XpanDH

Expanding Digital Health through a pan-European EHRxF-based Ecosystem

D1.5 – (D1.4) Definition of the EEHRxF adoption domains Report

WP1 – Coordination

30.06.2024

Authors:

Name	*Organisation*	*Name*	*Organisation*
Henrique Martins; Anderson Carmo Simon Lewerenz	ISCTE	Maria Marques; Fábio Januário	UNINOVA
Giorgio Cangioli; Catherine Chronaki	HL7	Dipak Kalra; Zoi Kolitsi	I~HD
Anja Hirche	EMPIRICA		
Alberto Zanini	ARIA		
Sofia Franconi; Alexander Berler	IHE-EUR		

Additional contribution:

Name	*Organisation*	*Contribution*
Konstantinos Chalkias, Haralampos Karanikas	KETEKNY	Contribution with the adoption domains, and document revision.
Eva Sabajová	NCZI	Contribution with the adoption domains, and document revision.
Evangelos Markatos	FORTH	Elaboration/revision of Cybersecurity aspects.
Maria Salazar	CHUP	Contribution with the adoption domains, and document revision.

Funded by the European Union

XpanDH Grant Agreement No. 101095594

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Document control	
Status	Final
Version	2.0
Type of Document	R: Document, report;
Dissemination Level	PU – Public
Work Package	WP1 – Coordination
Full document name	1.5 – (D1.4) Definition of the EEHRxF adoption
Link to access document	N/A
Partner lead(s)	ISCTE
Other partners involved	HL-7, EMP, IHE- EUR, UNINOVA, ECHA, I~HD
What did this document aim to achieve?	It intends to identify and refine some adoption domains, for different European EHRxF data categories and contexts of purposeful use.
Present the main methodological approaches in bullet point format	
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	
Which project stakeholder group would benefit the most from the document and why?	

Healthcare Professional	X
International Adherence Network/Initiative	
Investors and Funding	
Patient Organization	
Patient/Caregiver	
Pharma (Marketing&Sales / Medical Dept. / R&D)	
Public Authority or Policymaker	X
Regulatory body	
Standardization Body/ Open-Source Network Researcher/Academic	X
Statutory Health Insurance Company	
Technology & Service Provider	X
Other	

List any relevant organizations or social media accounts for wider visibility	

Revision History			
Version	**Date**	**Author**	**Description**
0.1	7/03/2023	Anderson Carmo	First deliverable draft
0.2	12/03/2023	Henrique Martins	Second deliverable draft
0.3	21/03/2023	Anderson Carmo	Incorporation feedback from partners and meeting on 16th March
0.4	18/04/2023	Anderson Carmo; Henrique Martins	Incorporation of additional round of contributions (from 21/3 to 8/4)
0.5	20/04/2023	Anderson Carmo; Henrique Martins	Inclusion of the contributions from the online workshop (19.4.2023) to close the Deliverable and agree on data categories.
0.6	27/04/2023	Giorgio Cangioli; Alexander Berler; Orsolya Becze; Zoi Kolitsi; Konstantinos Chalkias; Eva Sabajová;	Revision of the document, comments and text update regarding the chapter 4.1.
0.7	02/05/2023	Dipak Kalra; Zoi Kolitsi; Alberto Zanini	Revision of the document, comments and text update.
0.8	11/05/2023	Anderson Carmo; Henrique Martins	Revision of the document and restructuration of the content. Considering the partners and inputs from meeting with EC.
0.9	12/05/2023	Henrique Martins; Anderson Carmo; Eva Sabajova; Evelyn Donohoe; Maria Bastos Salazar; Anne Moen; Radhika Poojara; Luca Garbarino; Pier Angelo Sottile; Zoi Kolitsi; Anja Hirche; Maria Marques; Fábio Januário; Veli Stroetmann; Gil Araujo; Orsolya Becze.	Consolidation of the document during a revision meeting.
1.0	15/05/2023	Anderson Carmo	Final version of the deliverable.
1.1.	27/05/2024	Anderson Carmo; Simon Lewerenz	Deliverable changed with additional feedback and discussions from ongoing meetings with EC. Additional efforts into exploration of the Patient Summary and Imaging Data categories, are being added, as well as capturing national level efforts (via workshop held 5 dec 2023)
1.2.	12/06/2024	Fábio Januário Catherine Chronaki Alberto Zanini Anderson Carmo Simon Lewerenz Henrique Martins	Alignment with the approved Regulation on the European Health and incorporation of inputs from the workshop held to discuss the deliverable
2.0	30/06/2024	Anderson Carmo Simon Lewerenz Henrique Martins	Inputs from comments received after circulation of the Deliverable for all the consortium

DISCLAIMERS

Disclaimer of originality

This deliverable 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.

Disclaimer of confidentiality

This document contains information material from author propriety (identifiable, whether written, recorded (audio/video), computerized, or in reference to XpanDH beneficiaries). This statement highlights the intellectual propriety of the XpanDH authors, and may not be used (copied/reproduced) without a clear authorisation of the members.

1 Table of Contents

2 Table of Figures

3 Table of Tables

List of abbreviations

Acronym	Description
DRG Institute	Greek Centre for Documentation and Costing of Hospital Services
DSM	Digital Single Market
EC	European Commission
EKOK	Greek DRG Coding Guidelines
EOPYY	National Organization for Provision of Health Services
ETIP	Greek Medical Procedure Classification
eD	eDispensation
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Record
eP	ePrescription
ERN	European Reference Networks
EU	European Union
GP	General Practitioner
ICD-10	International Classification of Diseases - 10th Revision
IG	Implementation Guide
ICT	Information and Communication Technology
IDMP	IDentification of Medicinal Products
ISO	International Organization for Standardization
NCPeH	National Contact Point for eHealth
ODIPY	Organization for Quality Assurance in Health
PS	Patient Summary
ReEIF	Refined eHealth European Interoperability Framework
RT	The DigitalHealthEurope Roundtables
SSI	Surgical Site Infections
WP	Work Package

Executive summary

The release of the recommendation on European Electronic Health Record Exchange Format (EEHRxF), brings the European Commission and the Member States to work together on the development of the resources to achieve the real broad access and exchange of health data at national and cross-border levels.

XpanDH is devoted to facilitating the extensive adoption of the EEHRxF through the maturation of a pan-European Ecosystem of Early Adopters of new/adapted digital solutions that implement EEHRxF specifications, within a specific socio-technical ethos of support for trusted, sustainable and resilient solutions. In that sense XpanDH has been working on the definition of the Adoption Data cathegories for further development of their work, definition of priority work in their experimentation, and provision of contextual definitions of related concepts.

An EEHRxF adoption domain is an instantiation of a use case, with a specific business/life case application, that has meaning form a health system or clinical perspective, with defined implementable requirements (simple, if only one EEHRxF priority category, as per EHDS Regulation (Art.5 and Annex 1), is used, or composite, if data from more than one priority category is required), that satisfies all the conditions for users to be ready to implement data exchange in conformity to EEHRxF guidelines and specifications.

The development of further work on the Adoption Domains shall include clarification of the concept, identification/prioritisation of the implementable adoption domains and their further description to be developed and experimented on Work Packages (WP) 3 and 4.

This document brings the first overview about the key project concepts, and their definitions, as well as some strategic project decisions that will support many activities in all WPs.

1 Introduction

This deliverable is predominantly focused on the detailed description of the adoption domains that will be the base for important work in XpanDH, as well as description of related concepts and concrete strategic implications.

1.1 Background

Since the release of the recommendation on European Electronic Health Record Exchange Format[1] (EEHRxF), on February 6th, 2019, the European Commission (EC) through the DG's Santé & CNECT, and Members States, through the eHealth Network (eHN), and the bodies under the eHealth Digital Service Infrastructure (eHDSI), are working on the development of the resources needed to achieve the real broad access and exchange of health data at national and cross-border levels based on the concept of a common Format, that encapsules a set of interoperability parameters.

Based on the principle that citizens have the right to access their personal data, including health data, as provided by Regulation (EU) 2016/679, and in response to the growing demand for cross-border health services, the EEHRxF introduces an interoperability-focused concept. This concept facilitates the seamless exchange of health data among different health institutions both nationally and across borders, and is in line with the ethos, recitals and several articles of the recently approved EHDS Regulation.

As part of the Digital Single Market (DSM) Strategy[2], and particularly following the COVID-19 pandemic, European digital health actors increasingly feel a need to converge on common, usable, and reliable tools for real interoperable services that enhance healthcare cooperation for better health and European healthcare solidarity, paving the way to the European Health Union. The DigitalHealthEurope Roundtables (RT) on Interoperability[3], led by the coordinator (2021), demonstrated the need for compelling use cases for health data interoperability, showcasing the benefits health data standards bring, and demonstrating how much efficiency and good patient outcomes are lost without interoperability. Such interoperability tools include the EEHRxF. Its wider adoption, however, is not an easy task nor will it happen automatically due to many factors (e.g., legacy systems, non-interoperability

[1] Available at: https://digital-strategy.ec.europa.eu/en/library/recommendation-european-electronic-health-record-exchange-format
[2] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52015DC0192; It was revised in 2017 but in essence the pillars are the same.
[3] Available at: https://digitalhealtheurope.eu/results-and-publications/expert-roundtables-on-health-data-sharing-and-use-summary-of-discussions/

supporting systems, local or national specifications, that would need to converge as well).

XpanDH is devoted to facilitating the extensive adoption of the EEHRxF through the maturation of a pan-European Ecosystem of Early Adopters of new/adapted digital solutions that implement EEHRxF specifications, within a specific socio-technical ethos of support for trusted, sustainable and resilient solutions.

1.2 Scope and objectives

This document intends to:

1. Advance a working definition of "EEHRxF adoption domain", identify and differentiate this from "Use Case" and other important related concepts
2. Identify the selection criteria for the identification and prioritization of the EEHRxF adoption domains to be dealt with by XpanDH
3. List potential XpanDH adoption domains
4. Deeply describe the 3-4 adoption domains, from the list of potential EEHRxF data categories, that will be the focus in XpanDH, namely in WP4 as they constitute the core of the 'Experimentation Bubbles' the basis of the XpanDH development.
5. Support the EEHRxF development in line with the European Commission direction.

The selected adoption domains must align with XpanDH's intention to experiment on them in WP4. They should also help foster ecosystem formation in WP5, provide valuable insights for WP6, and be suitable for real testing with project partners and thought engagement of X-Nets participants[4]. Their definition and characterization need to be closely agreed with WP2/WP3 and with WP1/WP7/WP4 for market relevance and for feasibility/experimentation possibilities, respectively.

In addition, this document will contribute with more evidence and principles that can support the developments of the EEHRxF. It is intended to present new possible developments, considering the current EEHRxF data categories. This work can feed the current EU eHealth groups with some inputs and evidence and also create a link between the project and the EC groups, (e.g., eHealth Network[5] and its

[4] For more details about what are and which X-Nets XpanDH project has started please referring to Deliverable *D5.1 - XpanDH Ecosystem Report*, and the Report on X-Net progress (non-public, but available on request to the coordinator)

[5] Available at: https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_en

subgroups Technical, and Semantics; MyHealth@EU[6] (e.g. eHMSEG and HOMB) and the Joint Action, Xt-EHR[7]) that shall create an environment for EEHRxF cocreation.

1.3 Structure of the deliverable

This deliverable is structured by the following parts:

a) EEHRxF Adoption Domain definition and other related XpanDH project concepts and definitions used throughout the project
b) Selection methodology for identification of the EEHRxF Adoption Domains and prioritization of those for focus in XpanDH as specified on the scope.
c) Related aspects, including Legal, Cybersecurity, and Emerging technologies.

[6] Available at: https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en
[7] Available at: https://www.xt-ehr.eu/

2 Concepts: Adoption Domain, and other project concepts

In addition to the EEHRxF recommendation, the original proposal for a regulation on the European Health Data Space (EHDS)[8], followed by the final text of the European Parliament on the EHDS[9], have improved the first concept of EEHRxF by adding details such as a defined structure, data fields, international coding systems and technical specifications, including guidelines. These improved description of the EEHRxF calls for the development the concept of adoption domains as the same data categories can be adopted in different ways depending on the context, focus, and purpose. Additionally, to better deal with this related and connected concepts like use case, X-bundles or X-bubbles are useful as will be shown. In this context, several concepts supporting the format adoption and appraisal processes are outlined. It is important to note that these concepts are still under development but have beend evolved from its first versions and that it will be updated. **Erro! A origem da referência não foi encontrada.** presents a simplified overview on the definition of Adoption Domains and related concepts. The following concepts with be described in detail:

(a) Health verticals
(b) Use case
(c) Business case
(d) Adoption Domain
(e) X-Bubbles
(f) X-Nets
(g) X-Bundles

(a) Health verticals (e.g. healthcare, public health, health management) - are large sectorial activity areas which use health data differently (even if coming from the same source, e.g. the EHR) within a health system. Can be considered at a MS or EU level.

[8] Available at. https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en
[9] Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.html#title1

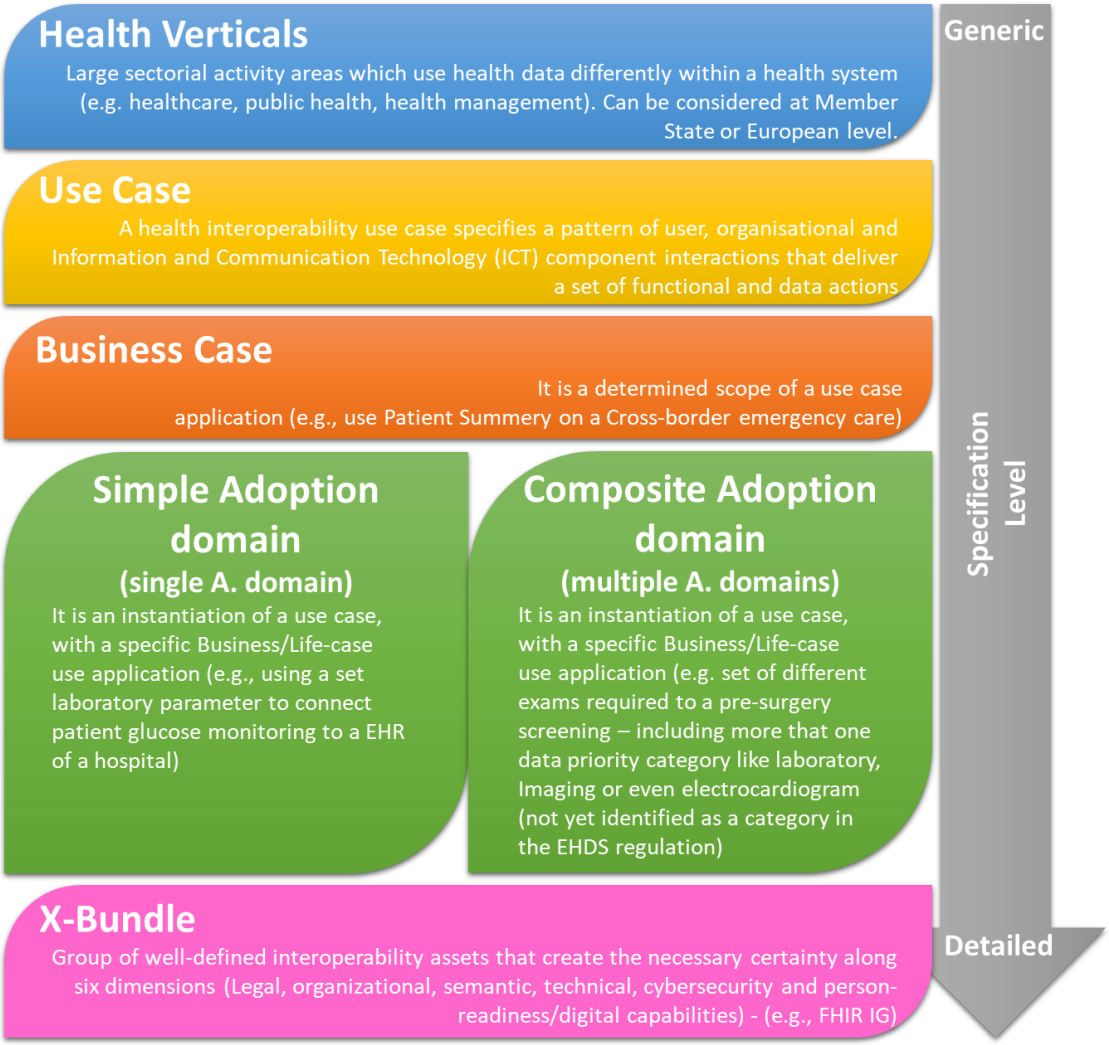

Figure 1 – Concepts definition around Adoption domains

(b) Use case

A health interoperability **use case**[10] specifies a pattern of user, organisational component and that of a Information and Communication Technology (ICT) component interactions that deliver a set of functional outputs and relate with a defined set of data (may be one or more data categories) . A use case specification is a formalisation of user requirements that informs, most of all, the ICT community about components, functions, interactions, data flows, interoperability and data processing that should be implemented. Ideally a use case is as generic as possible i.e., it consolidates all of the concrete user activities and needs, across care organisations and patient groups such as disease areas and ages, that could be implemented by the same technical solution(s). In particular for this project, it

[10] ISO/TR 28380-1:2014 - https://www.iso.org/standard/63383.html ; https://www.iso.org/obp/ui/#iso:std:iso:tr:25102:ed-1:v1:en

expresses the health data exchanges and level of interoperability that users need to achieve.

This definition can be complemented by the ISO definition: "*A textual and graphical depiction of the actors and operations that address information exchange in the context of a set of specific tasks for a workflow performed by different systems or devices. - A "Use Case Model" is simply a term to describe, and in many cases define, a user's view of interactions with (and within) the system. Use cases show how entities interact and are usually presented as structured text or diagrammatically*".

(c) Business Case (e.g. using the patient summary for supporting emergency care in cross-border settings) - it is a determined scope of application of a use case; It may require different types of health data combinations - i.e., different adoption domains and/or composite adoption domains to be used - and different related LOST processes to be further detailed but the main scope to be addressed from a business/real-world use application perspective is clear. It allows data variable flexibility. It requires a master value terminology catalogue (that will cover most of the terms to be used), however not all data fields may be used.

(d) Adoption domain

An **adoption domain** specifies the application of a use case to one or more particular care pathways and patient groups, (or clinical/organisational/inter-organisational workflows), for which the digital solutions implementing the use case are expected to deliver value. It therefore provides focus to the use case.

As such, an **EEHRxF adoption domain** could be considered as ***an instantiation of a use case, with a specific case application, that has meaning from a health system or clinical perspective, with defined implementable requirements (simple if only one EEHRxF priority category is used or composite if data from more than one is required), that satisfies all the conditions for users to be ready to implement data exchange in conformity to EEHRxF guidelines and specifications.***

This is also in line with End-to-End software testing[11] approaches that serve to verify the applicability of a software product or interconnection effort from start-to-finish taking not only technical interoperability but other aspects into consideration.

[11] **End-to-end testing** verifies that all components of a system can run under real-world scenarios, on the XpanDH context, the adoption domains with the proper set of actors and transactions involved.

In addition, the definition of "adoption domain" can be considered a narrow focus for a digital service to attend a defined clinical propose. Working to experiment with the EEHRxF in a given adoption domain means using all the specifications defined so far to verify for feasibility of its implementation in a given clinical context so that feedback can be provided about its completeness and adequacy, as well as, any necessary working assumptions that are identified during that process. In contrast, the 'use cases' can be theoretical (on the idealisation phase, without specifications deeply defined and any proven feasibility), and can also not be ready for implementation.

To contextualize the Adoption Domain definition, a set of related concepts can be considered. Annex I provides a preliminary overview of such conceptual interdependencies.

Considering the data priority categories outlined in the EHDS regulation, it is obvious that it is not possible to restrict Adoption Domains to single categories/priorities, but that univocal or multiple interrelations are possible. To classify Adoption Domains of the EEHRxF regarding where they make use of only one (simple) or many (composite) of such categories is not only theoretically useful, but also very important in practice, as alignment and testing of multiple specifications/implementation guides may become crucial for successful adoption.

To promote the focus of the EEHRxF experimentation and adoption in clinical setting and relevant to end-users, characterization of the type of clinical scenarios is very relevant.

The adoption domains can be considered simple or composite as follows:

- **Simple**

Requires **only data under one** of the European EHRxF data priorities (as per Article 6 EHDS Regulation[9]). For example, making the laboratory results of diabetic patients available to them by mobile application. It focusses on the implementation of only one specific use for the laboratory results among many possibilities.

- **Composite**

Requires **data from more than one** of the EEHRxF data priorities. For example, make key laboratory results available to a patient as well as parts or all of his/her patient summary in a combined manner, irrespective of using one or various electronic means, such as web portals and applications. It combines different uses of the laboratory results among many possibilities.

The adoption domains (simple or composite) should require a large description/specification nailing down to concrete usages (X-Bundle). The description/specification of one adoption domain will be required for each X-Bubble.

Clarifying differences between Use Case and Adoption Domain

Table 1 characterises the main differences between a use case and an adoption domain.

Table 1 - Adoption Domains Vs. Use Cases

Characteristic	Use Case	Adoption Domain
General	Use case if broader (eg. exchanging laboratory results with the patient)	Adoption Domain (e.g. exchanging urgent or actionable laboratory results with a health professional that have been signalled by the patient as creating doubts)
Purpose	Specifies a generic pattern of user, organisational and ICT component interactions that deliver a set of functional and data actions, and includes interoperability requirements	Specifies how the use case is applied to **one or more care pathways or workflow points** where it is expected to deliver value for patients (and others).
Scope for business case	Only at a high level	The health (outcomes), health system efficiency gains and economic value can usually be predicted and measured
Legal and regulatory interoperability[12]	Can usually be put in place at the use case level but some details may depend on the specific adoption domain	Can include reimbursement of the care pathway or digital technology adoption, if required
Organisational interoperability (policy, agreements, care process)[12]	Basic data sharing agreements, joint controller agreements and accountabilities can be defined	Detailed clinical responsibilities, care process and data flows can be specified
Semantic interoperability[12]	Most of the data specifications and data exchange standards are defined at the level of catalogues or nomenclatures (e.g. SNOMED CT, LOINC, etc)	Fine grained semantic specifications and datasets (data items and value lists) might only be specified per adoption domain

[12] These interoperability layers correspond to the Refined Interoperability Framework published by the eHealth Network https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5b56dffdc&appId=PPGMS

Characteristic	Use Case	Adoption Domain
Technical interoperability and technical and interface specifications[12]	Most of the technical interoperability layers can be specified at use case level but certain features of user interface may not	Domain specific apps and user interfaces may be unique to each adoption domain and its technical specification may be needed
Implementation	Infrastructures and some apps can be implemented at use case level, and usable by all adoption domains specialising the use case	A complete solution that will be capable of implementation and adoption
Nesting	Use cases are not usually nested, but may interact with each other	Adoption domains may be nested just as care pathways and workflows may be nested

(e) X-Bubbles

The '**Experimentation bubbles' or X-Bubbles** are collections of organisations that agreed to experiment with using the EEHRxF, in a set adoption domain and under the X-Bundle defined conditions, mostly on their own budget, or using other projects budgets, or pro-bono, but in effective articulation with XpanDH. The experimentation bubbles can be further extended to include other third-party organisations, and European or EU-funded initiatives and projects, and including can benefit from insights of organized groups of stakeholders.

(f) X-Nets

XpanDH will develop key activities through the XpanDH **X-Nets** - networks of organized groups of stakeholders (EU or MS organisations) that, linked by similar interests, form the existing pan-European (Digital) Health space and can potentially use or benefit from the widest adoption of the EEHRxF. Ten such networks will be promoted throughout the CSA, inspired by the Hospitals-on-FHIR initiative set out in March 2022 to network all Hospitals and Healthcare Providers (HCP) across Europe11. The following 10 XpanDH X-Nets have been established in the proposal stage, engaging already and just in a few days, around 20 organisations (local, regional, or national in nature) in total, out of 461 invited, and will be further enlarged and nurtured by the X-Net Agitators, throughout and beyond the project duration.

(g) X-Bundle

An **X-Bundle** consists of a group of well-defined interoperability assets that align with the six dimensions of the Refined eHealth European Interoperability

Framework (ReEIF): Legal, Organizational, Semantic, Technical, Cybersecurity, and Person-readiness/Digital capabilities. This ensures that a simple or composite adoption domain can be implemented across two or more connected ends of an EEHRxF-compatible health data sharing connection.

For example, an X-Bundle includes:

- Necessary semantic specifications (data sets, values, coding systems, nomenclature)
- Technical definitions (e.g., FHIR Implementation Guide - IG)
- Legal and organizational arrangements
- Individuals' capacity to use and understand shared health data
- Cybersecurity and information security safeguards mutually recognized by entities exchanging health data (e.g., between two hospitals, or between hospitals and payers)

The terms **interoperability asset collection** and **X-Bundle** are used to denote the collection of interoperability assets that need to be used in order to achieve the required interoperability and may include additional helpful resources such as requirements specifications and adoption guidance. For organizational readiness assessment XpanDH has to develop an **European EHR Exchange Format Readiness Model** (see Deliverables D3.1 - (D3.1.1)- First version of the X-Bundle Readiness model; D3.2 - (D3.1.2) - Final version of the X-Bundle Readiness model from WP3-Organisational Readiness)

3. Identification and prioritisation of EEHRxF Adoption Domains

Below, the process to select and prioritise the EEHRxF adoption domains for implementation and testing is described in further detail.

2.1 Using adoption domains in XpanDH

The six EEHRxF priority categories present different levels of maturity and usage among the EU. The Patient Summary (PS), ePrescription, and eDispensation (eP/eD) data categories can be highlighted as the most developed and used. Currently those services are already in place in many countries, and 13 countries (HR, CZ, PT, FR, NL, EE, FI, ES, LU, MT, PL, CY, EL) are exchanging health data through the MyHealth@EU infrastructure.

The 'medical test results, including laboratory and other diagnostic results and related reports' is foreseen to be implemented on eHDSI wave 8, 'medical imaging studies and related imaging reports and reports on wave 9 and 'discharge reports' on wave 9. Beside the continuous improvement of the information regarding those data categories, there is still a need for further development, which creates a huge opportunity for XpanDH to expand the adoption domains on them.

XpanDH has the remit to demonstrate and support the successful scale up of the EEHRxF. At a very simple level, use cases can be inferred from the data categories of the EEHRxF, as shown in the list below. Is also important to highlight that for all EEHRxF data categories below, the citizens shall have access to all their health data in the EHR systems.

Patient summary: contribute to safe clinical decision making and continuity of care in care organisations and countries that do not have an up to date and complete record of the patient, in particular if the patient is abroad and is in need of emergency or unplanned care. Also, the Patient Summary serves as a means for individuals to access their health data not just in travel situations but also to help manager his/her medical conditions better.

ePrescription/eDispensation: enable continuity of medication administration and consumption both in the patient's usual location of care and in case of travelling and in need of planned or unplanned care elsewhere.

Medical Test Results, Including Laboratory and Other Diagnostic Results and Related Reports: enabling the execution of a shared care pathway between care providers both in the patient's usual location of care and in case of travelling and in need of planned care elsewhere, and where the treating clinician needs access to recent or historic laboratory results in order to make a safe and effective decision.

Medical Imaging Studies and Related Imaging Reports: as for laboratory results

Discharge reports: as for the patient summary or for laboratory results. It should be noted that a hospital discharge report often is used as follow-up (e.g. by a GP after an episode of hospital care) and update of a patient summary with the new information and supplements the content of a patient summary with more disease or procedure related details. It often contains acute and short-term care planning details including treatments that are not included in a patient summary. Hospital discharge reports are also considered useful within a care organisation, as the consolidated summary of one or more prior hospital inpatient care episodes.

Each of the above priority categories outlined, although lacking the normal details of a use case specification, may be relevant to many different patient and care provision contexts (i.e. adoption domains), each of which would offer a different business case and value case, and would often require the specialisation (focusing) of some aspects of the interoperability.

3.1.1 Prioritising for XpanDH

Before developing adoption domains, the project needs to prioritise the use cases it will work with, as the complete list is too large to deliver well in the time and with the resources available. A choice was made to shortlist the adoption domains to be address based on two criteria:

- Level of existing maturity and implementation activity
- Technical feasibility within the resources available

The patient summary and ePrescription/eDispensation use cases are the subject of many existing European projects and national initiatives and have been implemented in the cross-border context within the MyHealth@EU community of Member States. It is one thing to implement in MyHealth@EU and completely another thing to implement at the level of an EHR system or at the level of a hospital. In fact, experimentation with PS and eP/eD at the local/EHR level is useful also to compare the maturity of specs for these data categories with that for new data categories.

Medical Imaging and Reports is an area that has been felt to be too complex to pursue here. This is however happening routinely in the European Reference Networks (ERNs) consultation platform, so we will learn from this experience and might even pilot the spec with some ERNs.

XpanDH will therefore work up adoption domains for use cases that utilise the interoperability of laboratory results and hospital discharge reports.

When considering possible adoption domains, a further prioritisation is being applied, on the basis of

- Feasibility of existing project ICT partners and/or invited companies to implement suitable deployable components.

- Interest and capability of existing project healthcare partners and/or invited sites to define, deploy and evaluate the implementations for a patient group and within a suitable care pathway.

As a consequence, the following adoption domains are currently being worked up. (The details below are only at the starting point of developing the definition of each adoption domain.)

3.1.1.1 Laboratory results (focused on patients with diabetes)

1a. Organisation to Organisation (national level)

Communicate a specific set of laboratory results of patients between different organisations so that each organisation can maintain a complete record of the results, in order to ensure continuity of care, and possibility to generate alerts to their General Practitioner (GP), nurse, etc.

1b. Organisation to Patient (national level)

Communicate the latest set of laboratory results to the patient so they can follow up on any pre-agreed actions, track their progress and contact the treating clinician with any concerns or questions.

3.1.1.2 Discharge reports

2a. Organisations (local level)

Communicate discharge reports between sub-systems in the same hospital network to enhance the ability to access to this document. In this case a hospital network might be considered as a set of sites, legally considered as a hospital, but comprising different departments with separate information systems.

2b. Organisation to Organisation (national level)

Exchange of discharge reports between different organisations, such as a hospital and a GP or between a hospital local to the patient and a specialist centre treating a disease such as a cancer, in order to enable each clinical actor to be well informed and contribute accurately to the same patient care pathway.

2c. Organisation to Patient (national level)

Communicate discharge reports from a hospital to the patient (within the same country) so that they can be informed, raise questions if needed, share this information with other caregivers and take any self-care actions indicated in the report.

2d. Organisation to Patient to Hospital (national & cross-border level)

Communicate discharge reports from a hospital to the patient (within a national or cross-border context), in a format that the patients can further share it

with another hospital within their own country or abroad, (enabling the patient to make the connection between two different hospitals). Supporting patient empowerment.

2e. National Authority to Organisation (national level)

The national authority communicates discharge reports to a hospital treating a patient, this authority has previously received from other hospitals treating that patient, to enable a smooth transfer and continuity of care (e.g. if a patient moves home).

2f. Organisation to National Authority (national level)

Communicate discharge reports from a hospital to a national authority to support reimbursement decisions or to contribute content to a national registry.

It should be noted that the application of the above use cases to rare diseases is a European priority. However, it was considered beyond the scope of XpanDH to actively pursue this. Instead, the field will be monitored to pick up on any initiatives that tackle this in order to access their experience and learning.

4 Experimentation within XpanDH

A further relevant concept is defined within XpanDH: X-Bubbles. An X-Bubble is a list of organisations what will collaborate within the project to jointly adopt and demonstrate use of digital solutions (including interoperability) for an adoption domain. The X-Bubble does not include the technical solution providers. It exemplifies one or more healthcare organisations that would jointly or separately procure, install and use interoperable solutions from one or more ICT providers, mimicking the market situation.

Some (but not all) of the above adoption domain outlines have been championed by a lead partner to establish an X-Bubble, and to conduct the deployment and evaluation for their domain.

Table 2 – Experimentation X-Bubbles

X-Bubble	XpanDH Adoption Domain	Lead partner
X-Bubble 1	Laboratory Results (diabetes patients) Organisation to Organisation (national level)	OKFŐ
X-Bubble 2	Laboratory results (diabetes patients) Organisation to Patient (national level)	CHUdSA
X-Bubble 3	Hospital Discharge Report Organisation to Patient (national level)	CHUdSA
X-Bubble 4	Hospital Discharge Report Organisation to National Authority (national level)	KETEKNY
X-Bubble 5	Hospital Discharge Report National Authority to Organisation (national level)	KETEKNY
X-Bubble 6	Hospital Discharge Report National Authority to National Authority (cross boarder)	NCZI

4.1 Methodology to progress the adoption domains

Four types of Adoption Domain experimentation are envisioned on XpanDH:

a) Active Experimentation with the EEHRxF
b) Adoption domains for conceptual experimentation
c) Adoption domains for exploration through partnerships and networking
d) EEHRxF Development/Evolution

The first corresponds to work outlined for WP4 (Feasibility & Experimentation) in XpanDH, the second for active partnership efforts with ongoing projects that are relevant, from an influencing to a more concrete technical collaboration effort. The third is envisioned to be develop in initiatives outside the project following the XpanDH approach, and the last is designed to identify new data categories and use cases for the European EHRxF.

Beyond the development/experimentation of the Adoption Domains in collaboration with the XpanDH partners through the X-Bubbles, the project XpanDH is open to receive new partners that are willing to experiment with the adoption domains in the different experimentation levels. The entities interested in experimenting with the Adoption domains shall compromise to follow the XpanDH guidelines, in order to ensure the correct development of the experiments under the related X-bubble. The inclusion of new entities can be done through a simple open call (Associated partners – that will happen on month 6 and 12 of the project) or through the inclusion on the X-nets.

4.2 Active Experimentation with the EEHRxF

The active experimentations will be developed under the WP4 on the 'X-bubbles', that will be defined around the identified adoption domains and the associated partners to be evaluated, taking into consideration their maturity / readiness levels in alignment with WP3 – 'Organisational Readiness'. Aspects, such as ethics and legal issues, differences in languages and terminologies will be considered as well as in international/national/regional contexts. Further details on this experimentation are available on the 'D4.1.-XpanDH Adoption Domains' such as the criteria for the selection of bubble sites and the concrete experimentation X-bubbles and adoption domains selected.

Two different types of experimentation bubbles are considered:

- **X-Bubbles**: They are constituted by groups of organizations, partners within XpanDH consortium, that voluntarily test the use of EEHRxF through the definition of concrete use cases for exchange and adoption scenarios. Their objective is to assess and validate the appropriateness of the format identifying gaps and plan its adoption via feasibility demonstrators.
- **"In Silico" Bubbles**: They are constituted by groups of organisations that are either associated partners to XpanDH or collaborate with the project in a more informal way. Their objective is to identify requirements to the EEHRxF and its implementation via structured (workshops and surveys) exercises.

Departing from Article 6 of the 2024 EHDS Resolution which states that:

> *"[The] format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. The format should support transmission of structured and unstructured*

health data. The format shall include the following elements:

(a) harmonised datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;

(b) coding systems and values to be used in datasets containing electronic health data;

(c) technical interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles."

On the following subsections there are described the XpanDH developments among the EEHRxF data categories. For each domain, there is described improvements on the current services that shall be further developed and implemented by the technical projects regarding this thematic, such as the XT-EHR and xShare.

For each adoption domain a set of parameters that will characterize each adoption domain need to be established and then worked in WP2 (Standards & Technical artefacts), in WP3 (Organisational Readiness) and in WP4 (Feasibility & Experimentation) for an adequate elaboration of the X-bundle specific for each adoption domain to be implemented in practice. Each Adoption Domain will be described according to the following parameters on Table 3:

Table 3 – Descriptor Items for the Adoption Domains

Descriptor	Aspects to describer
Partners willing to experiment	Name of the partner and a brief description of its function (e.g., large university and Hospital; eHealth agency)
Actor involved	Actors directly involved on the adoption domain (e.g., GPs, patients, nurses, etc): - Individuals - Organizations - Systems
Context of use	e.g., emergency care to an unconscious patient in a foreign country, online consultation, etc.
Health Information Exchange layer standards	e.g., , XDS, OOTS, etc
Semantic elements	Coding Systems, e.g., ICD10, Loinc, etc
Datasets	Datasets used
Technical Specification	e.g., Include the use of FHIR implementation Guide

Main data flow	e.g., organization ⟶ patient
Brief description of how the service impact the user	e.g., facilitate the access of the patients to the lab results directly on their mobile.

For each of the following: a brief description on these items is provided.

4.2.1 Lab. results – Organisation to Organisation (X-bubble 1)

Exchanging laboratory results in a structured format (PDF already available) to save time for the treating physician, provide better care for the patient and to pilot the use of EEHRxF for the standardisation of medical documentation. Diabetic patients are followed-up to assure that the value of a group of laboratory parameters are maintained in a safe range. The laboratory results are translated into a EEHRxF format by either the HIS or LIS. Structured laboratory results are stored in the EESZT and are available to all the physicians treating the patient. Currently, patients have access to their data through the EESZT patient portal (PDFs). However, the provision of data to the patient is outside the scope of this bubble. More details can be seen on Table 4

Table 4 – Lab. results – Organisation to Organisation

Descriptor	Aspects to describe
Partners willing to experiment	OKFŐ - National Directorate General for Hospitals EESZT - National Hungary eHealth Infrastructure
Actor involved	- Individuals: Physician - Organizations: EESZT - Systems: Hospital Information System
Context of use	Diabetes continuity of care
Health Information Exchange layer standards	As-Is: EESZT provides web services based on SOAP for healthcare providers to access documents and records. (SOAP based on national standards or international (tbd))
Semantic elements	As-Is: Hungarian implementation of ICPM and ICD-10 originally for billing purposes, LOINC has partial usage.
Master Value Sets	As-is: value sets based on the coding systems above.
Technical Specification	payload: HL7 FHIR
Main data flow	Organization A ⟶ EESZT ⟶ Organization B
Brief description of how the service impact the user	Continuity of care for diabetic patients is supported by structured data exchange, saving much time for the physician by providing an integrated view of the patient's condition through time. Possible improvements with the provision of alerts to the healthcare professionals based on the structured data etc.

4.2.2 Lab. results – Organisation to Patient (X-bubble 2)

The main objectives in terms of health information exchanging are: i) to provide efficient follow-up of diabetes patients; ii) to deliver comprehensive information to diabetes patients; iii) to exchange health information adopting standards and structured and open-data modelling. Laboratory results are coded in LOINC and structured as an Open-EHR compositions, then translated into a EEHRxF format. Laboratory results are made available to patients through the organisation mobile APP. More details are on Table 5.

Table 5 – Lab. results – Organisation to Patient

Descriptor	Aspects to describe
Partners willing to experiment	CHUdSA – University Hospital of Santo António (Porto – PT)
Actor involved	- Individuals: Doctors, Patients - Systems: HIS, AIDA Platform[13] (Agency for Integration, Dissemination and Archiving of medical information), CHUdSA mobile APP
Context of use	Diabetes continuity of care
Health Information Exchange layer standards	As-Is: AIDA-EHR (modelling in Open-EHR), transportation layer HL7 FHIR and AIDA-Services
Semantic elements	As-Is: National Health System Codes, LOINC, ICNP – International Classification for Nursing Practice
Master Value Sets	As-Is: Local datasets (AIDA-EHR) based on adopted terminologies/ontologies (Open-EHR)
Technical Specification	HL7 FHIR
Main data flow	Organization ⟶ mobile APP ⟶ Patient
Brief description of how the service impact the user	Deliver laboratory results through the organization mobile APP, in order to assure the continuity of care and help patients to better manage their disease. Data will be delivered via a downloadable PDF and make the data available in FHIR to show data under of higher relevance.

[13] AIDA is a platform developed to enable the dissemination and integration of information generated in a health environment by different systems, including for example information on Complementary Diagnostic and Therapeutic Means

4.2.3 Dis. Reports – Organisations to Patient (X-bubble 3)

The main objectives in terms of health information exchanging are: i) to provide efficient follow-up of patients; ii) to deliver comprehensive information to patients; iii) to exchange health information adopting standards and structured and open-data modelling. Discharge Report is coded in SNOMED-CT and structured as a set of Open-EHR compositions, then translated into a EEHRxF format. The discharge report is made available to patients through the organization mobile APP. More details are on Table 6.

Table 6 – Dis. Reports –Organisations to Patient

Descriptor	Aspects to describe
Partners willing to experiment	CHUdSA – University Hospital of Santo Antônio (Porto – PT)
Actor involved	- Individuals: Doctors, Patients - Systems: HIS, AIDA Platform (Agency for Integration, Dissemination and Archiving of medical information), CHUdSA mobile APP
Context of use	Continuity of care
Health Information Exchange layer standards	As-Is: AIDA-EHR (modelling in Open-EHR), transportation layer HL7 FHIR and AIDA-Services
Semantic elements	As-Is: National Health System Codes, SNOMED-CT
Master Value Sets	As-Is: Local datasets (AIDA-EHR) based on adopted terminologies/ontologies (Open-EHR)
Technical Specification	HL7 FHIR
Main data flow	Organization ⟶ mobile APP ⟶ Patient
Brief description of how the service impact the user	Deliver hospital discharge reports through the mobile APP, in order to assure the continuity of care and help patients to better manage their disease.

4.2.4 Dis. Reports – Organisations to National Authority (X-bubble 4)

The main objectives in terms of health information exchanging are: i) to use National Discharge Letter Standards, incorporating the data sets defined for this health data category in the EEHRxF specifications, ii) to collect structured and coded information on patient administrative data (as defined in the Greek DRG-Dataset) iii) as well as relevant clinical data, using ICD-10 Greek Modification, and ETIP (as foreseen in Greek DRG Coding Guidelines), iv) to achieve fair Remuneration for given Hospital Services by EOPYY and other insurance organizations.

The above objectives may facilitate the following: i) to provide comprehensive reports for hospitals, concerning their activity (case mix index, average duration of hospitalization, main reasons for admission and hospitalization, number and type of medical procedures, etc.), ii) to assist benchmarking between clinics and hospitals in terms of cost, quality and efficiency, iii) to assist the implementation of administrative and clinical audit by EOPYY and other insurance organizations, iv) to suggest and assist the implementation of quality indicators per healthcare provider and per individual health service, in collaboration with the Organization for Quality Assurance in Health (ODIPY) v) to provide source data in order to verify national KPIs on clinical outcomes and effectiveness vi) to provide Discharge data in order to trace and monitor treatment outcomes and specific complications of treatment i.e. Surgical Site Infections (SSI). More details are on Table 7

Table 7 - Dis. Reports –Organisation to National Authority

Descriptor	Aspects to describe
Partners willing to experiment	KETEKNY – Greek DRG Institute (Center for Documentation and Costing of Hospital Services)
Actor involved	- Individuals: Doctors, - Organizations: Hospital Financial and Administrative Departments, EOPYY (National Organization for Provision of Health Services) - Systems: Greek DRG Grouper Platform, Hospital EHRs ,
Context of use	Fair remuneration of Hospital Services, Assisting the implementation of administrative and clinical audit, Assisting Hospital Management and Benchmarking
Health Information Exchange layer standards	HL7 FHIR, HL7 CDA, XDS
Semantic elements	As-Is: ICD-10 Greek Modification, ETIP (Greek Medical Procedure Classification)
Master Value Sets	As-Is: Greek DRG-Dataset, EKOK (Greek DRG Coding Guidelines), National Discharge Letter Standards
Technical Specification	payload: HL7 FHIR
Master data flow	Hospital ⟶ KETEKNY (as national Authority)
Brief description of how the service impact the user	Use National Discharge Letter Standards, incorporating EEHRxF specifications, to collect structured and coded information on patient administrative data (as defined in the Greek DRG-Dataset), as well as relevant clinical data, using ICD-10 Greek Modification, and ETIP (as foreseen in Greek DRG Coding Guidelines) in order to achieve fair Remuneration for given Hospital Services

4.2.5 Dis. Reports – National Authority to Organisations (X-bubble 5)

The main objectives in terms of health information exchanging are: i) to contribute to the validation and cross-check of structured and coded information on patient administrative data (as defined in the Greek DRG-Dataset), ii) to contribute to the validation and cross-check of relevant clinical data, using ICD-10 Greek Modification, and GMPC/ETIP (as foreseen in Greek DRG Coding Guidelines), iii) to transmit DRG codes and names for each patient, computed by the algorithm of the Greek DRG Grouper Platform, according to the above validated and cross-checked patient data.

KETEKNY is the Greek organization made responsible for the electronic collection of all financial, medical & administrative data of all public hospitals in Greece.

Additionally, the follow objectives can be included as future use: i) provide Discharge data in the case of care transition (patient transfer etc) to ensure continuity of care, ii) provide Discharge data in order to support Patient Access. More details are on Table 8.

Table 8 – Dis. Reports –National Authority to Organisations

Descriptor	Aspects to describe
Partners willing to experiment	KETEKNY –Greek DRG Institute (Centre for Documentation and Costing of Hospital Services)
Actor involved	- Individuals: Doctors, - Organizations: Hospital Financial and Administrative Departments, EOPYY (National Organization for Provision of Health Services) - Systems: Greek DRG Grouper Platform, Hospital EHRs
Context of use	Fair remuneration of Hospital Services, Assisting the implementation of Administrative and Clinical Quality Control, Assisting Hospital Management.
Health Information Exchange layer standards	HL7 FHIR, HL7 CDA, XDS
Semantic elements	As-Is: ICD-10 Greek Modification, ETIP (Greek Medical Procedure Classification)
Master Value Sets	As-Is: Greek DRG-Dataset, EKOK (Greek DRG Coding Guidelines), National Discharge Letter Standards
Technical Specification	payload: HL7 FHIR
Master data flow	KETEKNY (as national Authority) ⟶ Hospital

Brief description of how the service impact the user	Use National Discharge Letter Standards, incorporating EEHRxF specifications, to deliver structured and coded information on patient administrative data in the case of care transition (patient transfer etc) to ensure continuity of care and Patient Access.

4.2.6 Dis. reports - National authority to National authority (X-bubble 6)

The pilot implementation of EEHRxF will showcase the seamless transmission of structured data from hospital discharge reports coded using international standards between national information systems, aligning with the future requirements set by the EHDS regulation. This demonstration will emphasize the importance and benefits of adopting FHIR standards for effective and standardized Hospital Discharge Report exchange across healthcare systems. More details are on Table 9.

Table 9 – Dis. reports - National authority to National authority

Descriptor	Aspects to describe
Partners willing to experiment	NCZI - Slovak National Health Information Centre OKFÖ – Hungarian Digital Health Authority
Actor involved	- Individuals: Health professionals - Systems: Hospital information systems ,
Context of use	Cross-border Continuity care
Health Information Exchange layer standards	As-Is: ISO 13606
Semantic elements	As-Is: Slovak national code systems, ICD-10 German modification
Master Value Sets	As-Is: Hospital discharge letter, Slovak national coding systems
Technical Specification	HL7 FHIR
Master data flow	Hospital A ⟶ National Authority Country A ⟶ National Authority Country B ⟶ Hospital B
Brief description of how the service impact the user	To ensure seamless care and efficient access to patient data, structured data from hospital discharge reports coded using international standards in one hospital information system are transmitted to the information system of another hospital.

The output of the current project will not involve the full implementation or deployment of the entire exchange process. Instead, the focus will be on conducting

a feasibility check of the technical and semantic transformation of the original hospital discharge report and exploitation of the potential solutions and challenges associated with cross-border document exchange of this kind.

4.3 Adoption Domains for Conceptual experimentation

The conceptual experimentation is conducted only at hypothesis level, it can also be called as "in silico X-bubbles". In this chapter is described the XpanDH developments among the EEHRxF data categories that were no described above. For each domain, there is described improvements on the current services that shall be further developed and implemented by the technical projects regarding this thematic, such as the XT-EHR and xShare.

4.3.1 Patient Summary

Status of FHIR IG: a proof-of-concept FHIR IG for the European cross-border Patient Summary is being developed by this project (see https://build.fhir.org/ig/hl7-eu/xpandh-ps/) to enable the collection of feedback about this representation. The guide is based on the current FHIR IPS, aligning with the global GDHP effort on interoperability[14].

This initial effort is deemed to be relevant for contributing to the format harmonization across the data categories, enabling the actual reusage of data in different kind of documents, e.g., reuse of the PS Allergy data in a Discharge Report.

Moreover, the adoption of HL7 FHIR facilitates the support of the patient mediated exchange of PS (exchange of data by personal consumer devices) and the adoption of smart health link techniques[15].

4.3.2 ePrescription & eDispensation

Status of FHIR IG: There is an IHE profile under development for the support of eP/eD with FHIR. Some proofs-of-concepts have been developed as part of the UNICOM project, but further developments are needed; above all for covering the cross-border scenario and provide a better support to IDMP. (See also the "Non-paper on ISO IDMP implementation challenges"[16]. UNICOM together with Gravitate Health has

[14] Available at: https://gdhp.health/work-streams/interoperability/
[15] Available at: https://docs.smarthealthit.org/smart-health-links/

[16] Available at: https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?spaceKey=eHN&title=Non-paper+on+ISO+IDMP+implementation+challenges

exercised in several FHIR connectathons the exchange of medication data to support cross domains scenarios. (mainly using FHIR PSs)

A transition from the current document CDA-based to a FHIR-based order-oriented approach, will also enable a better management on the cross-border eP/eD workflow, currently very limited; and it will contribute to a harmonized representation of medications across data categories.

4.3.3 Medical Imaging Studies and Related Imaging Reports;

Status of FHIR IG: no FHIR IGs (even as proof-of-concept) have been developed for the representation of Imaging diagnostic reports within the X-eHealth project. However, the general structural approach followed for the Lab report can be also applied for the Imaging report. There are some FHIR resources that can be used for describing Imaging Study and Key images selection; however, the DICOM (DICOMWeb) standard should be used for the image exchange.

Further analysis on the readiness on this domain is expected.

4.3.4 Medical Test Results, Including Laboratory and Other Diagnostic Results and Related Reports

Status of FHIR IG: A common European Standard for the Laboratory Report based on FHIR R4 is going to be balloted during fall 2023 and published by HL7 Europe as Standard for Trial Use by the end of 2023. This standard has been developed with the involvement of representatives of almost all European countries and eHMSEG Architecture WG representatives. It considers the inputs from previous (X-ehealth) and current (XpanDH) EU projects. Specialized (e.g MyHealth@Eu cross border exchange) and National FHIR IGs (e.g., Switzerland, Italy,) are planned to be defined as specialization of this EU standard.

This first version provides a specialty-agnostic common baseline, that will be further refined based also on the feedback of the XpanDH X-Bubbles, MyHealth@EU and the starting Xt-EHR (JA-09). This will eventually include the development of specialized profiles per speciality (e.g., micro-biology). A FHIR Connectathon hopefully engaging also the XpanDH Xbubble will be organized on January 2024 to exercise in practice the implementation of these EU and National Guides.

It is hoped that the work on the Laboratory Domain, could be also extended for providing support for the order management part of the cycle. This is an incoming request mainly at the National Level (see e.g Estonia).

4.3.5 Discharge reports

Status of FHIR IG: An initial example of the document structure was developed in X-eHealth based on the X-eHealth CDA template; refinements are being developed by this project (e.g. Encounter representation) in parallel with the EU PS representation.

However, considering the large variety in the report structures and details of information depending on jurisdictions, specialties and encounter type, it is hoped that the main goal of the workof partners on the (Hospital) Discharge Report could be mainly that of developing a library of generic and reusable components that can be applied beyond the case of the Patient Summary (see e.g., the C-CDA on FHIR); rather that defining a common fixed structure for discharge reports.

4.4 Adoption domains for exploration through partnerships and networking

XpanDH is a CSA, its resources are limited, and it aims to also stimulate and support others for action. In this case action towards using and disseminating the European EHRxF, as such, in many cases, it may be equally important to explore and stimulate the advancements in the EEHRxF by means of engaging with other projects/initiatives that may need to exchange information that falls into the EHDS regulation's priority data categories. This interaction intends to exchange information about the evolution of the developments among the EEHRxF definitions supported by those projects. It can speedup de development process and shall ensure the alignment among the different initiatives that intends to develop the EEHRxF.

We have identified the following ongoing opportunities:

a) **UNICOM** (Up-scaling the global univocal identification of medicines)- it focuses on the implementation of the International Organization for Standardization (ISO) suite of IDMP (IDentification of Medicinal Products) standards. This project foresees the exchange of medicinal product data benefiting from clear identification due to the usage of some fields provided by IDMP standard.
b) **PATHeD** (Enabling Patient Access to their Health Data)– it focuses on the patient access to their health data when travelling abroad, via mobile apps developed by their Country of Affiliation, with the goal of showing those health data in a language understood by a health professional in the Country of Treatment. The project will be re-using components already developed in MyHealth@EU (e.g., semantic/translation components)
c) **HealthData@EU pilot** (Piloting an infrastructure for the secondary use of health data - EHDS 2 pilot) – bringing together 17 partners from all over Europe (health data access bodies, health data sharing infrastructures and European agencies), this project will build a pilot version of the EHDS

infrastructure for secondary use of data. The aim of the project is to connect data platforms in a network infrastructure and develop services supporting the journey of the user for research projects using health data from different EU Member States. Guidelines for data standards, data quality, data security and data transfer to support the cross-border infrastructure will also be developed.

We have identified the following future opportunities:

a) **Xt-EHR** (Extended EHR@EU Data Space for Primary Use) - Joint Action on preparatory actions for an EHDS – primary use of health data (for healthcare) DI-g-22-22.06 – The joint action will contribute to promote better exchange and access to different types of health data. The objective of this joint action is to enhance cooperation among Member States regarding primary and secondary data by: a) preparing guidelines and technical specifications on interoperability of medical images, laboratory results and discharge letters towards the European electronic health record exchange format (EEHRxF); b) preparing guidelines and technical specifications on interoperability of telehealth, mobile health and other health software; c) preparing guidelines and technical specifications on the use of electronic identification in health, for health professionals and patients taking into account the developments of the European Digital Identity Framework; d) preparing guidelines and technical specifications on cross-border telehealth, including telemonitoring; e) preparing an assessment framework and technical specifications for the evaluation of the quality of mobile wellness applications; f) preparing an assessment framework and technical specifications for the evaluation of the interoperability of electronic health records, personal health data spaces and other software in health; g) preparing guidelines and technical specifications on the quality of mobile wellness applications.
b) **xShare** – this project envisions everyone sharing their health data in EEHRxF. Proposals in this call can be featured across health portals and patient apps and allow people to exercise their data portability rights under GDPR. Hence, the European EHRxF will be the driver for research and innovation in EHDS.

4.5 EEHRxF Development/Evolution

The need to further develop as well as iterate and image new data categories and use cases for the European EHRxF is identified even in the CSA Call text.

The XpanDH WP 6 included some proposed work on data categories associated with telehealth and telemonitoring in particular, but this now needs to be synchronized with the work of the further projects, such as the 'Extended EHR@EU Data Space for Primary Use' and 'HORIZON-HLTH-2023-IND-06-02: Expanding the EEHRxF to improve interoperability within EHDS'. These upcoming projects can be taking advantage of the pre-defined adoption domains developed on XpanDH.

In line with the projects that can take advantage to the XpanDH developments, and all the adoption domains referred on the chapter 4.2, below there are listed the adoption domains that should be further developed beyond the XpanDH scope:

- *Discharge reports – within Organisations (local level)*
- *Discharge reports – patient-mediated Org-Org exchange (national & cross-border level)*

Additional adoption domains can be identified and specified along the project. The register of these new adoption domains and their further adoption for experimentation can support directly new actions funded by EC or the X-nets, that are in close collaboration with the XpanDH project.

5 Legal aspects relevant to chosen XpanDH adoption domains

The development, feasibility analysis and the implementation of the Adoption Domains, shall consider the current EU and national legislation that sets the legal requirements about the data usage and the systems permissions.

The legal analysis must consider all the EU and the Member State respective legislation related with the selected Adoption Domain. As each Member State has their own laws, it may be necessary to proceed with individualised analysis regarding each Member State applicable laws that could condition the specific aspects of each adoption domain since this can be the reason for feasibility or lack of feasibility of the exchange of a certain personal health data category in a given context (for example, in some countries we found restrictions, created by national law to the direct sharing of certain laboratory results like in oncology or HIV without a previous medical consultation). At the same time, the European laws apply to all Member States and must be considered as a baseline for the specific Adoption Domain development and further implementation, considering also the national laws.

In this regard, we list below the main EU legislation texts in place that have direct impact on EU eHealth services and directly or indirectly relate to the EEHRxF and/or EHRs:

Table 10: legal acts around the EEHRxF

Legal Act	Relevance/Comments
Regulation on the European Health Data Space.[17]	Defines EHRs, the Format, the way the different data categories are set up and can be added/edited. Sets out different parameters about them (e.g. interoperability with Wellness APPs) that indirectly relate to EHRs/EHRxF
Data Governance Act COM/2020/767 final[18]	Aims to foster the availability of data for use by increasing trust in data intermediaries and by strengthening data-sharing mechanisms across the EU.
Harmonised rules on fair access to and use of data (Data Act) COM/2022/68 final[19]	Aims at building a genuine single market for data and at making Europe a global leader in the data-agile economy.

[17] Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf
[18] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52020PC0767
[19] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN

Laying down harmonised rules on artificial intelligence (artificial intelligence act) COM/2021/206 final[20]	Aims to implement the second objective for the development of an ecosystem of trust by proposing a legal framework for trustworthy AI.
Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format.[21]	It outlines the preliminary concept and first set of characteristics and data priorities associated with the European EHR Exchange format.
Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).[22]	Establishes the EU-wide rules for personal data protection establish several of them directly in relation with health data which determine certain limitations and possibilities to the use of the Format.
Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.[23]	Creates the grounds for the business case and the use case of cross-border ePrescription and eDispensation, without mutual recognition the interest of making the ePrescrition available outside the MS of origin would be limited.
Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare.[24]	Established the grounds for the two first cross-border services as well as the dynamic of the eHealth Network from which all guidelines and specifications have emerged with authority under a MS voluntary participation regime.
Commission Recommendation 2008/594/EC of 2 July 2008 on cross-border interoperability of electronic health record systems.[25]	The first EC recommendation that outlines the need to work on cross-border interoperability of EHRs. In a way this EC recommendation sets the course for much of ongoing work in this area leading up to the Format in the EHDS in 2024.

[20] Availabe at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206
[21] Available at : https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243
[22] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN
[23] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.L_.2012.356.01.0068.01.ENG
[24] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN
[25] Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594&from=EN

6 Cybersecurity concerns/issues relevant to chosen XpanDH adoption domains

The eHealth ecosystem has become an increasingly popular way for healthcare providers to offer medical services and for patients to access health information. eHealth platforms provide a convenient and efficient way for patients to receive medical advice and treatment without leaving their homes, but they also introduce new cybersecurity concerns and issues that must be addressed to ensure patient privacy and data security.

There are several attacks that can be (or have already been) launched by cyberattackers. Such attacks against individuals include:

- **Unauthorized data access**. Attackers may gain access to private or even sensitive data. Once they get access to the data, they may be able to find important health-related information about their victims. To make matters worse, attackers may leak (or even sell) these health-related data putting their victims in significant risk.
- **Unauthorized data modification**. Once attackers have access to a patient's data, they may be able to modify the data. For example, in the context of adoption domains, they may modify **Lab Results** leading to wrong diagnosis, wrong treatment, and eventually putting the lives of people in grave danger. They may also alter **Discharge Reports**, leading any follow-up medical treatments astray. Finally, they may also alter the **Patient Summary**, omitting an important allergy or a chronic illness, making the Patient Summary a ticking bomb waiting to explode and put the life of the victim in significant danger.

Cyberattackers may also attack the hospital infrastructure in several ways:

- **Data Breaches**: Attackers may leak sensitive data, such as medical records, insurance information, and personal identification details.
- **Ransomware**: Attackers may encrypt the data and demand payment in exchange for the decryption key. Such attacks can not only disrupt medical services and lead to delays in patient care but may also be life-threatening in some cases.
- **Compromised Medical Devices**. Attackers may gain control of medical devices and render them useless asking for money (ransom) in order to return the device in regular operation.

There are several ways that can be exploited by Cyberattackers to gain access to healthcare systems and launch their attacks. Some of these ways include:

- **Phishing**: Attackers may send phishing emails to health care staff trying to (and in some cases successfully) gain credentials such as passwords and PIN numbers. Once they have a username and a password, attackers

may be able to have access to the healthcare system and the associated data.

- **Software vulnerabilities**. Attackers may exploit (software) vulnerabilities (bugs) in eHealth systems to gain access to computers and patient data, which can then be sold on the black market or used for identity theft. This can lead to financial loss, damage to a patient's credit score, etc.
- **Misconfiguration in system access control**. Attackers may exploit misconfigurations in order to gain access eHealth systems. As eHealth platforms store sensitive patient information, it is important to ensure that only authorized personnel have access to the data.

To address these cybersecurity concerns, eHealth organizations can employ a variety of defence mechanisms such as:

- **Awareness and training**. Maybe the first line of defence is to train the healthcare personnel to be aware of possible attacks (such as phishing) and to know what to do when they see such an attack.
- **Strong authentication and authorization systems**: eHealth platforms should implement strong authentication (such as two-factor authentication) for all their users and should allow access only to authorized (and authenticated) personnel. Also, the audit trails of login/logout operations shall be stored by the eHealth organizations. It shall be applied for all evolved actors, as example, on MyHealth@EU there are two current scenarios:
  - **Health Professionals**: strong authentication is already required.
  - **Patients**: The patients are still identified via paper-based procedures.
- **Data protection**: platforms should employ relevant data protection approaches, such as encryption for data “at rest” and “in transit”, and also pseudonymisation techniques could be applied as well, when possible.
- **Attack Detection**: platforms must employ robust detection measures such as antivirus, firewalls, and intrusion detection systems.
- **Attack Recovery**: platforms should have plans in place that will enable them to recover from an attack and continue operation as soon as possible (contingency plans).

Although the above are clearly applicable to adoption domains, they are also applicable to the broader area of eHealth. The current eHealth systems must update the cybersecurity means and implement new ones to avoid any kind of cyberattack, in addition the implementation of new functionalities through the adoption domains shall ensure that the cybersecurity means are in place to protect the patient data and systems functionalities. Adoption domains, in particular, may be a very attractive target for “Unauthorized Data Access” and “Unauthorized Data Modification” as explained above.

7 Outlook to emerging technologies

While the current adoption domains cover a large portion of health and care scenarios, they remain non-exhaustive, and many data movements remain unaddressed. The scope of the EEHRxF is expected to evolve rapidly to adapt to the ever-changing landscape of eHealth. Whilst further future-looking developments remain possible, we hereby outline two emerging technologies which have been identified as holding great potential, both already being subjects of ongoing European collaboration initiatives: the EU digital wallet, and telemedicine.

7.1 EU Digital wallet

The EU Digital Wallet (EUDI Wallet), driven by the European Commission and further developed by different consortiums[26], represents a significant advancement in digital identity technology. Designed to provide secure, user-centric identity verification and data exchange, the EUDI Wallet aims to facilitate various digital interactions across sectors. This emerging technology has the potential to impact patient-related adoption domains within the European Electronic Health Record exchange format (EEHRxF).

7.1.1 Prospects

The EUDI Wallet offers numerous opportunities as an EHDS adoption domain and EEHRxF priority data category. While specific eHealth applications are often limited to solutions deployed at national level, there are ongoing efforts to expand its use at European level, leveraging e.g. the eIDAS login functionalities. For example, specifications for physical contact-based data sharing in pharmacies are being developed, highlighting the potential for wider applications. The principles of secure digital identity and data exchange inherent in the EUDI Wallet can enhance patient control over health data, improve interoperability between health systems, and ensure robust data protection. The EUDI Wallet can draw inspiration from digital wallets implemented globally, such as in Brazil, where they facilitate secure, efficient data sharing across sectors. Additionally, the EUDI Wallet holds potential to introduce seamless user journeys, leveraging several functionalities offered by the Wallet, such as for instance: authentication of the patient, coupled with the retrieval of their health data (e.g. ePrescription), payment of eDispensation in the pharmacy, and storing of the invoice issued by the pharmacy.

[26] Namely: POTENTIAL, EWC, DC4EU, and NOBID. See more at: https://ec.europa.eu/digital-building-blocks/sites/display/EUDIGITALIDENTITYWALLET/What+are+the+Large+Scale+Pilot+Projects.

7.1.2 Challenges

Despite its potential, integrating the EUDI Wallet into eHealth poses challenges. The standards used in the EUDI Wallet differ significantly from those in current eHealth systems, necessitating efforts to harmonise these standards. Additionally, the current scopes of large scale pilots funded by the European Commission indicate many potential connections and data exchange scenarios that have yet to be fully explored. Addressing these challenges requires coordinated efforts to align technical specifications and develop comprehensive use cases. Furthermore, stakeholders would have to ensure that the EUDI Wallet's implementation does not compromise existing data protection and security measures in eHealth.

7.2 Telemedicine

Telemedicine, encompassing remote consultations, diagnostics, and continuous patient monitoring, is an emerging technology with the potential to transform healthcare delivery. By enabling healthcare access regardless of geographical constraints, telemedicine can significantly enhance patient care. However, its integration with the EEHRxF remains underdeveloped, presenting both opportunities and challenges. That the time of XpanDH preparation the EC proposal on a Regulation on the EHDS included Article 8 about telemedicine and in Article 10 (point (k) offer, in compliance with national legislation, telemedicine services and ensure that such services are easy to use, accessible to different groups of natural persons and health professionals, including natural persons with disabilities, do not discriminate and offer the possibility of choosing between in person and digital services;"). In practice, while the final text of the EHDS Regulation is scarce about telemedicine and in no way relates this with the EEHRxF that those do not mean such connections are not important and should be explored. For example, in countries where telehealth is linked to eP/eD services both are synergic, similarly in cases of cross-border telemedicine.

7.2.1 Prospects

The integration of emerging technologies like telemedicine holds promise for advancing patient-related adoption domains within the EEHRxF. Telemedicine offers transformative potential by enabling remote consultations, diagnostics, and continuous patient monitoring, thereby enhancing healthcare accessibility and outcomes.

Currently, while comprehensive telemedicine solutions integrated with the EEHRxF are lacking, ongoing efforts aim to develop specific applications. For instance, projects focus on creating secure, interoperable platforms for remote patient monitoring and virtual consultations. These initiatives underscore numerous potential connections and data exchange scenarios, suggesting fertile ground for further exploration and development. Two at least can be foreseen: i) producing a

telehealth encounter report, possibly as an extension of the discharge report? Or healthcare encounter report?; ii) using the logic of the laboratory domain explore how telemonitoring data should be reported from different home telemonitoring devices in specific cases like chronic obstructive pulmonary disease or health failure.

7.2.2 Challenges

Integrating telemedicine into the EHDS and EEHRxF faces significant challenges. There is currently insufficient evidence regarding the standards and technologies best suited for telemedicine in eHealth contexts. Comprehensive evidence assessments are needed to determine effective approaches and technologies for integration. Moreover, ensuring interoperability between telemedicine platforms and existing health systems is complex. Addressing these challenges requires rigorous evaluation and standardisation efforts. Additionally, the secure and user-centric nature of telemedicine must be maintained to protect patient data and privacy while fostering patient trust and engagement. An additional challenge - which is the need to have a secure identification of the patient (and possibly of the healthcare professional) during the telemedicine (remote) encounter. The EUDIWallet may potentially help on the patients' side. There is an ongoing discussion in Xt-EHR on this subject.

8 Exploitation of preliminary learnings from X-Bubbles

8.1 Laboratory Reports

The analysis of laboratory reports suggests a high level of alignment with established guidelines, indicating that the fields required by the EEHRxF may be comprehensively covered. Notably, no missing fields were identified in the evaluated reports. The use and consideration of LOINC (Logical Observation Identifiers Names and Codes) and SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms) seem to be widespread. These international standards could facilitate consistent and accurate exchange of laboratory data.

In countries with a national strategy for health data exchange, such as Portugal, catalogues that map local coding systems to international standards have been developed. This approach may ensure compatibility and enhance data interoperability on a global scale. Conversely, in countries where data exchange is based on unstructured formats, each laboratory appears to use its own coding system. This presents an opportunity to define and implement a national coding system that aligns with international standards.

8.2 Patient Summaries

In the context of patient summaries, it appears that many of the required fields are already present in some current systems. However, in many countries, these fields might not be integrated in a format that complies with EEHRxF guidelines. Where compliance is observed, the integration approach seems to align mostly with the International Patient Summary (IPS) standards.

The inconsistency in the integration of fields suggests a need for concerted efforts to harmonise patient summary formats. This harmonisation could ensure that patient data is consistently captured and exchanged in a manner that supports continuity of care, especially in cross-border healthcare scenarios.

8.3 Hospital Discharge Reports

The evaluation of hospital discharge reports indicates a good alignment with the guidelines for general structure, although in some instances, some fields are missing. Preliminary results hint that there are misalignments between data fields required in practice and those included in the current eHN guidelines. For instance, one such field that resulted required in X-Bubbles but not present in the eHN guidelines is is “Hospitalization outcome” (the patient’s discharge condition). These cases are summarised in Table X below.

Table 11. Data fields suggested to be added to eHN guidelines.

Field	Description	Details
Admitting weight	Weight on admission. To be completed for patients age less than 1 year.	In grams
Hospitalisation outcome	Patient' discharge condition.	HL7.PV2.PatientCondition Code (From Greek Values - NOT STANDARD HL7) A. Satisfactory C. Critical P. Poor S. Stable O. Other U. Unknown D. Death
ID organisation	code of healthcare organisation	-
ID department	code of department in the healthcare organisation	-

A notable observation is the use of national implementations of ICD-10 (International Classification of Diseases, 10th Revision). This highlights the need for strategies to manage the transition period and ensure that data can be effectively mapped between different versions of ICD. Furthermore, the required and optional data fields in hospital discharge reports might vary depending on the medical specialty. This indicates that a one-size-fits-all approach may not be feasible, and tailored solutions that consider specialty-specific requirements could be needed. The analysis in this area is still ongoing, suggesting that further refinements and adaptations might be necessary as more data becomes available.

9 Final remarks

Along this document it is possible to access the definition and understand what the adoption domains and their relevance to the broad adoption of the EEHRxF by the European eHealth ecosystem are. In line with the evolution of the eHealth concepts and considering the proposal of the EHDS regulation, XpanDH assembles the EC guidance with the innovation on the eHealth ecosystem to bring to the patients advances on the usage of their health data.

This document is also intended to be a 'live document' in order to follow the current evolution of the eHealth ecosystem, the specifications that have been developed on XpanDH and other projects and also consider the EC recommendations. We intend to revise and update this document around month 8-9 to provide an update content to the partners.

The document statements shall be revised in collaboration with the EC groups (such as eHN and eHDSI) in order to ensure the alignment with the EC recommendations and vision.

Finally, it is important to note that, considering the European Parliament's April 24th, 2024, adoption of a Resolution on the EHDS which reviewed the 2022 EHDS Proposal, future developments around the EEHRxF will need to take account of broader priority categories of personal electronic health data for primary use. The present document remains relevant for the time being. The updated priority categories are listed below, with modifications of to the 2022 Proposal being marked **in bold** (sourced from Article 5, 1.)[9]:

(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.