mean in practice (Art. 3(2) right to access) - the deliverable's own discussion column is unclear about downstream use.
- **Gatekeeping mechanism**: Is there a defined process for physician-mediated approval before wellness data enters the EHR, or is this left to national/local implementation?

D9.3 – Requirements for uptake of telemedicine services

- **Cross-border regulatory equivalence**: For many health professions not covered by "automatic recognition" under Directive 2005/36/EC, how will qualification/scope-of-practice equivalence be assessed across Member States for telemedicine providers? How to avoid commercial business models, e.g. prescriptions which game the system.
- **Indemnification**: No mechanism specified for verifying that a remote-consultation provider is adequately insured across jurisdictions.