



Digital health interoperability and the uptake of digital health solutions

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This document aims to accelerate the adoption of the **European Health Record Exchange Format (EEHRxR)** by offering recommendations to boost digital health uptake across the EU, building upon the regulatory framework outlined in the **European Health Data Space (EHDS)**. This document also builds upon the previous **“The interoperability of EHR systems and health apps in the European Health Data Space Executive Digest”**,¹ the EHDS Regulation will enforce legal, semantic, and technical standards to ensure seamless cross-border health data exchange, empowering European citizens and healthcare providers to access and share health records securely and efficiently. By focusing on **harmonising standards, building trust through transparency, and enhancing capacity** among healthcare professionals and technical teams, this policy brief outlines strategies to foster greater acceptance and engagement with digital health tools. Successfully implementing the EEHRxR will enable Europe to leverage interoperable health systems, ultimately improving cross-border healthcare delivery and innovation, as envisaged in the EHDS initiative.

State-of-the-art for digital health data interoperability in the EU.

Policy and project background on digital health interoperability and how it can impact digital health acceptance. Efforts to establish technical specifications for health data exchange were initiated through the e-Health Digital Service Infrastructure, which the European Commission and EU countries have implemented via the Connecting Europe Facility Programme in 2014.² The e-Health Digital Service Infrastructure, known today under the European Health Data Space (EHDS) as MyHealth@EU, links national eHealth contact points, enabling the secure exchange of patient summaries and ePrescriptions. The EHDS turns this infrastructure from voluntary to compulsory, and currently there are 13 countries with operational eHealth contact points³, and the first cross-border health data exchanges began in January 2019 between Estonia and Finland.⁴ This work was then built on by the Smart Open Services for European Patients (epSOS) project, a large-scale pilot that

tested cross-border sharing of health data.⁵ epSOS, was then enhanced by the EXPAND project, which aimed to fill this gap between piloting and deployment.⁶ EXPAND utilised various eHealth tools and resources developed through previous initiatives, moving from individual, localised solutions to a broader, large-scale implementation of cross-border health data exchange.

European Interoperability Framework. These initiatives aligned with the broader European Interoperability Framework (EIF), which is a set of guidelines developed by the European Commission to guarantee that IT systems and public services across Member States can communicate and work together effectively, which is necessary for enabling unified cross-border health data exchange. It aims to ensure that different IT systems, policies, and processes work together seamlessly across national and sectoral borders, providing efficient and interconnected digital public services throughout Europe. The EIF serves as a high-level policy framework within health data that sets the groundwork for interoperability

¹ Dipak Kalra, Zoi Kolitsi, and Petra Wilson, ‘The Interoperability of EHR Systems and Health Apps in the European Health Data Space – Digital Health Uptake (DHU)’, accessed 24 October 2024, <https://digitalhealthuptake.eu/resource/the-interoperability-of-ehr-systems-and-health-apps-in-the-european-health-data-space/>.

² European Commission, ‘Connecting Europe Facility- European Commission’, 12 June 2024, https://cinea.ec.europa.eu/programmes/connecting-europe-facility_en.

³ European Commission, ‘eHDSI Monitoring Framework (KPIs)’, accessed 10 October 2024, https://experience.arcgis.com/experience/77f459be23e545b48f46a79cfaf19423/page/1_1/.

⁴ European Commission, ‘First EU Citizens Using ePrescriptions in Other EU Country’, Text, European Commission- European Commission, accessed 10 October 2024, https://ec.europa.eu/commission/presscorner/detail/en/ip_18_6808.

⁵ European Commission, ‘Cross-Border Health Project epSOS: What Has It Achieved? | Shaping Europe’s Digital Future’, 7 July 2014, <https://digital-strategy.ec.europa.eu/en/news/cross-border-health-project-epsos-what-has-it-achieved>.

⁶ European Commission, ‘EXPAND: Deploying Sustainable Cross-Border eHealth Services in the EU | Shaping Europe’s Digital Future’, 14 February 2014, <https://digital-strategy.ec.europa.eu/en/news/expand-deploying-sustainable-cross-border-ehealth-services-eu>.

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between different healthcare systems. To address the specific needs of cross-border health data exchange, projects such as Antilope⁷ and HITCH⁸ projects contributed to developing a specialised version of the EIF tailored to healthcare, known as the Refined eHealth European Interoperability Framework.⁹

A new format that builds upon all these previous initiatives. The implementation of cross-border health data exchange initiatives like eHDSI, epSOS, and the EXPAND project has been instrumental in driving digital health adoption in Europe by establishing secure, interoperable infrastructures for sharing patient data. By 2020, these efforts facilitated over 50,000 ePrescriptions and 26,000 patient summaries exchanged among Member States.¹⁰ These projects set the base for advanced digital health technologies, such as electronic health records and telemedicine, by creating common standards and ensuring seamless communication between systems. Building on this, the EHDS and the European Health Record Exchange Format (EEHRxF) aim to enhance data access and reuse even further, fostering innovation and adopting new digital solutions across the EU. This new format supports a unified digital health market, making it easier for stakeholders to implement innovative health technologies and improve cross-border healthcare delivery.

Current roadmap for the EEHRxF. The EEHRxF is a key initiative under the EHDS, aimed at establishing a standardised approach for the secure and efficient exchange of health data across EU Member States.¹¹ The EEHRxF will enable seamless cross-border healthcare delivery by addressing fragmentation in digital health standards, building on existing European initiatives and frameworks. Once implemented, the EEHRxF will empower patients with secure

access to their own health data, support healthcare professionals in providing better coordinated and informed care, and facilitate secondary uses such as research, public health planning, and innovation. As a basis of the EHDS, the EEHRxF will ensure that European health systems are better interconnected, more patient-centric, and can leverage data for evidence-based decision-making. The implementation of the EHDS will occur in stages. According to recent updates, the timelines for EHDS) and the EEHRxF has been extended. Initially, it was expected that patient summaries and ePrescriptions would be applicable within 12 months, and full compliance for all specified health data types would be required within 36 months. However, due to significant delays, the earliest date for the applicability of patient summaries, electronic prescriptions, and electronic dispensations is now 4 years after the regulation's entry into force. Full compliance for other health data types, such as laboratory reports and imaging results, will take longer than initially anticipated 6 years after the entry into force. This process also means that EEHRxF will transition from a non-binding recommendation to a legally enforceable technical standard across the entire EU.¹²

European health record exchange format and the practical impacts and contributions made by the Digital Health Uptake project.

What is the Digital Health Uptake (DHU) project doing to foster health data exchange. The DHU project plays a role in making interoperable digital health solutions more accessible and widely adopted by both professionals and the

⁷ Antilope Project', 2013, <https://www.antilope-project.eu/about-antilope-project/>.

⁸ 'HITCH Project', 1 December 2014, <https://joinup.ec.europa.eu/collection/ehealth>.

⁹ European Commission. Directorate General for the Information Society and Media and Deloitte, *eHealth European Interoperability Framework* (LU: Publications Office, 2013), <https://data.europa.eu/doi/10.2759/10138>.

¹⁰ Jan Bruthans and Klára Jiráková, 'The Current State and Usage of European Electronic Cross-Border Health Services (eHDSI)', *Journal of*

Medical Systems 47, no. 1 (11 February 2023): 21, <https://doi.org/10.1007/s10916-023-01920-9>.

¹¹ K Trunner et al., 'The Development of New Electronic Health Record Exchange Format Use Cases- an Evaluating Perspective', *European Journal of Public Health* 32, no. Supplement_3 (21 October 2022): ckac131.171, <https://doi.org/10.1093/eurpub/ckac131.171>.

¹² European Commission, 'European Health Data Space', 24 April 2024, https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en.

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public. The [DHU's Radar Repository](https://digitalhealthuptake.eu/radar/)¹³ offers a database of guidelines and good practices that can be replicated to foster digital health uptake and data interoperability. Also, the project's [Twinning Program](https://digitalhealthuptake.eu/twinnings/)¹⁴ pairs less mature regions with more advanced ones, sharing expertise and facilitating real-world implementations of interoperable systems.



For instance, through adoption twinning activities, DHU has supported local authorities in integrating interoperable eHealth tools, such as digital prescription systems and patient health portals, into their healthcare services. These initiatives build trust among healthcare providers and patients, who are more likely to embrace digital technologies when they see seamless and secure data sharing in practice. Additionally, the DHU Knowledge Community creates a space for exchanging best practices and conducting training workshops that address specific barriers to digital health adoption. This targeted capacity-building ensures that stakeholders—including healthcare professionals, developers, and decision-makers—are well-prepared to implement EEHRxF-compliant solutions.

Practical Impact: health data interoperability to increasing digital health acceptance. In particular, the DHU Radar currently maps over 140 digital health practices from across Europe,

providing a rich repository of information on digital health solutions, policies, and strategies. The mapped initiatives are spread across various maturity levels and countries, allowing stakeholders to gauge the readiness of Member States for integrating digital health solutions. Some countries are particularly active in implementing these practices, such as Spain, Italy, and the United Kingdom. This diverse geographical representation makes benchmarking and analysing the digital health landscape easier, highlighting best practices and areas needing further support.

Digital health data interoperability remains a key focus. A substantial portion of the solutions tracked in the DHU Radar specifically focuses on interoperability, including tools for integrating patient health records, AI-based decision support systems, and secure data-sharing platforms. These solutions align with the goals of the EHDS and the EEHRxF, helping ensure that new technologies can communicate seamlessly across different systems and borders. For instance, initiatives like Chino.io tackle health data security and interoperability, ensuring compliance with the EU's data-sharing requirements. In addition to mapping digital solutions, the DHU Radar features EU health strategies and policies from multiple Member States. By analysing these strategies, DHU can identify which countries are most prepared for the upcoming EEHRxF standards and where additional capacity building might be needed. This mapping creates a benchmark for policymakers, providing insights into national readiness for interoperability and guiding targeted investments and training.

Impact on uptake and adoption. The DHU Radar's detailed categorisation of solutions and policies allows stakeholders—especially local governments and healthcare providers—to identify proven, scalable practices and adopt them in their own settings. As digital solutions become more interoperable and user-friendly, citizens are more likely to engage with these technologies, knowing that their data can be

¹³ 'Radar – Digital Health Uptake (DHU)', 24 March 2023, <https://digitalhealthuptake.eu/radar/>.

¹⁴ 'Twinning – Digital Health Uptake (DHU)', 13 March 2024, <https://digitalhealthuptake.eu/twinnings/>.

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securely accessed and used for better healthcare outcomes. DHU lays the basis for higher public confidence and uptake of digital health technologies across the EU.

Adoption challenges in health data interoperability and EEHRxF adoption for digital health acceptance

Simplifying access and increasing patient uptake through health data interoperability. At its core, the EEHRxF is designed to tackle one of the most significant barriers to digital health adoption: different levels of interoperability in the Member States. Despite ongoing efforts and existing standards, healthcare systems struggle with compatibility issues, information sharing, and varying state regulations, hindering efficient data exchange and impacting the quality of patient care. Further standardisation and policy interventions are necessary to overcome these challenges.¹⁵ Fragmented health records have long been a pain point, making navigating disparate systems challenging for patients and clinicians. Imagine a scenario where a patient with multiple chronic conditions—say diabetes and hypertension—receives care from several providers across different regions. Each clinician might maintain separate records without a unified format, leading to redundant tests, conflicting treatment plans, and a disjointed care experience.

Barriers to digital health interoperability Across EU Member States. The adoption of digital health data interoperability and EEHRxF face several barriers across EU member states.

These include low interoperability of healthcare system infrastructures, lack of systems to represent complex processes, and insufficient information exchange between heterogeneous providers. A significant challenge is the absence of universally adopted standards for semantic and syntactical interoperability.¹⁶ Harmonising these frameworks could significantly lower implementation costs and enable faster adoption of the EEHRxF across the EU.

The shortage of health information engineers and domain-specific experts is a significant barrier to achieving digital health interoperability across the EU. According to an impact assessment made in 2022 on the EHDS development, about 36% of EU countries lack sufficient technical and semantic interoperability experts, which hinders the application of standards like SNOMED CT¹⁷ and HL7 FHIR.¹⁸ Additionally, 43% of Member States have not yet implemented essential health IT terminologies, creating a significant gap in the workforce needed to drive standardisation and digital health adoption.¹⁹ The EU faces a significant shortage of skilled digital experts, particularly in areas like health IT. To meet its 2030 target of 20 million ICT professionals, the EU needs 7 million more ICT specialists. This shortage is further compounded by a lack of standard training pathways and insufficient reskilling programs, making it difficult to support complex digital health acceptance such as EEHRxF implementation. Over 60% of EU companies hiring ICT specialists report difficulty filling these roles, which slows digital transformation in healthcare.²⁰

Lack of interoperability is a major barrier for key industry players and healthcare providers.

¹⁵ Bharath Perugu, Mba et al., 'Pragmatic Approaches to Interoperability – Surmounting Barriers to Healthcare Data and Information Across Organizations and Political Boundaries', *Telehealth and Medicine Today* 8, no. 4 (24 July 2023), <https://doi.org/10.30953/thmt.v8.421>.

¹⁶ Caroline Stellmach, Michael R. Muzoora, and Sylvia Thun, 'Digitalization of Health Data: Interoperability of the Proposed European Health Data Space', in *Studies in Health Technology and Informatics*, ed. Philip Scott et al. (IOS Press, 2022), <https://doi.org/10.3233/SHTI220922>.

¹⁷ SNOMED CT is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information and is also a required standard in interoperability specifications of the U.S. Healthcare Information Technology Standards Panel. <https://www.nlm.nih.gov/healthit/snomedct/index.html>

¹⁸ Fast Healthcare Interoperability Resources (FHIR) is a next-generation interoperability standard created by the standards development organization Health Level 7 (HL7). FHIR is designed to enable health data, including clinical and administrative data, to be quickly and efficiently exchanged.

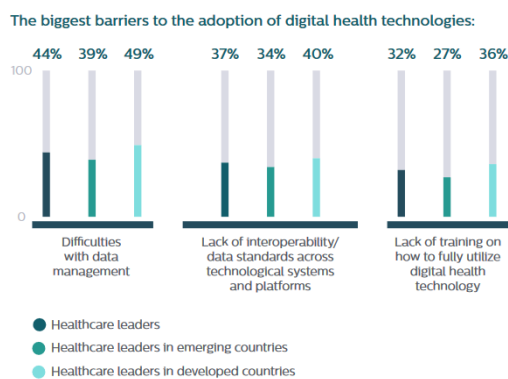
<https://www.healthit.gov/sites/default/files/page/2021-04/What%20Is%20FHIR%20Fact%20Sheet.pdf>

¹⁹ European Commission, 'Impact Assessment Report on The European Health Data Space', 2022, https://health.ec.europa.eu/system/files/2022-05/ehealth_ehds_2022ia_3_en.pdf.

²⁰ Stavros Nikou, 'Digital Experts: A Deep-Dive', 26 September 2023, <https://digital-skills-jobs.europa.eu/en/latest/briefs/digital-experts-deep-dive-0>.

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Interoperability is fundamental for unlocking the full potential of digital health innovations and improving healthcare delivery and adoption. It enables effective use of artificial intelligence, big data analytics, and mobile applications in medicine. Lack of interoperability between systems is a significant challenge hindering the acceleration of digital transformation in healthcare.²¹ A 2021 report from Philips found that 37% of healthcare leaders identified a lack of interoperability and data standards as a key obstacle to adopting digital health technologies. When digital tools, such as health apps, are designed to be interoperable, they improve clinical workflows and facilitate seamless data exchange, providing a more comprehensive view of patient health across multiple settings.²²



Philips, 'A Resilient Future - Healthcare Leaders Look beyond the Crisis', 2021, p. 13

In the EU, interoperability challenges continue to limit the effective use of health data. A recent study pointed out that data sharing is still constrained due to legal, technical, and interoperability barriers, preventing citizens from managing and deciding on what to share, with whom, and for what purposes. This

limitation impacts the continuity of care across EU Member States, with citizens, healthcare providers, and researchers unable to benefit from integrated and efficient healthcare services fully. Despite ongoing efforts, cross-border health data sharing is only feasible under specific cases and scenarios, highlighting the need for a more robust interoperability framework at the European level.²³

SMEs' challenges and readiness for health data interoperability and uptake. SMEs in the digital health ecosystem also face significant challenges in meeting interoperability standards like the EHRxF. High compliance costs and complex technical requirements—such as upgrading systems to support HL7 FHIR or implementing secure data exchange—make it difficult for these companies to align with EU regulations. This issue is further compounded by fragmented national rules, leading to repeated costs and delayed rollouts when expanding to new markets.²⁴ For example, in a recent workshop with industry players from different sizes, it was identified that platforms like Leyr.io had to create custom tools to bridge different EHR systems across borders, while larger firms like Philips have dedicated significant resources to interoperability libraries that are out of reach for most SMEs.²⁵ A survey from MedTech Europe shows that fragmented interoperability standards create confusion and increase compliance costs, hindering the ability of SMEs to scale their solutions across Member States.²⁶

²¹ Emmanouil S. Rigas et al., 'A Hackathon as a Tool to Enhance Research and Practice on Electronic Health Record Systems' Interoperability for Chronic Disease Management and Prevention', *Frontiers in Digital Health* 5 (14 November 2023): 1275711, <https://doi.org/10.3389/fdgth.2023.1275711>.

²² Philips, 'A Resilient Future - Healthcare Leaders Look beyond the Crisis', 2021.

²³ Athanasios Kiourtis et al., 'Electronic Health Records at People's Hands Across Europe: The InteropEHRate Protocols', in *Studies in Health Technology and Informatics*, ed. Bernd Blobel, Bian Yang, and Mauro Giacomini (IOS Press, 2022), <https://doi.org/10.3233/SHTI220973>.

²⁴ Leah Taylor Kelley et al., 'Barriers to Creating Scalable Business Models for Digital Health Innovation in Public Systems: Qualitative Case

Study', *JMIR Public Health and Surveillance* 6, no. 4 (10 December 2020): e20579, <https://doi.org/10.2196/20579>.

²⁵ Radhika Poojara, 'Impact of the European Electronic Health Record Exchange Format (EHRxF) in the Healthcare Industry', *XpanDH Project* (blog), 25 June 2024, <https://xpanDH-project.iscte-iul.pt/impact-of-the-european-electronic-health-record-exchange-format-ehrx-f-in-the-healthcare-industry/>.

²⁶ MedTech Europe, 'Interoperability Standards in Digital Health - A White Paper from the Medical Technology Industry', 2021, <https://www.medtecheurope.org/resource-library/interoperability-standards-in-digital-health-a-white-paper-from-the-medical-technology-industry/>.

Exploiting digital health interoperability and the EEHRxF for digital health accession

EEHRxF to increase data visualisation and technology acceptance. The EEHRxF may increase patient uptake in digital health technologies by establishing a standard for data exchange, enabling a consistent flow of information across various healthcare settings. When a patient's data can move seamlessly from one system to another, it enhances the usability of digital health tools like electronic personal health records.²⁷ As proven by research, with a single, consolidated view of their health data, patients are more likely to engage with digital platforms, track their progress, and even share information with their caregivers.²⁸ When it comes to getting patients more engaged with digital health platforms, having a clear and easy-to-use view of their health data can generate considerable added value.²⁹ If everything—from lab results to activity tracker info—is neatly organised and accessible, people are likely to take an active role in their health.³⁰ While the ability to share your health data may create more patient engagement, systems also need to ensure their functionalities are simple to use, match each person's comfort level, and fit with the users' health needs.³¹

Trust perspective when sharing health data and its impact on adoption. Take fitness trackers, for example. Sharing that step count and heart rate data with a doctor can lead to more meaningful conversations and, potentially, better health outcomes. However, not everyone is ready to hand over that personal information. Concerns about who sees your data and how it's used are real barriers. That's where trust and transparency come in—

patients need to feel safe sharing their information. Interoperability allows for consistent, accurate, and meaningful use of health data across various systems, which boosts confidence in digital health technologies. For example, when different electronic health records, wearable devices, and healthcare applications follow interoperability standards like HL7's FHIR or the Integrating the Healthcare Enterprise (IHE) framework, it ensures that data is not just shared but understood and integrated across systems. This integration reduces errors, such as conflicting medication records or incomplete health histories, which can otherwise undermine trust.³² Moreover, true interoperability provides context to data—transforming raw information into actionable insights. For instance, a patient's step count and heart rate might mean little when viewed in isolation. However, when interoperable systems can combine this data with clinical records (e.g., recent lab results or medication history), the information becomes useful for identifying trends and potential health issues. This reliability and utility of data foster patient and provider confidence, as healthcare decisions are based on a comprehensive view.³³

Additionally, interoperability facilitates smoother transitions between care settings, reducing patient frustration. A study highlighted by the Office of the National Coordinator for Health Information Technology showed that non-interoperable systems lead to data silos, causing unnecessary duplication of tests and confusion among patients, which

²⁷ Stefano Bonacina et al., 'Can the European EHR Exchange Format Support Shared Decision Making and Citizen-Driven Health Science?', in *Studies in Health Technology and Informatics*, ed. John Mantas et al. (IOS Press, 2021), <https://doi.org/10.3233/SHTI210346>.

²⁸ Robin Van Kessel et al., 'Exploring Potential Drivers of Patient Engagement with Their Health Data through Digital Platforms: A Scoping Review', *International Journal of Medical Informatics* 189 (September 2024): 105513, <https://doi.org/10.1016/j.ijmedinf.2024.105513>.

²⁹ Van Kessel et al.

³⁰ Grace Donghee Shin et al., 'Improving Patient Engagement by Fostering the Sharing of Activity Tracker Data with Providers: A Qualitative Study', *Health Information & Libraries Journal* 37,

no. 3 (September 2020): 204–15, <https://doi.org/10.1111/hir.12300>.

³¹ Shin et al.

³² Zahra Niazkhani et al., 'Barriers to Patient, Provider, and Caregiver Adoption and Use of Electronic Personal Health Records in Chronic Care: A Systematic Review', *BMC Medical Informatics and Decision Making* 20, no. 1 (December 2020): 153, <https://doi.org/10.1186/s12911-020-01159-1>.

³³ Anton Isaacs et al., 'Hospital Medication Errors: A Cross-Sectional Study', *International Journal for Quality in Health Care* 33, no. 1 (20 February 2021): mzaa136, <https://doi.org/10.1093/intqhc/mzaa136>.

diminishes trust.³⁴ Therefore, by integrating data across multiple systems, interoperability supports continuity of care and reinforces confidence in digital health solutions. This approach prevents discrepancies when switching between care settings and ensures consistency in patient care. Moreover, flexible consent frameworks, as recommended by the Office of the National Coordinator for Health Information Technology, give patients granular control over which data to share and with whom, fostering a stronger sense of privacy and security and increasing technology acceptance. Trust in health data sharing grows when systems provide transparency, involve caregivers, and offer customisable sharing options that respect patient autonomy. This is further supported by the increased engagement and safety outcomes seen when interoperable systems are used effectively in patient care. In short, digital tools have a ton of potential to get people more involved in their health. But it is not a one-size-fits-all solution. Success depends on trust, ease of use, and how much control people feel they have over their own information.

Policy recommendations

Policy recommendations at a glance

1. Incorporate international standards into the EHDS implementing acts, Article 6(1).
2. Promote a unified labelling mechanism to demonstrate compliance with the EEHRxF to increase user adoption.
3. Monitor the adoption of the EEHRxF in the Member States via an EU-wide dashboard.
4. Conduct stakeholder engagement and awareness campaigns.
5. Address the human resource gap (skills) in health IT.
6. Create a centralised support hub for EEHRxF implementation and maintenance.

1. Incorporate international standards into the EHDS implementing acts, Article 6(1).

The EU should support the implementing acts under Article 6(1) of the EHDS regulation by incorporate already-in-use international standards—specifically HL7 FHIR and SNOMED CT—within the EEHRxF. These standards should be embedded into the common specifications in Article 23 to ensure a consistent, interoperable framework for health data exchange across Member States.

Firstly, the implementing acts should require the adoption of HL7 FHIR as the foundational framework for structuring and exchanging health information. FHIR provides a modular and flexible approach to health data exchange, and its implementation should focus on FHIR profiles specific to the priority data categories outlined in Article 5 of the EHDS, such as patient summaries, e-prescriptions, and laboratory results. The European Commission should mandate the development and use of EU-wide implementation guides for these data categories, ensuring that Member States' health information systems can uniformly exchange these data sets based on international standards. For example, a patient summary profile based on FHIR could specify the exact structure and coding system required for fields like patient demographics, medical conditions, and medications, ensuring that the data is interoperable across all Member States.

In conjunction with FHIR, the implementing acts should mandate the use of SNOMED CT as the standard for clinical terminology within the EEHRxF. SNOMED CT ensures that health data, such as diagnoses, procedures, and clinical observations, are uniformly coded, reducing the variability and ambiguity of clinical information exchanged between systems. The European Commission should specify that SNOMED CT must be used in conjunction with FHIR to populate fields in FHIR resources, such as diagnostic codes in Condition or Observation resources. When linking the structure provided by FHIR with the detailed clinical terminology of

³⁴ Anam Parand et al., 'Carers' Medication Administration Errors in the Domiciliary Setting: A Systematic Review', ed. Imti Choonara, *PLOS ONE*

11, no. 12 (1 December 2016): e0167204, <https://doi.org/10.1371/journal.pone.0167204>.

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SNOMED CT, the EU can ensure that health data exchanged between Member States is both syntactically and semantically interoperable.

Additionally, the implementing acts should outline requirements for conformance testing and certification of national health information systems against these standards. Systems must be validated for compliance with the FHIR profiles and SNOMED CT mappings, and certification should be required before integration into cross-border services like MyHealth@EU. Embedding HL7 FHIR and SNOMED CT into the common specifications through implementing acts will help the EU lay the foundation for a fully interoperable and secure cross-border health data exchange system. This process might enable seamless healthcare delivery and improve patient outcomes across Member States

2. Promote a unified labelling mechanism to demonstrate compliance with the EEHRxF to increase user adoption.

To promote the certification of digital health systems, apps, and related products across EU Member States, it is recommended to establish a unified industry label certifying compliance with the EEHRxF. This label would help healthcare providers and developers ensure their systems meet the technical and legal standards for secure and interoperable health data exchange, as outlined in the EEHRxF. The primary benefit would be increased adoption and trust in digital health technologies, as both providers and patients could be confident in the security, quality, and interoperability of certified systems. Additionally, this certification would facilitate the movement of digital health services across borders, reduce the administrative burden on health organisations, and improve patient care by enabling smoother cross-border health data sharing. Eventually, the label would drive the wider uptake of digital health tools, fostering innovation and strengthening the EHDS.

3. Monitor the adoption of the EEHRxF in the Member States via an EU-wide dashboard.

The European Commission could enhance the adoption of the EEHRxF by developing an EU-wide dashboard to monitor the implementation progress across Member States. This dashboard would provide a clear overview of the levels of compliance, offering valuable benchmarking data to identify gaps and guide policy actions specific to each country. By tracking the status of EEHRxF adoption, the dashboard could support efforts to harmonise health data exchange within the EU, ensuring that all Member States are aligned in their progress. Digital Health Authorities in each Member State would play a critical role in reporting on implementation, allowing the European Commission to set targeted policies and timelines, such as a 48-month compliance period. This tool could eventually reduce fragmentation, lower integration costs, and facilitate smoother cross-border health data exchanges, benefiting both public and private stakeholders.

4. Conduct stakeholder engagement and awareness campaigns.

Extensive EU-wide awareness campaigns targeting politicians, decision-makers, healthcare professionals, patients, and IT experts are essential to building support and driving adoption. These campaigns should use case studies from successful initiatives such as the eHealth Digital Service Infrastructure and the European Reference Networks to demonstrate improved patient outcomes and operational efficiencies. Such targeted engagement will create political momentum and increase buy-in from all relevant stakeholders.

5. Address the skills gap in health informatics.

The EU must address the shortage of digital health specialists by establishing targeted training and certification programs, particularly focused on the technical and semantic standards required for implementing EEHRxF and SNOMED CT. Collaboration with academic institutions and professional associations can create fast-track certification pathways, which will help build the necessary workforce to

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support large-scale digital health implementations and sustain these systems over the long term.

6. Create a centralised support hub for EEHRxF implementation and maintenance.

Establish a centralised EU support hub to provide technical assistance, knowledge-sharing resources, and guidance for Member

States in implementing and maintaining cross-border digital health systems. This hub could offer best practices, templates, and real-time support for any issues related to interoperability, ensuring that once systems are live, they remain functional, up-to-date, and aligned with EU standards. Such continuous support would build long-term sustainability and trust in digital health solutions.