# xShare

Expanding the European EHRxF to share and effectively use health data within the EHDS

## EHRxF in a nutshell

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## Working paper description

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| **Number and name of working paper:** | EHRxF in a nutshel |
| **Publishable summary:** | The European Electronic Health Record Exchange Format (European EHRxF), introduced by the European Commission in 2019, aims to ensure secure, interoperable, cross-border access to electronic health data across the EU. To enhance public understanding, "EHRxF in a Nutshell" was developed, illustrating its benefits through eight storylines based on perspectives of citizens, workforce, health system, and market. For citizens, the European EHRxF, allows amongst other benefits, that their health data be easily exchanged between organizations intra and cross-border and even supports dispensation of medication abroad. For the workforce, it helps doctors overcome language barriers with foreign patients by providing accurate health records. For health systems, it ensures efficient data sharing during international crises, enhancing healthcare delivery. For the market, it provides EHR vendors with an interoperability framework in order to provide solutions more easily across markets. These scenarios demonstrate European EHRxF's practical applications and value, promoting widespread adoption and implementation by raising public awareness. |
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### Statement of originality

This working paper contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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## Executive Summary

The European Electronic Health Record Exchange Format (European EHRxF) was introduced in a recommendation of the European Commission on February 6, 2019.[1] The objective of the European EHRxF is to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data across the European Union (EU). Although its pre-dates the European Health Data Space (EHDS) Regulation by several years, its implementation is central to the execution of the EHDS in the Member States (MS) and across the EU. The EHDS regulation, proposed in 2022, and provisionally adopted by the April 24th, 2024, sets out a comprehensive framework for the secure and interoperable exchange of health data across the EU, for both primary and secondary use.[2] Beyond the cross-border use cases, the European EHRxF offer also a unique opportunity to develop a dynamic and transparent eco-system which paves the way to the development of a wide number of new business cases and to create new connexions between primary use in care provision and for secondary use in research and policy making[3] While the Recommendation of 2019 is not binding upon MS, the EHDS Regulation mandates that priority categories of data contained in EHRs conform to the European EHRxF.

To promote general understanding on the European EHRxF to a broader audience and its relation to the implementation of the EHDS Regulation, "EHRxF in a Nutshell" has been developed for use in communication with a range of different audiences, including citizens, healthcare professionals, healthcare system managers, and policy makers. It aims to provide more insight into the European EHRxF and its added value for organisations and individuals throughout the healthcare ecosystem landscape.

By means of eight storylines, this document provides insight on the role of the European EHRxF as it applies to the six priority health data categories addressed in the EHDS Regulation (patient summaries, electronic prescription, electronic dispensation, medical images and image reports, laboratory results[4] and discharge reports), from the perspectives of the citizens, the workforce, the health system, and the market. It also tries to do some foreseeing its future potential for healthcare in the envisioning sector of each storyline.



[1] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243
[2] Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.html
[3] Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.html
[4] Note: The initial Proposal for an EHDS Regulation referred to laboratory results. This is the reason why the majority of material and guidelines produced to date focus on that category.

**Citizen perspective:**

1. Emma, a Belgian citizen travelling abroad, needs additional medication for her chronic condition. By means of an ePrescription issue in conformance with the European EHRxF, a local pharmacy is able to provide her with the correct medication and update her record with an eDispensation in the European EHRxF which her treating doctor can access back home.
2. Paul, diagnosed with inflammatory bowel disease, uses the French government's "Mon Espace Santé" app to share his health data with clinical trial platforms. Through the xShare Yellow Button[5], his data is matched with an ongoing clinical trial, STUDYIBD001, and he able to provide consent to participate in a trial and potentially access new therapies not yet available on the market.

**Workforce perspective:**

3. Dr Weber in Germany, a health care professional, receives Miguel from Spain. Miguel is showing serious symptoms, but the language barrier between them does not allow Miguel to give his history to Dr. Weber. Using the Miguel's Patient Summary, which conforms to the European EHRxF, Dr. Weber can obtain the key medical information and can select appropriate treatment options for Miguel.
4. Dr Leena, a primary healthcare provider in Estonia, uses the European EHRxF to access updated health records for Marek, an Estonian worker in Finland, allowing her to provide continuous care and issue prescriptions through telemedicine despite travel constraints. This cross-border health data interoperability enhances care coordination, ensuring seamless and effective treatment for patients like Marek, regardless of their location.

**Health system perspective:**

5. Due to an international health crisis, the need arises to share medical data across borders. However, the lack of uniformity hinders the exchange and correct interpretation of such data. The European EHRxF paves the way for interoperable, more efficient, cost-effective, and patient-centric healthcare delivery, enabling continuity of care across the European Union.

[5] The xShare Yellow Button is further discussed and presented in other xShare documents and is one of the core aims of the project, as a tool to make data available to individuals exploring the potential of the EEHRxF.

6. Personal Health Records (PHRs) that have adopted the European EHRxF-specifications enable public health authorities to efficiently gather pseudonymous data from citizens with their consent, significantly enhancing research capabilities on antibiotic usage. This system empowers citizens to control their personal health data and incentivizes them to share their health data securely and perhaps pseudoanonymised for specific purposes, improving public health or population health outcomes.

**Market perspective:**

7. An innovative EHR-vendor wants to take the next step in patient centred care but is limited by the lack of interoperability. The European EHRxF provides the EHR-vendor with the opportunity to gain an early adopter competitive advantage and enhance the operation of their solution.
8. A health start-up focused on use of AI tooling is hindered by the wide range of formats and standards used by EHR and imaging systems. By implementing the European EHRxF in their tooling, these barriers are removed by providing standardized data structures and coding systems.

For the purposes of this report on the European Electronic Health Record Exchange Format (or "The Format") is understood as a set of requirements and technical specifications, as well as endorsed support materials, targeted at ensuring the interoperability of electronic health record systems following the Regulation on the European Health Data Space and other applicable law. It is designed to enable the exchange of personal electronic health data between two or more EHR systems, other digital health applications or medical devices and support interoperable capture and reuse in a meaningful way.

In addition to providing a definition and details of the format, this **European EHRxF in a nutshell** publication provides contextual indicative examples of how the format can be put into practice, thoroughly illustrating its potential concrete impacts. The perspectives from the four dimensions of the digital health compass are developed: the citizens, the workforce, the health system, and the market.

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## Glossary

In alignment with the European Health Data Space regulation where applicable the Table 1 presents the definition of the main concepts and abbreviations. For further details, also refer to the xShare Glossary[6].

*Table 1: Glossary*

| Term | Abbreviation | Definition |
|---|---|---|
| **Antimicrobial Resistance** | AMR | Antimicrobial Resistance occurs when bacteria, viruses, fungi and parasites no longer respond to antimicrobial medicines. As a result of drug resistance, antibiotics and other antimicrobial medicines become ineffective and infections become difficult or impossible to treat, increasing the risk of disease spread, severe illness, disability and death.[7] |
| **Artificial Intelligence** | AI | Artificial intelligence refers to systems designed by humans that, given a complex goal, act in the physical or digital world by perceiving their environment, interpreting the collected structured or unstructured data, reasoning on the knowledge derived from this data and deciding the best action(s) to take (according to pre-defined parameters) to achieve the given goal. |
| **Continuous Glucose Monitoring** | CGM | A medical device system used to track glucose levels in real-time throughout the day and night. It involves a sensor placed under the skin that measures interstitial glucose levels and transmits the data to a monitor or smartphone, providing frequent updates and alerts for high or low blood sugar levels. |
| **eDispensation** | eD | The act of electronically retrieving a prescription and giving the medicine to the patient.<br>Note: the data about the performed dispensation (including the details of the dispensed medicinal product) are to be added to the patient's electronic health record. |
| **Electronic Health Record** | EHR | A comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form and providing for ready availability of these data for medical treatment and other closely related purposes. |
| **European Centre for Disease Prevention and Control[8]** | ECDC | The ECDC was established in 2005. It is an EU agency aimed at strengthening Europe's defences against infectious diseases.<br><br>Its mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. |

[6] Available at: https://glossary.ramit.be/public/home.cfm?pid=11.
[7] Available at: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance.
[8] Available at: https://www.ecdc.europa.eu/en/about-ecdc/what-we-do

| | | |
|---|---|---|
| **European Electronic Health Record exchange Format** | European EHRxF | The European Electronic Health Record Exchange Format (or "The Format") is a set of requirements and technical specifications, as well as endorsed support materials, targeted at ensuring the interoperability of electronic health record systems following the Regulation on the European Health Data Space and other applicable law. It is designed to enable the exchange of personal electronic health data between two or more EHR systems, other digital health applications or medical devices and support interoperable capture and reuse in a meaningful way. |
| **ePrescription** | eP | A medicinal prescription issued and transmitted electronically.<br>Note: the data about the prescription (including the details of the prescribed medicinal product) are to be added to the patient's electronic health record. |
| **General Practitioner** | GP | A physician who provides primary care. |
| **Inflammatory Bowel Disease** | IBD | Inflammatory bowel disease (IBD) is a group of idiopathic chronic inflammatory intestinal conditions. The two main disease categories are Crohn's disease (CD) and ulcerative colitis (UC), which have both overlapping and distinct clinical and pathological features.[9] |
| **International Patient Summary** | IPS | The core data set for a patient summary document that supports continuity of care for a person and coordination of healthcare. It is specifically aimed at the use case scenario for 'unplanned, cross border care'. |
| **Interoperability** | - | The "ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support" (EHDS Regulation, Art 2.2.f) |
| **Machine Learning** | ML | A subset of artificial intelligence (AI) that enables computers to learn from and make decisions based on data. It involves the use of algorithms and statistical models to identify patterns, make predictions, and improve performance over time without being explicitly programmed for each task. |
| **Master value sets catalogue** | MVC | The collection of terms used within certain parts of the eHDSI (eHealth digital service infrastructure: term used for the generic and core services for the cross-border services of ePrescription and Patient Summary during "connecting Europe facility" financing) pivot documents (either parts describing the patient demographics or the clinical problems for example) based on standardised code systems. |

[9] Available at: https://www.worldgastroenterology.org/guidelines/inflammatory-bowel-disease-ibd

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|---|---|---|
| **Medical Device Regulation**[10] | MDR | Is a regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation. |
| **MyHealth@EU** | - | The infrastructure which allows the electronic cross-border health services to be made available in European countries to protect and assist travellers. These services enable citizens in Europe to benefit from healthcare services in their country of travel in the same way that they benefit in their country of residence. |
| **National Contact Point for eHealth** | NCPeH | The organisational and technical gateway in a member state for the provision of cross-border eHealth information services. |
| **Personal Health Record** | PHR | A personal health record (PHR) is an electronic summary of health information that a patient can update with their own health data, maintains and controls by himself, as opposed to their healthcare provider(s)-updated data. The information contained in a PHR can be self-reported, generated by their providers or a combination of the two. Future products are expected to incorporate structured data, genomics data, wearable generated data and personalized medicine approaches.[11] |
| **Primary use of electronic health data** | - | The "processing of electronic health data for the provision of healthcare to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social, administrative or reimbursement services".[12] |
| **Priority categories of personal electronic health data** | - | Six data categories defined as priority for primary health data exchange: a) patient summaries, b) electronic prescriptions, c) electronic dispensations, d) medical imaging studies and related imaging reports, e) medical test results, including laboratory and other diagnostic results and related reports, f) discharge reports. |



[10] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

[11] Available at: https://www.techtarget.com/searchhealthit/definition/personal-health-record-PHR (modified for better comprehension)

[12] EHDS Regulation, Art. 2.2.d. Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.html

# 1 Introduction

The digital transformation of health and care is seen as a vital development in sustaining the high levels of access to healthcare across Europe, whilst improving patient engagement in managing their health and care, as well as improving patient safety.[13] Much has been achieved already, but the secure flow of trusted data across the healthcare continuum remains an issue across different applications, clinics, institutions, organisations, both within and between EU Member States. Health information of individuals is often scattered across different computer systems such as electronic health record (EHR) systems, other digital health solutions and increasingly medical devices and wellness APPs. Ideally, whenever needed, some or most of such personal health data should be able to seamlessly flow through the health system to support health promotion, prevention and restoration, being accessible, with due controls and safeguards to point of care needs, be easily accessible and usable by the healthcare professionals for the provision of healthcare to the individual, to him/herself and/or to be used for secondary usage such as diagnosis assistance, public health, health policy, etc. In the digital health compass, depicted in Figure 1, the citizen and the workforce in healthcare are the crucial perspectives for transforming health and care.[14] Trusted and secure access to personal electronic health data are the central theme of the compass (Figure 1).

The health system, which includes health care provider organisations and territorial authorities, is responsible for adopting EHR systems to support the provision of healthcare. These EHR systems are used at the point of care and are the supports on which healthcare professionals and patients view the relevant portions of the electronic health record. This is where the trusted data needs to flow, both from the EHR systems that hold portions of a patient's record, and to the EHR system that is being used at the point of care. That is what is meant by "interoperability" – succinctly, the **ability** to exchange data **between** (*inter*) two or more systems and to **use** (*operate on*) that data by the receiving system. Ultimately, this aims at supporting optimal integrated care throughout the health system.

[13] See the Communication of the European Commission COM(2018) 233 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. Available at: https://digital-strategy.ec.europa.eu/en/library/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering

[14] A "citizen" in the context of the Digital Health Compass refers to a person engaging with digital health tools and services in a general, non-medical capacity. An "individual" under the EHDS regulation denotes any person whose health data is being processed, while a "patient" specifically refers to someone receiving medical care or treatment.

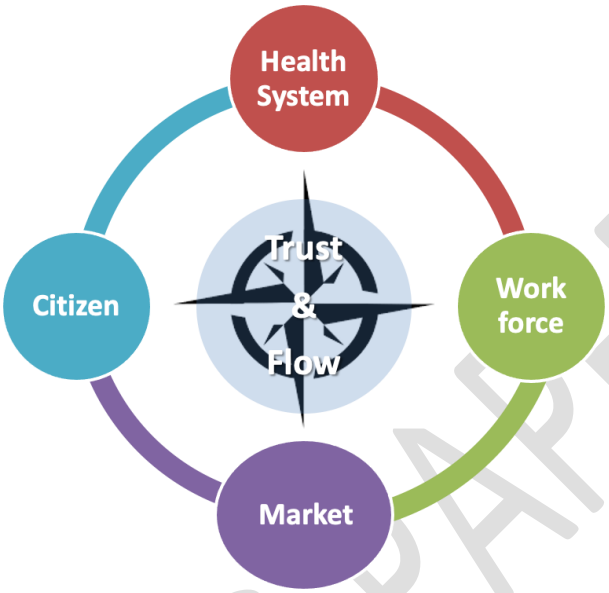


*Figure 1: The Digital Health Compass of Perspectives.*[15]

EHR systems are highly complex software systems that are offered by vendors on the digital health market. Procurement and implementation of EHR systems takes place across the health system, serving citizens and the workforce with systems to manage their health and care. Currently, some EHR systems are not able to provide the trusted flow of or access to data between EHR systems as described in the digital health compass.

In addition to providing a definition and details of the format, this **European EHRxF in a nutshell** publication provides contextual examples of how the format can be put into practice, thoroughly illustrating its potential concrete impacts. The perspectives from the four dimensions of the digital health compass are developed: the citizens, the workforce, the health system, and the market. Its last section includes content useful for those interested in exploring early implementations of the format.

[15] Adapted from the eHealth Stakeholder Group report "The case for eStandards", February 2019. Available at: https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=58930

# 2 The European EHRxF and the European Health Data Space

The European EHRxF is introduced to facilitate value creation for the digital health actors represented in the digital health compass. This chapter describes the European EHRxF to promote safe access to and the flow of trusted personal electronic health data across different EHR systems that each hold relevant parts of the overall electronic health record of an individual citizen.

## 2.1 The European EHRxF

The European EHRxF represents a key ingredient to achieve the goals set out for the transformation of digital health and care within the European Union (EU)[16]. These are carried by three pillars as suggested by the European Commission: Secure data access and sharing (Pillar 1); Connecting and sharing health data for research, faster diagnosis and improved health (Pillar 2)[17]; Strengthening citizen empowerment and individual care through digital services (Pillar 3). The Format also helps make data accessible for secondary use for research and policy development and other usages, as it promotes its quality recording, transfer and semantic harmonization. In other words, we can say that the format, helps individuals and health systems, in different ways, and in particular facilitates: i) authorised access to patient data across the care continuum to improve diagnosis, care delivery and continuity of care, ii) access to anonymised health data to be used in research and policy development, and, iii) access to personal health data with option to amend so as to empower patients to be more engaged in their own health management.

The European EHRxF is designed to facilitate the secure and seamless exchange of health data across member states, enhancing the quality and continuity of care for EU citizens. The Recommendation set up a framework establishing a set of principles governing cross-border access to and exchange of electronic health records; a set of common technical specifications for the cross-border exchange of data in specific baseline health information domains[18]; a process to facilitate ongoing development of a standardised European EHRxF. The latter underscores a key feature of the European EHRxF, in that it will remain an ever-evolving endeavour.

[16] https://health.ec.europa.eu/ehealth-digital-health-and-care/overview_en#communication

[17] For more see point 4. “Better data to promote research, disease prevention and personalised health and care” in https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:233:FIN

[18] Note that what was referred to as “health information domains” in the 2019 European EHRxF Recommendation is now referred to as “priority categories of personal electronic health data” in the EHDS Regulation texts, including in reference to the scope of the European EHRxF.

To date, the European EHRxF can be defined as a set of requirements and technical specifications, as well as endorsed support materials, targeted at ensuring the interoperability of EHR systems following the EHDS Regulation and other applicable law. It is designed to enable the exchange of personal electronic health data between two or more EHR systems or other digital health applications or medical devices in a meaningful way.

The format currently focuses on six different priority categories of personal electronic health data for primary use as defined in the EHDS Regulation provisionally approved as of April 24th, 2024:

(a) Patient summaries;
(b) Electronic prescriptions;
(c) Electronic dispensations;
(d) Medical imaging studies and related imaging reports;
(e) Medical test results, including laboratory and other diagnostic results and related reports;
(f) Discharge reports.

These categories find their source in the priorities established by the eHealth Network, on the basis of current work on the MyHealth@EU services and clinical relevance for cross-border healthcare.

With the EHDS, the applicability of the European EHRxF extends to cover also national or regional health data exchange that involves EHR systems.

## 2.2 The European Health Data Space Regulation

The objective of the EHDS Regulation is to provide a legal basis for the secure exchange of personal electronic health data for care provision and access to health data for secondary use in research. It aims to support the rights of natural persons, as specified in the General Data Protection Regulation [19] (GDPR) in relation to access to and portability of personal electronic health data processed as part of the provision of healthcare services. For primary use of electronic health data, the EHDS is a means to broaden the scope of MyHealth@EU content specifications from cross-border to just any electronic health data exchange with patients choose to include and which arise outside the traditional healthcare environment.

[19] Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj

The European EHRxF is explicitly mentioned in the EHDS Regulation within the scope of the six priority categories of personal electronic health data to which the EHDS applies. The EHDS Regulation does not just mentions the Format it creates legal conditions to elevate it from recommendation status to a standard that has is to be mandated in Member States by way of Implementing Acts. The issuance and acceptance of health data in conformity with the European EHRxF will be mandatory. This will, for example, make the right of individuals to access their data (as per GDPR) more tangible and implementable, allowing patients to download their data and provide it to the healthcare provider of their choice. Once the regulation enters into force, the European EHRxF will have three important mandatory implementations:

1. Member States will be required to set up Digital Health Authorities to ensure the implementation of the European EHRxF.
2. Vendors of EHR systems are required certify conformity of the systems they place on the market with the "European interoperability component" and the European logging component" of their systems. The "European interoperability component" is designed to ensure that priority data categories of electronic health data may be accessed, exchanged or added conforms to the European EHRxF.

3. When vendors of medical devices, in vitro diagnostic medical devices, high risk AI systems (as defined in the AI Act), or wellness apps, claim interoperability of their systems or services with EHR systems, they must also certify inclusion of the "European interoperability component" so that data can be shared or exchanged in the European EHRxF. It is important to understand that the European EHRxF consists of a set of requirements, technical specifications, and supporting materials. These requirements outline the necessary standards for the dissemination, adoption, and use of the format by various stakeholders in the healthcare ecosystem. The technical specifications will be accompanied by detailed guidelines for implementing the format, using common standards and aiming for compatibility with global standards.

For each of the six priority categories of personal electronic health data, the European EHRxF will be the basis of different but compatible specifications, tailored to the different purposes that the European EHRxF serves within the EHDS regulation:

- Technical specifications for national contact points for digital health to connect to the services of MyHealth@EU;
- Common specifications for the conformity of EHR systems and possibly other digital health applications.

The European Commission shall, by means of implementing acts, lay down the specifications that various stakeholders must comply with in order to meet the interoperability requirements that the EHDS Regulation demands. Developing these specifications under the framework of the evolving European EHRxF is already taking place and will be incorporated into implementing legislation within the two years after entry into force of the EHDS Regulation. This means that new implementing acts, legislation on European EHRxF is expected to be adopted by mid-2026 and apply to patient summaries, electronic prescriptions and electric dispensation by mid-2028 and to images, laboratory reports and discharge reports by mid-2030.

# 3 The Storylines and perspectives of the main digital health actors

In this chapter, the Table 2 presents a short overview about the eight storylines provided to contextualise the European EHRxF into use cases narrated from the four perspectives of the Digital Health Compass: the Citizen, the Workforce, the Health System, and the Market.

*Table 2: Matrix Overview of the Working paper's Eight Storylines*

| Storyline | Perspective | Level | Business Use Case |
|---|---|---|---|
| 1<br>Emma | Citizen | Cross-border | ePrescription / eDispensation |
| 2<br>Paul | | National | Clinical Trial Screening |
| 3<br>Dr. Weber | Workforce | Cross-border | International Patient Summary (IPS) and Discharge Report |
| 4<br>Dr. Leena | | National | Telemedicine |
| 5<br>EU diabetes network | Health System | Cross-border | Lab Reports |
| 6<br>Anti-microbial resistance | | National | Public and Population Health |
| 7<br>HealthDataSys | Market | National | Care Planning |
| 8<br>HealtInnoTech | | Cross-border | Imaging |

The eight storylines in this document present use cases highlighting the format's potential and added value for each actor. They cover the different priority categories of personal electronic health data addressed by the European EHRxF, by depicting real-world scenarios. Obviously, the following scenarios remain non-exhaustive.

## 3.1 The perspective of the Citizen

In this section, the perspective of the citizen is outlined, with two storylines: the story of Emma, who runs out of her daily medication while on a European trip, and the story of Paul, a patient grappling with serious illness who seeks innovative treatments.

**Insight 1**: **Citizens, individuals, patients**

A "citizen" in the context of the Digital Health Compass refers to a person engaging with digital health tools and services in a general, non-medical capacity. In contrast, an "individual" denotes any person whose health data is being processed, while a "patient" specifically refers to someone receiving medical care or treatment.

### 3.1.1 A Journey to Seamless Healthcare Across Europe with ePrescription

**Summary:** Emma, a busy professional from Brussels managing a chronic condition, faces a daunting challenge when an unexpected business trip to Rome leaves her without her daily medication. Concerned about navigating a foreign pharmacy, Emma encounters relief through the European EHRxF initiative. This innovative system allows her pharmacist in Rome to access her ePrescription from Belgian health records, ensuring accurate translation and secure sharing of her health data between systems. Upon her return to Brussels, Emma's General Practitioner seamlessly integrates the record of the medication dispensed in Rome into her care plan, illustrating the efficacy of cross-border ePrescriptions in maintaining continuity of care.

**Scene 1: A Busy Professional in Brussels:**

Emma has been managing a chronic condition for years with the help of her local healthcare provider in Brussels. She relies on regular consultations and a carefully managed prescription plan. One day, Emma is required to travel to Rome for an urgent business meeting. Her trip is extended unexpectedly, and she runs out of her daily medication. She is a patient dealing with a rare condition and medication regularity is critical for her.

**Insight 2**: **Prescriptions Abroad**

The EHDS regulation states 6 Priority categories of personal electronic health data for primary use, including ePrescription and eDispensation in the European EHRxF. These services are also provided when you're in a foreign country, since obtaining appropriate prescription medication can be challenging. The European EHRxF aims to bridge this gap by ensuring that your electronic prescriptions are accessible across borders, making it easier for pharmacies abroad to dispense the correct medication.

**Scene 2: The Challenge of a Foreign Pharmacy:** Concerned about her health, Emma visits a local pharmacy in Rome. She is anxious about the language barrier and the possibility of not being able to refill her prescription.

**Scene 3: The European EHRxF Comes to the Rescue:** Facilitated by the European EHRxF and under Emma's control, the pharmacist in Rome can access her ePrescription from her Belgian health records. The format ensures that her health data is accurately translated (due to the use of common specifications in both systems) and securely shared between the Belgian and Italian healthcare systems. The pharmacist in Rome is able to recognise her medication need based on the drugs key attributes i.e., substance, strength, pharmaceutical form (e.g. pill, solution, spray, ...), route of administration, allowing the pharmacist to dispense an appropriate medicine if the exact medicine is not available. Emma is relieved when the pharmacist provides her with the correct medication. She is impressed by the seamless care facilitated by the cross-border ePrescription and supported by the European EHRxF, despite being away from home.

**Insight 3**: **Citizens in control of their health data.** Patients' health data is personal and sensitive. Under the EHDS regulation, and relying on the European EHRxF, patient control is key. Patients should have control over who accesses their health records, ensuring privacy and supporting trust. New technologies such as the 'EU Wallet' (for multi-governmental electronic identification) can support patients in managing their personal data, including electronic health data, strengthening the autonomy of patients' health data management.

**Scene 4: Back to Base:** Emma returns to Brussels and during her medical appointment, her GP can access the information about which medication was dispensed to her abroad. She asks if she should continue with this medication until it runs out or stop and switch back to her original medication directly. For this, her GP accesses her recent eDispensation information, thanks to which he is able to compare the two medications carefully and provide a recommendation accordingly. In this case, Emma can continue taking her medication bought abroad until it runs out. After that, she will go back to her usual medication.

**Looking forward:** Looking ahead, the European EHRxF aims to continue to evolve, with innovations like the xShare Yellow Button on the horizon. This feature will enable patients like Emma to securely share structured health data in the European EHRxF, with trusted third parties, such as caregivers or specialists, facilitating collaboration, improving continuity of care, and allowing integrated care. With

advancements like this, the European EHRxF is set to further enhance the healthcare experience for citizens across Europe, promoting interoperability, privacy, and patient-centred care.

### 3.1.2 Usefulness of the Format for Pre-screening in Clinical Trials

**Summary:** Paul, a diagnosed patient in France, has been dealing with an inflammatory bowel disease (IBD) for three years, enduring treatment side effects. Seeking innovative alternatives, he engages with the "Mon Espace Santé" application, endorsed by the French government, consenting to personal data sharing for potential clinical trial eligibility. Concurrently, a researcher gastroenterologist at a nearby hospital is the principal investigator in a phase 3 clinical trial, STUDYIBD001 He is aiming to streamline patient screening. Through the Mon Espace Santé application, Paul's shares his health data, converted to European EHRxF International Patient Summary (IPS) format, with a service that check if it aligns with trial selection criteria. Informed of his potential eligibility, Paul selects a local hospital and authorizes data sharing. Subsequently, the investigation team validates his pre-screening and schedules an on-site visit for further assessment, potentially facilitating his inclusion in the trial. This narrative underscores the significance of patient access to clinical trials and the pivotal role of digital health platforms in expediting the process.

**Scene 1: A Diagnosed Patient in France:** Paul has been diagnosed 3 years ago with IBD. He is followed by a gastroenterologist in a private practice that does not conduct clinical research. However, Paul suffers side effects from his treatment, and he wants to know if there is an alternative innovative therapy, for example new treatments which are not yet on the French market, which can remove his current side effects. He logged into the “Mon Espace Santé” application provided by the French government. In the app Paul allows and consents for data sharing for the potential eligibility to a clinical trial, i.e., pre-screening to a clinical trial.

**Insight 4**: **Innovative Treatments**

The access to clinical trials for a patient is the opportunity to access a new drug in the safest possible conditions, prior to it being marketed. This opportunity is very important in serious diseases for which there is no existing or poor treatment. Due to the EHDS regulation, the patient can selective share their personal electronic health data with a point of care, including services checking eligibility for clinical trials studies.

**Scene 2: Patient Recruitment for an Ongoing Clinical Trial:** Close to Paul's home, there is a hospital conducting clinical trials, where the Principal Investigator (PI) is a busy gastroenterologist and IBD specialist seeking a more efficient way to prospectively screen patients. In this hospital, there is an ongoing study which is a phase 3 clinical trial for IBD patients called STUDYIBD001. Paul's health condition meets-screening for a clinical trial is usually conducted by health care professional on clinical investigation sites (e.g., hospital, private clinics and health centres). The patient is invited to participate to clinical trial once the investigative team has identified his/her potential eligibility, often during a routine visit. Clinical research versus standard practice is often a challenge because of the time constraint and the workload of health centres in France.

**Insight 5: The "Mon Espace Santé" application**

This application is a personal, secure digital space proposed by the French national Health Insurance and the French Ministry of Health, designed to be an interactive digital health record for all insured persons, enabling everyone to play an active role in monitoring and storing their health data.

**Scene 3: The European EHRxF Comes to the Rescue:** Clinical data from Paul's "Mon Espace Santé" in the CDA/FHIR standard format are sent and converted into the European EHRxF IPS. Paul's data contained in the IPS automatically fulfil a pre-screening tool. There is a match between Paul's health data and the eligibility criteria of the clinical trial STUDYIBD001.

**Insight 6**: **Patient detection, pre-screening tool**

The EHDS regulation highlights the importance of making electronic health data accessible, high-quality, and suitable for creating scientific and innovative value. Trial pre-screening services (e.g., CT-SCOUT) allow the patient to check if they are potentially eligible for clinical trials ongoing at the investigation site, by submission of IPS and a short medical questionnaire, with an automatic filter to propose the right clinical trials according to the patient profile.

**Scene 4: The patient is informed of their potential eligibility to a clinical trial:** The results of the compatibility with the clinical trial STUDYIBD001 and participating investigation sites are accessible to Paul in "Mon Espace Santé" app. He chooses the hospital closed to his home and gives his consent for data sharing to the investigation team.

**Scene 5: Pre-screening Validation and Patient Inclusion Management:** Following Paul's consent to share his data, the on-site investigation team has received the answer to his pre-screening

questionnaire and his essential personal information for communication. Paul has been contacted for an on-site visit planned in the following month. This visit aims to assess his full eligibility and to potentially proceed with his inclusion in the clinical trial STUDYIBD001.

**Looking forward:** Looking forward, the automation of the pre-screening process will empower patients like Paul to share their health data for clinical trials. Moreover, such a process may be beneficial for their health in being included in the best clinical trial according to their health condition. In the case of no clinical trial match, health data may be reused for future clinical trials. Besides, improving the pre-selection process will help in overcoming a major challenge in clinical trials, which is the timely recruitment of patients.

## 3.2 The perspective of the Workforce

In this section, the perspective of the workforce is outlined, with two storylines: the story of Dr Weber, a cardiologist in Berlin navigating the complexities of a foreign health record to provide urgent care to a Spanish patient, and the story of Dr Leena, a primary healthcare provider in Estonia who leverages telemedicine and cross-border health data access to manage the chronic condition of an Estonian worker residing in Finland amidst a pandemic lockdown. The "workforce" in the context of the Digital Health Compass refers to healthcare professionals and support staff who engage with digital health tools and services to deliver patient care. This encompasses medical practitioners, nurses, administrative personnel, and allied health professionals who utilise digital health solutions to enhance care coordination, improve patient outcomes, and ensure continuity of care across borders.

### 3.2.1 Bridging Care Across Borders with MyHealth@EU present and future services

**Summary:** Dr Weber, a cardiologist in Berlin, receives an urgent call from a hotel regarding a Spanish patient, Miguel, in need of medical attention during an academic conference visit. Despite initial language barriers, Dr Weber utilizes her mobile phone to access her clinic's EHR system that has been upgrade with a European EHRxFormat compliant version and can access Miguel's local patient summary, facilitating a seamless exchange of critical health information. However, recognizing the insufficiency of the summary, Dr Weber uses the MyHealth@EU platform to access further vital information including Miguel's Spanish hospital discharge report in a structured, translated format. This process underscores the power of the European EHRxF framework in facilitating cross-border healthcare collaboration. With comprehensive health records at her disposal, Dr Weber makes informed treatment decisions swiftly, highlighting the unparalleled efficiency enabled by the European EHRxF. Through collaborative care facilitated by this framework, Dr Weber ensures continuity of Miguel's care, irrespective of geographic boundaries. Ultimately, the European EHRxF emerges as a transformative tool, empowering healthcare providers like Dr Weber to deliver high-quality, patient-cantered care across the European Union.

**Scene 1: A Doctor in Berlin:** Dr Weber, a seasoned cardiologist in Berlin, is working in her private practice and receives an urgent call from a hotel about a patient from Spain who is visiting Germany for an academic conference and who is not feeling well. The patient, Miguel, has alerted the hotel staff and wants to see a cardiologist. The cardiologist asks to be put on the phone with Miguel and tries to discuss his medical history. The language barrier hinders their communication, so Dr Weber invites

Miguel to share his patient summary from his smartphone with the clinic, through the clinic's portal, using the xShare Yellow Button.

**Scene 2: The Challenge of International EHR Data:** The patient, Miguel, 67 years old, has a complex medical history with critical information locked in his Spanish health records. Using xShare's Yellow Button, he shares his patient summary with Dr Weber. The original document is in Spanish but is delivered in an accurate translation to German (thanks to the use of common specifications in both systems), enabling Dr Weber to fully understand and make use of the information it contains. Still, the doctor asks Miguel to come to her office, as she realises that the information in the patient summary is insufficient. In preparation for the visit, she accesses Miguel's latest hospital discharge report from the Spanish hospital. Again, she wonders how she will get access and how she will make sense of this report since she doesn't understand Spanish.

**Insight 7**: **EHR Translation and Transcoding**

Various health or EHR systems are not using the same language, nor are they required to employ identical coding systems. What is essential for proper translation of personal health data is that both National Contact Points for eHealth (NCPeH) ensure appropriate transcoding to/from the master value sets catalogue (MVC) approved coding terms in Miguel's patient summary, in alignment with MyHealth@EU standards which are based on the European EHRxF framework.

**Scene 3: The Power of the European EHRxF:** Dr Weber uses the MyHealth@EU service to request the hospital discharge summary from the Spanish hospital. Miguel receives a notification on his phone to provide consent for Dr Weber to access his records in the Spanish Hospital. Seamlessly, Dr Weber gets access to the Spanish hospital discharge report, with a trusted translation into German. The format ensures that the critical information is accurately translated and structured, even though the Spanish hospital does not use the same coding system as its German counterpart, allowing Dr Weber to review Miguel's medical history, previous treatments, and ongoing care plans.

**Scene 4: Informed Decision-Making:** With complete and understandable health records at her disposal, Dr Weber makes informed decisions about Miguel's care. The speed of care is incomparable to when the European EHRxF was not available, when Dr Weber would have had to find a workaround

to access and then translate Miguel's EHR data. Dr. Weber promptly adjusts the treatment plan to account for Miguel's existing medications and conditions.

**Scene 5: Collaborative Care:** Dr Weber's treatment decisions can be communicated back to Miguel's healthcare provider in Spain using the European EHRxF, ensuring continuity of care for when he travels back, incorporating the medical episode that happened in Berlin. Dr Weber appreciates the simplicity of sharing the patient's IPS and hospital discharge report without any revision needed, everything being automatically taken care of by MyHealth@EU processes, exploiting the European EHRxF.

**Insight 8**: **MyHealth@EU**

MyHealth@EU plays a pivotal role in facilitating seamless healthcare delivery for professionals like Dr Weber. Through the EHDS, MyHealth@EU provides a unified platform for accessing and exchanging critical patient information across borders. For Dr Weber, this means easy access to patient summaries and hospital discharge reports from other EU countries, even when faced with language barriers. MyHealth@EU offers robust translation services, ensuring that medical documents are comprehensible, regardless of the language in which they were originally generated.

**Looking forward:** As the EHDS continues to evolve, the integration of technologies and broader standardisation across member states promises even greater efficiencies. Future developments may include real-time updates, predictive analytics, and enhanced patient autonomy through secure, accessible health data portals. These advancements will not only improve clinical outcomes but also bolster patient confidence in receiving quality care regardless of location. By fostering a more interconnected and responsive healthcare ecosystem, the European EHRxF framework and MyHealth@EU pave the way for a future where seamless, collaborative, integrated and patient-centred care is the norm across the EU.

### 3.2.2 Connecting Care Across Borders with Telemedicine and ePrescription / eDispensation

**Summary:** The storyline unfolds with Dr Leena, a primary healthcare provider in Estonia, facing the challenge of managing the chronic condition of Marek, an Estonian worker residing in a remote rural area of Estonia, amidst a pandemic lockdown. With travel restrictions hindering Marek's access to regular medical consultations, Dr Leena telemedicine challenge seeking ways to continue providing essential care and prescription refills to Marek remotely. The European EHRxF emerges as a solution,

enabling Dr Leena to securely access Marek's updated health records and support him through telemedicine appointments conducted using a secure telemedicine platform. This integration of local records in Finland with her own records in Estonia facilitates enhanced coordination and care, ensuring uninterrupted treatment for Marek regardless of his remote location. Dr Leena leverages the system to issue new prescriptions seamlessly, which can be immediately accessed and utilized by Marek in local pharmacies. The confidence instilled by the European EHRxF in managing cross-border healthcare reinforces Dr Leena's commitment to delivering high-quality care, ultimately improving the healthcare experience for patients like Marek.

**Scene 1: Managing Remote Care:** Dr Leena, a primary healthcare provider in Estonia, regularly provides consultations to Marek, who resides in a remote rural area of Estonia, to manage his chronic condition. During a pandemic lockdown, Dr Leena faces challenges as Marek cannot travel for his regular medical checks and consultations.

**Scene 2: The Telemedicine Challenge:** With travel restrictions in place, Dr Leena is concerned about how to continue providing necessary medical advice and prescription refills to Marek. Marek has been receiving medical care locally, adding new data to his health records. Dr Leena needs a way to access Marek's updated medical information from his local healthcare providers to deliver accurate and timely care through telemedicine.

**Insight 9**: **Enhanced Coordination and Care.**
The EHDS underscores the importance of ensuring interoperable access to electronic health data for telemedicine services and promoting cross-border healthcare without hindrances related to differing healthcare policies. The European EHRxF plays a critical role in telemedicine by enabling healthcare providers like Dr. Leena to access accurate and comprehensive patient records including data from remote or isolated sources. This integration supports continuous and effective care regardless of the patient's remote situation.

**Scene 3: The European EHRxF to the Rescue:** Thanks to the European EHRxF, Dr Leena can securely and efficiently access Marek's health data regardless of its provenience. During a telemedicine appointment, Dr Leena retrieves Marek's health records stored by local healthcare providers. The European EHRxF ensures that the data is interoperable, correctly transcribed, and easily accessible, allowing Dr Leena to provide informed medical advice and issue new prescriptions as needed.

**Scene 4: Coordinated Care and Prescription Management:** Dr Leena issues a new prescription based on the telemedicine consultation. Thanks to the European EHRxF, the prescription is immediately accessible to Marek and can be used at his local pharmacy. This ensures Marek's treatment continues without interruption. Additionally, the system records the dispensation, allowing Dr Leena to review the information in subsequent appointments, ensuring a comprehensive view of Marek's treatment history.

**Scene 5: Enhanced Confidence in Remote Healthcare:** Dr Leena's positive experience with the European EHRxF reinforces her confidence in providing remote healthcare. The ability to access necessary patient data and manage treatments seamlessly reassures her of the system's effectiveness, ultimately improving the overall healthcare experience for patients like Marek.

**Looking forward:** Telemedicine, supported by the European EHRxF, offers significant potential to reduce healthcare access inequalities, especially for residents of remote areas and increasingly in large cities with busy streets. By enabling secure, interoperable exchange of EHRs, healthcare providers can deliver high-quality care regardless of remote situations. This advancement not only ensures continuity of care during crises like pandemics but also fosters greater equity in healthcare access, improving outcomes for underserved populations. Telemedicine embracing the European EHRxF within the EHDS framework promises to enhance patient care quality, streamline medical processes, and ultimately create a more resilient and inclusive healthcare system.

## 3.3 The perspective of the Health System

In this section, the perspective of the health system is outlined, with two chapters: the story of a Brussels eHealth Network meeting envisioning a seamlessly connected EU healthcare system and the story of Belgium's innovative approach to studying antibiotic usage. The "health system" in the context of the Digital Health Compass refers to the overarching structures and institutions that govern, regulate, and deliver healthcare services. This includes efforts to harmonise health data exchange, enhance system resilience, and improve public health outcomes through digital integration. The narrative highlights the challenges posed by disparate regulations and the transformative potential of the European EHRxF framework in enabling interoperability, facilitating data-driven public health research, and promoting a more efficient, accessible, and patient-centric healthcare system across the European Union.

### 3.3.1 United in Health: System Resilience using the European EHRxF as a tool

**Summary:** During the last eHealth Network meeting Member States revisit actions taken and make possible due to what is now the Format. The COVID-19 pandemic highlighted these challenges and the potential of data sharing, prompting the EU to prioritise interoperability, exemplified by the successful EU Digital COVID Certificate initiative. The same participants envision a seamlessly connected EU healthcare system where patient data flows securely across borders, enhancing accessibility, efficiency, and affordability. Despite sophisticated national healthcare systems, differences in language, regulation, and protocols hinder digital health integration. To address these issues, the European Commission introduces the European EHRxF, harmonising health data exchange and facilitating the integration of digital health tools, and data. Suddenly an *Escherichia coli* (*E. coli*) outbreak in several EU Member States in which a widely imported food product is expected has been identified. There is a need for widespread laboratory data to be made available to the European Centre for Disease Prevention and Control (ECDC), and other EU-level actors. Laboratory reports needed to be quickly accessed and evaluated across at least five Member States to identify the potential source, and progression of this public health threat. Member States and the EC now convey under the new EHDS Board and create a dedicated committer to deal with data support for this crisis.

**Scene 1: The Vision of Connected Care:** In a meeting in Brussels, healthcare policymakers envision a connected system where patient health data flows securely and efficiently both within and across national borders. The Healthcare leaders see the digital health as a key contributor to keeping healthcare services accessible, effective and affordable for the population of each country.

**Scene 2: The Challenge of Diverse Systems:** Each EU country has developed its own sophisticated healthcare system, with all EU countries ranking in the top-half worldwide according to the health index score. [20] However, differences in language, regulation, care guidelines and protocols pose challenges to the effective deployment of digital health. Patient administration systems and electronic health record systems have been developed within the local peculiarities of each healthcare system; standards for sharing health data – if available at a national scale – are often incompatible across borders. During the COVID pandemic this problem became critical, as some patients had to be transferred to facilities across borders, but hardly any clinical electronic health data could be shared to support cross-border care. The Member States and the EC gained experienced in the time of COVID-19 and the eHealth Network, now the EHDS board has to help face this *E. coli* outbreak.

**Insight 10**: **System Resilience**

The broader landscape of digital health deployment continues to face challenges, including disparities in digital infrastructure, administrative processes, and regulatory frameworks across European countries and even within regions. The COVID-19 pandemic showed the potential of health data sharing: it prompted EU governments to prioritise interoperability, as exemplified by the establishment of the 'EU Digital COVID Certificate'. This initiative encompassed test results, vaccination records, and recovery certificates, with member states collaborating to develop a user-friendly, interoperable tool facilitated by QR code scanning. The success of this joint effort highlights the potential and possibility of achieving better health outcomes by developing interoperability within the EU health system when interest and collaboration among stakeholders are high.

**Scene 3: The Need for More Interoperability:** Despite its potential to greatly enhance patient care, streamline workflows, and lead to much better health outcomes, the European EHRxF had not yet been tested for an *E. coli* outbreak or similar public health threat following the EHDS Regulation approval. The varying general regulatory landscapes and regional and local public health practices present as obstacles to the collection of data of public health relevance. However, with the European EHRxF, particularly, in the data priority category of Medical Exams (including laboratory), it is quicky

[20] It can be accessed at: https://www.statista.com/statistics/1290168/health-index-of-countries-worldwide-by-health-index-score/

possible to mandate the collection of structured, interoperable, laboratory results from all laboratories in the EU.

**Insight 11**: **Intervention Duplication**

Without a common system for sharing patient data, healthcare providers may inadvertently order redundant tests, leading to unnecessary use of resources, delays in treatment, and potential risks to patient safety. Tackling this issue will reduce the burden for clinicians, empowering them to provide better levels of care. Developing EHR interoperability, data sharing, and efficient access supports the minimisation of unnecessary repetition in healthcare processes.

**Scene 4: The Introduction of the European EHRxF:** Amidst these complexities, the urgency for a common European solution becomes apparent. By having harmonised regulations at EU level, streamlining data exchange processes, and promoting collaboration among EU Member States, a unified approach can pave the way for more efficient, cost-effective, and patient-centric healthcare delivery across the Union. In this case a much faster response to the challenge of collecting relevant laboratory data on a new emergent strain of *E. coli* helps identify the source in one of the MS and trace the movements of the contaminated foods as well which populations where at risk and eventually infected.

**Looking forward:** Looking ahead, the EU's commitment to harmonising health data exchange through the European EHRxF represents a significant step towards a unified healthcare system. This initiative promises not only to enhance the accessibility and quality of care but also to foster innovation and collaboration across borders. By addressing interoperability challenges, the EU paves the way for a resilient and patient-centric healthcare landscape, ensuring better health outcomes for all its citizens.

**Insight 12**: **Automatic Conversion of Units and Standardised Terminology**

One real challenge in health data interoperability is ensuring that measurements are comparable. This can be addressed by adopting a classification system for measurement methods. The EHDS regulation recognises the importance of standardizing data elements, including units of measurement and medical terminology, to ensure interoperability and facilitate data exchange in healthcare. It's crucial to implement automatic conversion of units and standardised terminology across different healthcare systems to accommodate the various devices used for measurement, making health data exchange more accurate and reliable.

In the specific case of the Continuous Glucose Monitor (CGM) devices and report integration, the various EHR systems at all diabetes centres will one day be able to accept data following the European EHRxF and any CGM device that produces reports to be integrated in the EHR system have to provide such reports in the standardised format. This will substantially limit the necessary investments to adopt these devices in the day-to-day management of a type 1 diabetes condition. Ramifications with Medical Device Regulation (MDR) and different barriers will need to be transposed, but as we move to more non-communicable disease public health threats to system resilience and sustainability, having common tools for health data management is a powerful leverage.

### 3.3.2 New approach in the combat of Antimicrobial Resistance with European EHRxF-integrating Personal Health Records

**Summary:** In response to the growing challenge of bacterial resistance, a new approach has been proposed to study antibiotic usage in Belgium. The Belgium Ministry of Health seeks to gather detailed data on patient adherence to antibiotic prescriptions over the past two years, including the handling of leftover medication and the role of laboratory reports in prescribing antibiotics. Previous efforts have been hindered by the lack of a standardized data format and lack of smart consent mechanisms. However, with the advent of the European EHRxF framework, laboratory reports, prescriptions and dispensations are now available in a computable format. Personal Health Records (PHRs) systems may include different types of data, those already European EHRxF compliant originating from healthcare providers but also data from wearables supporting well-being with digital health apps referred to in the article 31 of the EHDS regulation and data provided by the citizen himself. The PHR may thus become an essential instrument to communicate with a variety of stakeholders and create bridges between primary and secondary uses of data. This enables automatic matching with relevant consultations, streamlining data collection for studies. Citizens may dynamically interact with researchers, ensuring efficient, accurate, and secure data gathering while maintaining privacy through anonymisation. This approach promises to enhance public health research by offering valuable insights into antibiotic use and fostering deeper patient-researcher interactions, ultimately informing better public health recommendations and practices.

**Scene 1: information on Antibiotics Handling:** A unit of the Belgium Ministry of health would like to conduct a study to gather detailed information about how antibiotics and specifically second- and third-line ones have been handled by patients during the last two years. In particular, they are interested in knowing if patients have been taking their antibiotics as prescribed and - if pertinent - what they have done with the remaining pills. Furthermore, it is deemed interesting to include whether the prescription of such antibiotics has been preceded by a lab report. Unfortunately, due to a lack of a common format, such research has not been fruitful up until now. Furthermore, it has proven difficult to determine the relevant population and actually obtain the data without a smart and trusted consent service.

**Scene 2: Citizen Empowerment:** Thanks to the European EHRxF, laboratory reports and prescription/dispensation are available in a computable format. By providing preliminary consent in a centralized and smart manner, citizens indicate their availability to share their personal health data (upload in the systems by the patient) to participate in studies which could support public health developments. As data is stored in citizens' PHRs including their consent, the approach of inclusion in clinical studies involves two steps:

1. **Matching Inclusion Criteria:** The European EHRxF is used to match possible inclusion criteria based on the patient's health records, such as recent antibiotic dispensation and lab reports. If the patient meets these criteria, they are considered for the survey.

**Insight 13**: **Personal Health Records (PHRs)**

The EHDS regulation supports the individuals to be able to update their own health data in EHR systems or in a separate system. According to Article 8b of the provisionally accepted EHDS Resolution, "natural persons […] shall have the right to insert information in their own EHR through electronic health data access services or applications linked to these services". PHRs are under the exclusive control of citizens and include data originating from different sources: data created by healthcare professionals, data provided by wearables or specific well-being or care support APPs, or data directly inserted by citizens. The last two data categories must be distinguished from health data inserted by healthcare professionals. A PHR is usually made available to citizens through dedicated Apps, developed either by public or private organisations.

2. **Patient Participation:** The patient is then asked to answer a specific survey, which includes data not usually available in the European EHRxF, such as the handling of leftover pills and quantity of antibiotics stored at home. After a process of notification, the patient receives a request to confirm their engagement in the survey and by doing so release their data for this specific purpose. After confirmation, the patient receives a new notification with a guarantee to keep those data pseudonymous[21], leaving the possibility to collect supplementary information if needed.

**Insight 14**: **Difference between PHRs and EHRs**

With PHRs, the individual is responsible for uploading their own health information. With EHRs, the health professionals are the ones responsible for including the relevant electronic health data. However, information shared by healthcare professionals may be directly accessible and activable through PHRs without any specific action by the citizen if the PHR is connected to a regional or national trusted network.

**Scene 3: Benefitting Public Health**: Thanks to the European EHRxF, the information made available, accessible and xShare activable to the citizen via a PHR compliant with the European EHRxF, the Unit analysis will have access to a very large cohort of patients matching objective and verified criteria. Analysis will always take place with the patient consent and will be based on the responses provided and if pertinent, on the available standardized PHR

**Insight 15**: **Clinical value of PHRs and EHRs**

As all data always needs to be able to be traced track of the original data producer's identity and specific role, the fact that it is stored in a EHR or PHR does not make any difference. It is thus the role associated with the data which can determine its clinical value. The clinical value of other types of data such as those provided by wearables is controlled thanks to the MDR which will be completed by the implementing acts referred to in article 31 of the EHDS regulation.

[21] "'Pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person". Source: GDPR Regulation (EU) 2016/679, Article 4, (5). Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj

information. This two-step approach allows public health analysts to leverage existing data for initial screening and then gather more detailed information directly from patients, ensuring comprehensive insights. The process will also allow to consider deeper interactions between patients and the research unit. The results of the survey will provide critical insights for improving recommendations and messages linked to the use of Antibiotics.

**Looking forward:** Looking ahead, the integration of European EHRxF-compliant Personal Health Records (PHRs) will be one example of transformative benefits for public and population health. By empowering individuals to manage and share their health information securely across borders, PHRs will enable proactive engagement in public health initiatives. When allowing to share their anonymised EHR data for secondary use, patients contribute to the re-use of real-world data for policy making and research. This provides valuable insights into disease trends, risk factors, and treatment outcomes. This collaborative approach will not only enhance individual health management but will also inform evidence-based public health interventions. As patients become partners in health surveillance and research, the EU will advance towards a more patient-centred healthcare model, where collective data will drive tailored public health strategies for the benefit of all.

**Insight 16**: **Relationship between PHRs and EHRs**

A PHR may interact with an EHR either directly, including the possibility for EHR systems to receive PHR data in a specific section and to integrate the health history of the patient, or indirectly, if errors or inconsistencies are noticed by the patient, with the possibility to request the correction of the data (provisional EHDS Art 8c). Data collected by the patients themselves through for example wearables or specific questionnaires can also be made available to a specific or shared EHR. In the best-case scenario, a PHR will connect to the network where information provided by EHR systems is shared, thus creating a direct, immediate link between the PHR and the shared EHR. In other scenarios, PHR data can be stored in a different system which can be or not be linked to the EHR or create ad hoc connections with specific EHR systems though dedicated protocols. As per EHDS regulation data exchanges between and PHR and an EHR would naturally follow the European EHRxFormat for the data categories for which Implementing Acts have been approved.

## 3.4 The perspective of the Market

In this section, the perspective of the market is outlined, with two chapters: the story of HealthDataSys Solutions in Stockholm, a fictitious leading vendor of electronic health record (EHR) systems, and the story of HealthInnoTech, a fictitious Warsaw-based start-up developing an AI-driven diagnostic support tool. The "market" in the context of the Digital Health Compass refers to the ecosystem of providers, vendors, and stakeholders involved in the creation, deployment, and use of digital health services and systems. This market is shaped by the need for interoperability and standardisation to ensure that diverse health services and products can seamlessly operate across different health information systems, thereby meeting the varying needs of digital health actors. By adopting the European EHRxF, these companies enhance data sharing efficiency, improve care continuity, and foster innovation, ultimately driving advancements in healthcare technology and sustainable growth in the EU healthcare market.

### 3.4.1 Futureproofing the Industry: EHR System Vendors and the European EHRxF

**Summary:** In Stockholm, HealthDataSys Solutions, a leading vendor of electronic health record (EHR) systems, is pioneering a revolution in healthcare by developing advanced software to create patient-centred care networks. However, they face the challenge of ensuring their systems communicate seamlessly with other EHR systems across Sweden, a task complicated by varying standards among hospitals. The introduction of the European EHRxF, a new format standardising personal health data exchange across the EU, offers a solution. This format will be mandatory for all EHR systems and will also apply to apps and telemonitoring services which are designed to integrate with EHR systems, enhancing convenience for patients. Recognising the strategic advantage, HealthDataSys Solutions integrates the European EHRxF with their systems, engaging clients and the Swedish digital health authority to promote unified standards. This integration enhances data sharing efficiency, both within Sweden and across European borders, improving care continuity and fostering clinical research and innovation. The early adoption of the European EHRxF positions HealthDataSys Solutions as a market leader, futureproofing their systems and increasing customer satisfaction through improved interoperability and data exchange, ultimately driving advancements in healthcare technology and sustainable growth in the EU healthcare market.

**Scene 1: A Tech Revolution in Healthcare:** In the bustling city of Stockholm, a leading EHR system vendor, HealthDataSys Solutions, is gearing up to revolutionise the healthcare industry. They've been

developing cutting-edge software that helps realise patient centred care networks, involving professionals from several different care provider organisations.

**Scene 2: The Challenge of Interoperability:** Despite their advanced technology, HealthDataSys Solutions faces a challenge: their systems need to communicate with other EHR systems across Sweden, as not all care provider organisations are using the HealthDataSys Solutions' system. With almost all hospitals having different standards, ensuring seamless data exchange is a complex task. Yet, that is exactly what is needed: the patients and their network of healthcare professionals working together as a dedicated team, each from their own expertise and trusted work environment, keeping track of all relevant progress, setbacks and (un)planned care activities.

**Scene 3: Embracing the European EHRxF:** The team at HealthDataSys Solutions learns about the European EHRxF – a new format designed to standardise the exchange of personal health data across the EU. They realise this could be the solution they have been looking for. It will become a mandatory requirement for all EHR systems in Europe, so they can use it for their strategic advantage. It will open the diversity of EHR systems across the patient centred care networks they envision. In addition, the European EHRxF will also apply to apps and telemonitoring services, to make health management more convenient for patients. The team also realises that using the European EHRxF expands their solution, which at first is aimed at the national level in Sweden, to new possibilities across the EU.

**Insight 17**: **Beyond EHR systems.**

Medical devices, including in-vitro diagnostic medical devices, produce very important data to be included in an EHR system. These devices are referred on the EHDS regulation and shall present common specifications, interoperability requirements and certification of the components to be compliant with the European EHRxF. Similarly, wellness apps can submit data to the EHR system. This enables vendors to develop functionalities which healthcare professionals can use to monitor their population – e.g., to identify who needs attention urgently, who should be called in for a consultation, who should be rewarded for doing really well. Rather than investing time and money in developing interfaces for several different devices and apps (getting and structuring the data), the focus can be set on providing real value added (using data) to their clients, i.e., professionals and provider organisations.

**Scene 4: A Strategic Pivot:** HealthDataSys Solutions decides to integrate the European EHRxF with their systems. They work diligently to align their software with the format's specifications, ensuring that their products can easily exchange data with other systems. They engage patients and professionals from their existing clients to develop the most appropriate ways of integrating the data exchange in the routine workflows their system supports and is famous for. With the help of the Swedish digital health authority, they advocate for the adoption of the format among the other vendors active in patient-centred care networks, pushing for unified standards.

**Scene 5: Breakthrough and Expansion:** With the European EHRxF integrated, HealthDataSys Solutions' EHR systems become more versatile and valuable. Their clients across Sweden can now share patient data effortlessly, with decreased friction points, leading to increased efficiency of care and sustainable economies by modernisation. They are also able to seamlessly exchange information across European borders, enabling continuity of care and thriving clinical research and innovation.

**Looking forward:** Looking ahead, the integration of the European EHRxF by EHR system and Digital health vendors like HealthDataSys Solutions will play a pivotal role in driving innovation and collaboration in healthcare technology. As industry players embrace the European EHRxF, we anticipate significant advancements in interoperability and data integration, with EHR systems seamlessly communicating not only within national borders but also across European territories. This proactive stance by EHR system vendors will demonstrate the commitment to enhancing patient care, streamlining workflows, and leading the charge towards a more connected, patient-centric, and technologically advanced healthcare ecosystem across the EU. By leveraging the opportunities presented by the European EHRxF, industry players will help shape standards, drive advancements, and pave the way for sustained growth and market leadership in the evolving EU healthcare landscape.

### 3.4.2 Pioneering Health Tech: A Leap Forward for Innovation Start-Ups with the European EHRxF

**Summary:** In Warsaw's bustling tech hub, a start-up named HealthInnoTech is developing an AI-driven diagnostic support tool capable of analysing medical imaging and patient history to identify high-risk factors and diagnose a range of diseases. However, the team faces challenges due to the varied formats and standards of health records across the EU, leading to costly manual labour and errors. To overcome this, HealthInnoTech integrates the European EHRxF, standardising data structures and enabling access to diverse and extensive health data. This integration enhances the tool's accuracy, allowing it to diagnose rare conditions and facilitate data sharing and interpretation. Consequently,

HealthInnoTech's success encourages other start-ups to adopt the European EHRxF, strengthening the EU's digital health system and positioning it as a global leader in healthcare technology. The European EHRxF proves to be a catalyst for innovation, supporting the practical and seamless integration of Artificial Intelligence (AI) systems with EHR systems, thereby transforming the healthcare industry.

**Scene 1: The Tech Start-up Challenge:** In a bustling tech hub in Warsaw, a start-up named HealthInnoTech is developing an AI-driven diagnostic support tool. Based on a machine learning algorithm, the tool is able to highlight areas of interest in medical imaging and relate them to patients' medical history to detect high risk factors that might be relevant for determining the correct diagnosis. By doing so, a broad range of diseases could be diagnosed, and corresponding reports could be produced. The tool must be able to access patient-specific data throughout the European Union to provide the diagnosis of the patient as well as the access to large sets of international data to feed the algorithm with information for its learning process.

**Scene 2: The Innovation Barrier:** The team at HealthInnoTech struggles with the different formats and standards of health records used by the various EHR and imaging systems, and the format supported by the tool itself. External service providers are too costly for HealthInnoTech to outsource the localisation and translation task. Because of these issues, significant manual labour is involved in correcting and validating data also leading the introduction of new errors by faulty manual processing. As a result, the tool only proves useful in a select number of cases due to misinterpretation and errors. This severely limits the potential of the application and subsequently, the possible benefit for patients.

**Scene 3: Embracing the European EHRxF** HealthInnoTech decides to integrate the European EHRxF as one of the building blocks of their AI tool, leveraging its standardised data structures and coding systems. Published data from all over Europe can be used, increasing the diversity of information that can be accessed. By doing so, this enables the AI tool to also detect rare diseases. The established format and interoperability assets make it possible for the AI tool to process vast amounts of interoperable health data efficiently and improve the deep learning algorithm.

**Scene 4: Breakthrough in AI Diagnostics:** With the use of the European EHRxF, HealthInnoTech's AI tool has been better trained to review medical imaging and produce the corresponding reports. By doing so, the AI tool has achieved unprecedented accuracy in diagnosing even rare conditions, drawing from a wide pool of EU health data that otherwise could not be utilized in such a centralised manner. Thanks to the adoption of the European EHRxF, the results of the AI tool can also be easily shared and interpreted by others, paving the way for other organisations using the AI tool and integrating it into their current landscape without altering data models or needing complicated additional integration procedures.

**Scene 5: Industry Transformation:** HealthInnoTech's success story spreads rapidly, inspiring other start-ups to adopt the European EHRxF, strengthening the digital health system across the EU. The European EHRxF lowers the threshold for innovation by providing ready to use stepping stones and the shared interpretation of data in a semantic and technical sense.

**Looking forward** the adoption of the European EHRxF by innovative start-ups like HealthInnoTech promises to revolutionize health technology. Such start-ups will leverage the European EHRxF to enhance medication management apps and AI-driven diagnostic tools, improving medication adherence and diagnosing rare diseases with unprecedented accuracy. By seamlessly integrating with EHR systems across Europe (and potentially beyond), these tools will streamline patient care delivery, driving innovation and positioning the EU as a global leader in healthcare technology.

**Insight 18**: **Seamless Integration.**

The EHDS regulation recognizes the AI systems' potential impact on electronic health data exchange and interoperability. By emphasizing compliance with interoperability standards and consultation processes, the regulation aims to promote the secure and efficient integration of AI systems in the healthcare data landscape. Dedicated AI systems for diagnostic support will be much more practical and successful when they are integrated with EHR systems, supporting the various steps in the delivery of patient care. Without such integration, the chances of successful adoption of a dedicated AI system at scale will be slim. The European EHRxF enables the seamless invocation of dedicated AI systems by an EHR system (providing the AI system with the personal electronic health data of the individual patient) and the direct integration of the results of applying AI to individual patient data in the EHR system. The AI Act and the EHDS regulation and MDR will of course need to be interpreted and used in articulation.

# 4 European EHRxF for implementers

## 4.1 Historical perspective

During the 13th eHealth Network (eHN) meeting held on 15 May 2018, the eHealth interoperability and policy actions were discussed, and the needed improvements were identified, considering the state of the EU health system. A constructive discussion was initiated, with members of the eHN noting that an 'European EHRxF' should be developed. The first mention of the format in a document was on the eHAction's working paper 'D8.2 – Policy document about technology report'[22]. The European EHRxF[23] was introduced more widely in a recommendation of the European Commission on February 6, 2019.[24] This document also included the core principles behind the format: *(a) Citizen-centric by design; (b) Comprehensiveness and machine-readability; (c) Data protection and confidentiality; (d) Consent or other lawful basis; (e) Auditability; (f) Security; (g) Identification and authentication and (h) Continuity of service.* The objective of the European EHRxF is to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union.

The recommendation for the European EHRxF (2019) presented the content specifications and guidelines that were available at the time for five priority health data categories. These are largely implemented in MyHealth@EU and are shown in Table 3, while mentioning that new technologies and standards will be evaluated moving forward. Indeed, the eHN at its November 2022 meeting decided to adopt HL7 FHIR for future priority data categories.



[22] Available at: http://ehaction.eu/wp-content/uploads/2021/06/eHAction-D8.2-Policy-document-about-technology-report-_-for-adoption_19th-eHN.pdf
[23] For ease also referred to as "the format"
[24] Recommendation of the European Commission (EU) 2019/243 on a European Electronic Health Record exchange format

*Table 3: Health Information Domains or priority data categories in 2019*

| Health information domains | Clinical information for cross-border exchange (2019) |
|---|---|
| **Patient Summary** | Structured according to the provisions in the 'GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 — Patient Summary for unscheduled care' adopted by the eHealth Network on 21 November 2016 |
| **Electronic Prescription/ Electronic Dispensation** | Structured according to the provisions in the 'GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Release 2 — ePrescriptions and eDispensations' adopted by the eHealth Network on 21 November 2016 |
| **Medical test results, including laboratory and other diagnostic results and related reports** | Enable cross-border exchange according to the clinical information structure currently used by the sender electronic health record system, while common clinical information structures for cross-border exchange are developed and agreed. |
| **Medical imaging studies and related imaging reports** | |
| **Discharge reports** | |

## 4.2 Current Status of the European EHRxF

The European EHRxF Format has developed significantly since 2018. The current status as of June 28, 2024, appears on Table 4. The eHN network has developed new guidelines for lab results, imaging reports, and discharge report. The maturity of specifications for the different categories in not the same. However, xShare is working closely with the XpanDH[25] (coordination and support action) to advance development and maturation of tools and specifications for European EHRxF, once the Xt-EHR[26] joint action supports the process of moving towards to the implementation actions. Looking at the table the IPS is quite advanced[27].

[25] Available at: https://xpandh-project.iscte-iul.pt/
[26] Available at: https://www.xt-ehr.eu/
[27] Available at: https://experience.arcgis.com/experience/77f459be23e545b48f46a79cfaf19423/page/1_5/

*Table 4: European EHRxF documentation evolution per health category*[28]

| Health information domains or priority health data categories | Content representation for cross-border exchange (at 2024) | Clinical Information available to European EHRxF (June 2024) | Trends for content representation input to the European EHRxF (June 2024) | Maturity |
|---|---|---|---|---|
| **Patient Summary** | Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 Level 3 and Level 1 (PDF A) (version 8) | Guidelines on Patient Summary - European Commission (europa.eu), release 3.3, Date 3 July 2023 | Move to HL7 Fast Healthcare Interoperability Resources (FHIR). A Proof of Concept of EU PS in HL7 FHIR has been developed by the XpanDH project | High |
| **Electronic Prescription/ Electronic Dispensation** | HL7 CDA Release 2 Level 3 and Level 1 (PDF A) (version 8) | ePrescription and eDispensation of Authorised Medicinal Products - Guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU, release 3, Date June 1, 2022 | Move to HL7 FHIR<br>An European Standard for Medicinal Prescription and Dispense is under developed as joint activity of HL7 Europe and IHE | High |
| **Medical test results, including laboratory and other diagnostic results and related reports** | HL7 FHIR R4 MeHealth@EU Laboratory Report IG | eHN Laboratory Result Guidelines - European Commission (europa.eu), Release 1.1, Date: July 2, 2023 | HL7 Europe Laboratory Report | Medium |
| **Medical imaging studies and related imaging reports** | HL7 CDA Release 2 Level 1 (PDF) | eHN Guidelines on Medical imaging studies and reports - European Commission (europa.eu), Release 1, Date November 11, 2023 | An European HL7 FHIR IG for Diagnostic Imaging Reports is under discussiondiscussion as collaboration between HL/ Europe and IHE Radiology.<br>For medical imaging Digital Imaging and Communications in Medicine (DICOM) | Early |
| **Discharge reports** | Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2 Level 1 (PDF) | eHN guidelines on Hospital Discharge Report - European Commission (europa.eu) | | Medium |

[28] Table extracted from the European EHRxF recommendation of 2019, modified to include the current documentations.

# 5 Conclusion

In conclusion, the European EHRxF represents a pivotal milestone in the European Union's effort to establish secure, interoperable access to electronic health data across borders aligned to the objectives of the EU Digital Decade policy program. Through a meticulous exploration of eight distinct storylines, each representing a unique perspective within the healthcare ecosystem in which the individual/citizen/patience is always present, this document has underscored the profound impact of the European EHRxF.

From the perspective of citizens, it has illuminated how the European EHRxF facilitates seamless access to vital healthcare services, exemplified by scenarios where travellers receive necessary medication abroad or foreign patients receive timely and accurate treatment despite language barriers. In the workforce perspective, the European EHRxF emerges as a crucial tool for healthcare professionals, enabling them to overcome interoperability challenges and deliver optimal care to patients regardless of geographical boundaries. Moreover, from the standpoint of the health system, the European EHRxF has been showcased as a catalyst for greater efficiency, cost-effectiveness, and patient-centric care delivery, particularly evident during international crises where the exchange of medical data is imperative. Furthermore, in the market perspective, the European EHRxF emerges as a catalyst for innovation and competitiveness, empowering EHR system vendors and start-ups alike to leverage standardized data exchange for the development of cutting-edge solutions such as medication management apps and AI-driven diagnostic tools.

By fostering awareness and understanding of the European EHRxF, this document aims to catalyse widescale adoption and implementation, contributing to driving the EU towards a future of connected, patient-centric healthcare delivery. As the EU progresses towards the establishment of a fully integrated European Health Data Space, the European EHRxF stands poised to play a pivotal role in shaping the future of healthcare in Europe and beyond, driving innovation, enhancing patient outcomes, and fostering collaboration across borders.

This document is a 'live document' in which xShare will update accordingly the European EHRxF developments. It will be also used as a primary source of capacity building materials elaboration through xShare *WP7 – Capacity Building, Cybersecurity & Privacy, and Innovative Procurement* targeting the main health actors, such as health professionals, individuals, developers, industry and others to support the clear understanding about the format among the European health ecosystem.