xShare

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

WP3
D3.2 v2024-09-25 *xShare Data portability business use cases, validation process, and localization requirements – Final*-WP3-*UNINOVA*
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List of abbreviations

Please refer to the i~HD Glossary: https://glossary.ramit.be/public/index.cfm

Abbreviation	Term
AI	Artificial Intelligence
AMKA	National Social Security Number Registry
API	Application Programming Interface
AS	Adoption Site
BUC	Business Use Case
CDA	Clinical Document Architecture
CDM	Common Data Model
CEF	Connecting Europe Facility
D	Deliverable
DMP	Dossier Médical Partagé
DoA	Description of Action
DoH	Department of Health
EEHRxF	European Electronic Health Record exchange Format
EESSI	Electronic Exchange of Social Security Information
EHR	Electronic Health Record
EHRxF	Electronic Health Record exchange Format
ePS	European Patient Summary
ERP	Enterprise Resource Planning
EU	European Union
EUDI	European Union Digital Identity
FHIR	Fast Healthcare Interoperability Resources
FTGM	Fondazione Toscana Gabriele Monasterio per la Ricerca Medica e di Sanita Pubblica
FTSS	Fundació TIC Salut Social
GB	Gigabyte
GDPR	General Data Protection Regulation
GP	General Practitioner
HCP	Health Care Professional
HID	Health Information Domain

Abbreviation	Term
HIS	Health Information System
HL7	Health Level 7
HP	Health Practitioner
HSE	Health Service Executive
ICT	Information and Communication Technology
IDIKA SA	Electronic Governance of Social Security and Health Services
IHE	Integrating Healthcare Enterprise
IPS	International Patient Summary
IT	Information Technology
LMS	La Meva Salut
MVC	Master Value Catalogue
MVP	Minimum Viable Product
NCP	National Contact Point
NCPeH	National Contact Point for eHealth
NeHA	National eHealth Authority
NHS	National Health System
NPS	Net Promoter Score
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
OTP	One-Time Password
PCM	Partnership Council Meeting
PDF	Portable Document Format
PHR	Personal Health Record
PI	Principal Investigator
PROM	Patient-Reported Outcome Measure
PS	Patient Summary
PSSUQ	Post Study System Usability Questionnaire
PTCA	Percutaneous transluminal coronary angioplasty
QR	Quick Response
RWD	Real World Data
SCR	Shared Care Record

Abbreviation	Term
SDO	Standards Development Organisation
SISCAT	Comprehensive Public Health System of Catalonia
SME	Small and Medium-sized Enterprise
SRS	Secretaria Regional de Saúde e Proteção Civil
SUS	System Usability Scale
T	Task
TRL	Technology Readiness Levels
TTSA	Telemedicine Technologies
UC	Use Case
UNINOVA	Instituto de Desenvolvimento de Novas Tecnologias
UR	User Requirement
US	User Story
WP	Work Package
XDS	Cross Enterprise Document Sharing
XML	Extensible Markup Language

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Executive summary

D3.2 *xShare Data portability business use case, validation process, and localisation requirements – Final* reports on the work performed until M9 under T3.1 *Business service use cases for continuity of care*. As reported in the previous version of this deliverable (D3.1, M6), the work started with the definition of the co-creation methodology applied in WP3 and the Business Use Cases (BUCs) template definition based on previous projects and adapted for the specific needs of the xShare project. A physical co-creation workshop during the Partnership Council Meeting (PCM) in Athens (January 17-19, 2024) was carried out to collect the consortium vision regarding the xShare Yellow Button. Then, a complete picture of the Adoption Sites scenarios was gathered by the definition of their specific BUCs and their User Stories (USs) definition, in a series of meeting with the Adoption Sites representatives (adopters and implementers).

D3.2 presents the xShare Yellow Button requirements, derived based not only on the Adoption Sites BUCs and USs, but also on previous projects that were analysed to gather additional requirements regarding health and health-related data sharing. Reference USs were defined to aggregate the Adoption Sites USs. Then, the initial xShare Yellow Button requirements (from D3.1) were revisited, and a final set of requirements is presented in D3.2. Additionally, the assessment method was extended with additional details for the validation process of the xShare Yellow Button in the Adoption Sites. This work was presented and validated in a physical workshop held at the Madeira Digital Transformation Week in Madeira (June 27th, 2024).

Lastly, the xShare Yellow Button main components were identified based on the elicited requirements. The initial version of the xShare Yellow Button reference architecture will be presented in D3.3 *xShare toolbox for data portability under GDPR - Interim 1* (M12).

1. Introduction

D3.2 *xShare Data portability business use case, validation process, and localisation requirements – Final* is related to T3.1 *Business service use cases for continuity of care*, under WP3 *Patients' Right to Data Portability: the case of continuity of care*. Its main purpose it to provide the xShare vision on the fundamental business and user objectives of the project, the requirements of the xShare Yellow Button, and the xShare Yellow Button validation process.

A detailed assessment of the xShare project Adoption Sites' needs and challenges was performed, in the form of Adoption Site-specific BUCs and USs. This is a critical process for creating the xShare Yellow Button requirements and the necessary inputs for producing specifications for the different technological components of the xShare Yellow Button. The list of BUCs and requirements was derived through the stakeholders' participation and involvement in a series of workshops for the xShare Yellow Button requirements formalisation.

This document is divided in chapters and structured as follows:

- Chapter 2 reports the overall WP3 methodology, presenting the co-creation approach, the Agile methodology for requirements elicitation, the localisation requirements, and the xShare Yellow Button validation process.
- Chapter 3 reports to the outcomes of the execution of the WP3 methodology until M09, namely:
    - Co-creation workshops present various workshops that were held, including workshop held in Madeira (June 27th, 2024) where the audience provided their feedback regarding the xShare Yellow Button requirements and their prioritisation regarding the xShare Yellow Button implementation.
    - xShare Yellow Button basic functionalities were updated to reflect the work made in the Adoption Sites harmonisation and distillation.
    - Analysis of the Adoption Sites BUCs presents the main results of the Adoptions Sites BUCs analysis.
    - xShare Yellow Button reference US, requirements and MVP, and its main components.
- Chapter 4 presents the concluding remarks of the work performed so far under T3.1.

D3.2 contains the most updated information regarding the work performed in T3.1. For the previous work, the reader must refer to D3.1 (M6).

2. WP3 Methodology

2.1 Introduction to methodology

The xShare project aims at developing a health data sharing button (named the xShare Yellow Button) with a large and diverse potential user-base, spanning from different national health care systems with their respective approaches to digital health, and a variety for rather different cultural settings.

The WP3 co-creation approach aims to provide a lively co-creation environment, which accompanies the whole design, development, and implementation process of the xShare Yellow Button. The co-creation will be happening all along the process of development and design and will consist of many different settings in which co-creation happens in parallel. At different instances of the project, we will use different methods to engage with users and will address different problem areas from the technical to the social. At different points in time, different parts of the consortium will be involved, and different temporal and spatial aspects will come to matter. The co-creation approach will be also carried out in the adoption sites, where different sets of users will be engaged in different cultural settings.

The xShare project thus needs a multi-faceted, responsive, and well-structured co-creation environment and approach in order to develop the xShare Yellow Button and the functionalities/services it will offer (Figure 1). The main focus of this deliverable is on Step 1, while Step 2 and Step 3 will be targeted in later WP3 deliverables.

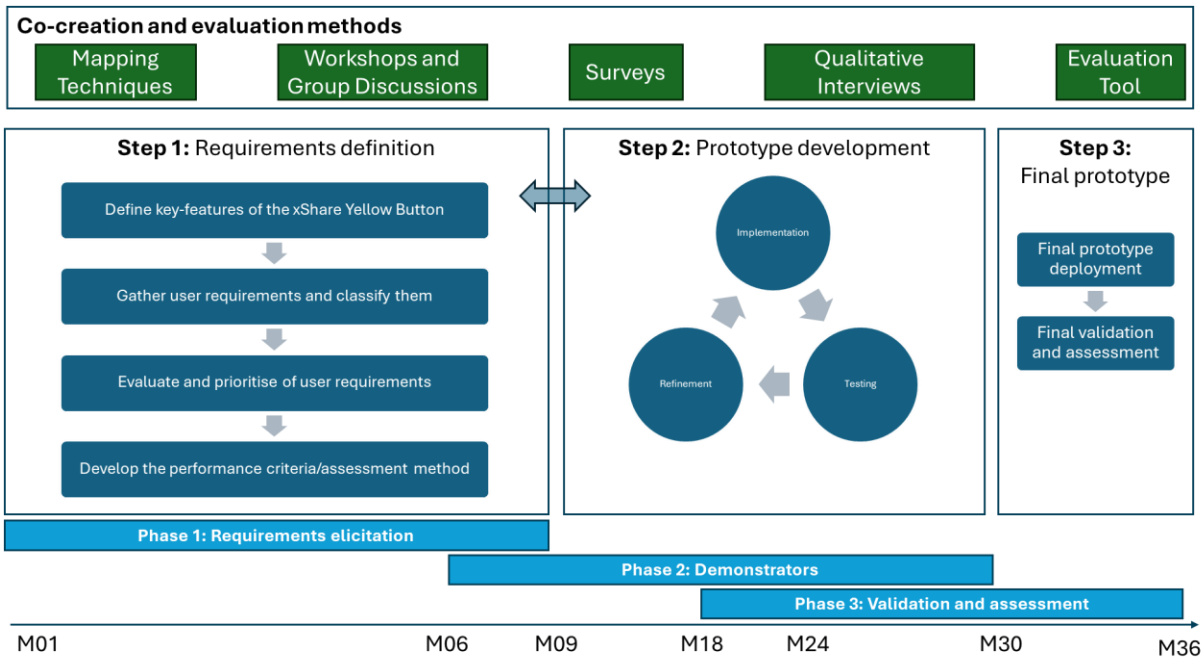

Figure 1. WP3 co-creation approach and timeline.

The description of the WP3 co-creation approach and the agile methodology applied can be found in the previous version of this deliverable (D3.1 *xShare Data portability business use cases, validation process, and localization requirements – Interim*, M06). Additionally, D3.1 also includes the Minimum

Viable Product (MVP) description. In the following section, it is presented an extended version of the validation process that was presented in D3.1.

2.2 Agile Methodology

This section describes the co-creation Agile methodology used in the 8 Adoption Sites and later the Open Call winners for the requirements definition for business uses cases, as well as validation and assessment of prototypes and MVPs (step 1 and step 2 of the co-creation approach). This process is driven by the stakeholders in close collaboration with the implementers and the technical partners. This type of methodology is comprised by multiple steps in which the main focus is the BUCs definition and the USs that drive the technical requirements elicitation (Figure 2). This Agile methodology comprises distinct, interactive, and interdependent steps. The outcome of these steps constitutes the foundation for the design of the xShare Yellow Button requirements and high-level USs.

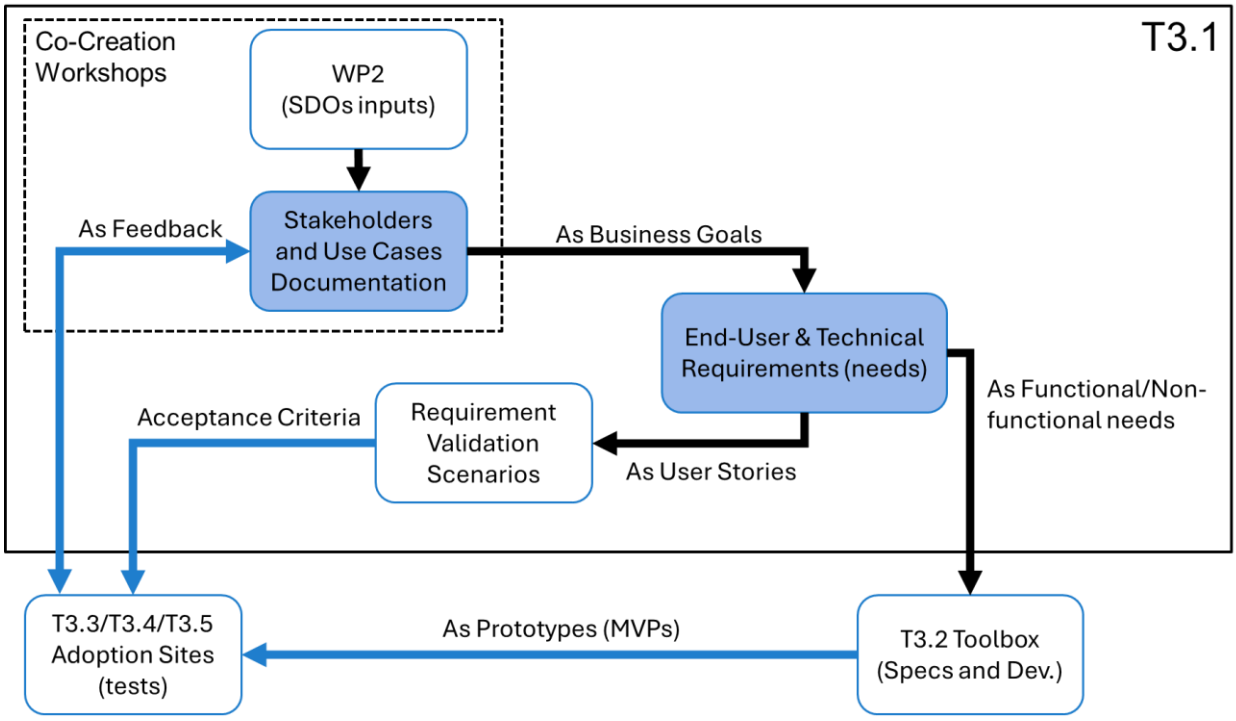

Figure 2. T3.1 Agile methodology for requirements elicitation for business use cases, their localisation, validation, and assessment.

2.3 Localisation Requirements

Data localisation requirements are related to how the data is processed within a specific country, i.e., how data is stored, collected, or processed within a system and its transferability to other systems. The health sector is not left out of this situation. Although specific data may not be available on the full impact of cross-border health data flow restrictions, the ongoing regulations development addressing data privacy, residency, sovereignty, and localisation underscores the need to assess

these laws and policies[1]. While storage of personal electronic health data by health data access bodies and secure processing environments might be a reasonable safeguard to implement, broader data storage requirements would pose significant risks, for example, in terms of their potential adverse effects on life-saving international health R&I collaborations, the functioning of pan-European medical registries, or the provision of ubiquitous digital health services through anytime-anywhere connectivity[2]. During the xShare Yellow Button requirements elicitation, different countries' regulations can emerge, and the overall requirements need to consider and comply with the national and EU regulations.

2.4 Validation Process

The assessment method used in the validation process of the xShare Yellow Button will be based on user and technical evaluation. The validation process occurs in the *Phase 3: Validation and Assessment* of the co-creation approach (Figure 1). Briefly, the technical evaluation will verify if the requirements were implemented and how it was assessed. For the user evaluation, the co-creation and evaluation methods presented in D3.1 (section 2.2.3) will be applied, together with System Usability Scale (SUS) to evaluate the user acceptance of the xShare Yellow Button. There will be also a synergy with WP6 to monitor the EEHRxF adoption and implementation by the Adoption Sites, as described in D6.1 *Monitoring framework on national EEHRxF uptake and EHRxF Standards Hub performance – 1* (M08).

To validate the way the xShare Yellow Button prototype is adopted and used, a mix of qualitative and quantitative methods will be used. The qualitative part will be using a set of research methods that are part of the co-creation methods. These methods include the following:

- Workshops and group discussions.
- Qualitative interviews.
- Surveys.

Note that, a qualitative validation approach is not meant to assess whether or not a user requirement has been fulfilled. Rather, the aim is to collect detailed insights into

1. Where, when, and how users might encounter issues.
2. The degree to which development facilitated the use.
3. Where explicit satisfaction with the usability was expressed.

Such an approach allows for a nuanced understanding of potential problems encountered by users, which in turn is the precondition to develop appropriate and sustainable solutions. In addition to this, quantified metrics will be used. An initial proposition for these metrics include:

- Number of downloads executed.

[1] 1.Chumak A. Cross-border health data transfer rules around the world [Internet]. InCountry. 2024. Available from: https://incountry.com/blog/cross-border-health-data-transfer-rules-around-the-world/
[2] DigitalEurope. European Health Data Space (EHDS): key issues to address in trilogues [Internet]. DIGITALEUROPE. Available from: https://www.digitaleurope.org/resources/european-health-data-space-ehds-key-issues-to-address-in-trilogues/

- Number of one-time sharing executed.
- Number of linked options established.
- Number of datasets downloaded.

The validation of the xShare Yellow Button implementation in each Adoption Site consist in an execution scenario with a list of actions to be execute and its preliminary actions (pre-conditions). Test cases comprise sets of actions to be performed during the Adoption Sites executions, with the actions being tailored to demonstrate how the xShare Yellow Button satisfy the identified requirements. The evaluation of test cases will be based on execution scenarios that will be executed in the context of each Adoption Sites and/or of each xShare Yellow Button basic functionality. For each test case, the steps outlined in Table 1 will be followed and reported.

Test Case ID	
Release	*xShare Buton release version.*
Test Case Description	*What feature is being tested / what function is being verified.*
Test Environment	*The environment in which the test is being executed, including all relevant hardware and software components.*
Test Preconditions	*Conditions to be met before test case execution, related to system, data, network, etc.*
Test Data	*Variables and values relevant to the test case.*
Test Case Steps	*Step 1*
	Step 2
	Step 3 ..
Expected Result	*Result expected after the test case execution.*
Actual Result	*Result obtained after the test case execution.*
Status	*Pass, Fail, Blocked*
Defects Identified	*Defect ID:*
	Defect description:
	Severity:

Table 1: Test Case Template.

3. Work performed and achieved results

This section provides an overview of the results achieved until M06, following the co-creation approach described in section 2.

3.1 Co-creation Workshops

This section presents the workshops that were carried out during the initial six months of the project to collect different points of view and encourage reflection and debate between the consortium members; and explore expectations and concerns of the Adoption Sites (Figure 3).

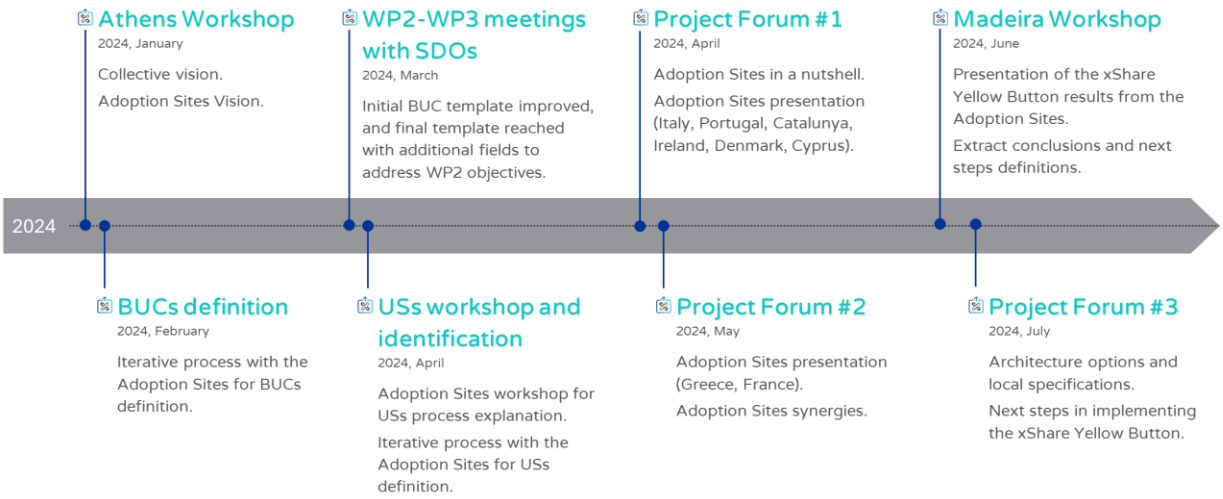

Figure 3. Co-creation workshops timeline.

Workshops, carried out until M06 (May 2024) were described in the previous version of this deliverable (D3.1 *xShare Data portability business use cases, validation process, and localization requirements – Interim*, M06). Additionally, D3.1 also includes the Minimum Viable Product (MVP) description. In the following section, an extended and updated version of the validation process is presented, reflecting the work done since D3.1 (M06).

Another co-creation workshop was held at the Madeira Digital Transformation Week on June 27th, 2024, in Madeira (Portugal)[3]. This workshop pivoting towards a comprehensive discussion on mechanisms for ensuring secure health data sharing, particularly through the adoption of the xShare Yellow Button and how it will contribute to bring EHDS to reality (Appendix 1).

3.2 xShare Yellow Button basic functionalities definition

This section describes the envisaged xShare Yellow Button basic functionalities. These functionalities derived from the DoA, and its workflow was initially defined in a workshop with the Adoption Sites (adopters and implementers) and the technical partners. The workflows were then continuously

[3] Madeira Digital Transformation Week [Internet]. mdtweek.digit-madeira.pt. [cited 2024 May 15]. Available from: https://mdtweek.digit-madeira.pt/

updated reflecting the inputs from the different workshops that were carried out. These basic functionalities have the following pre-conditions and assumptions:

- The citizen has an account and health data in the health provider or third-party app.
- The citizen is authenticated in the health provider portal/app.
- The HIS of the health provider or the third-party app is able to export and import health information in EEHRxF or in a non-EEHRxF format accompanied with a clear specification or implementation guide.
- The HIS of the health provider must be able to provide a reason in case some data is not available for exporting.
- Authorised recipient can vary between an authorised person (trusted one or HCP) to a healthcare organisation. When is a trusted one without access to a health provider portal/app, the shared health data is transferred using another method.

3.2.1 Download

The download functionality ( ) enables the citizen to download their health data (in the EEHRxF machine readable format and optionally also human readable format, e.g., PDF) with a click-of-a-button, from a health provider portal/app to their computer or smartphone, according to the following workflow:

1. Citizen (data owner) clicks on the xShare Yellow Button and selects the download functionality.
2. Visualises and selects from the health data available to download (e.g., all the HID, a data group, or a specific data field of a data group in a HID).
3. (optional) Configures the xShare Yellow Button download options:
    a. Data transformation: anonymisation, password, translation, and digital signature.
    b. Data format: EEHRxF and optionally also in a human readable format.
4. Clicks on the Download/Accept button.
5. Selects the download destination.
6. The health data is available on the chosen destination in the selected format (post-condition).

3.2.2 One-time Share

The one-time share (consent) functionality ( ) enables the citizen to consent and share their health data (in the EEHRxF) with a click-of-a-button, from a health provider portal/app to a trusted one (e.g., healthcare provider, relative, or a third-party health app), according to the following workflow:

1. Citizen (data owner) clicks on the xShare Yellow Button and selects the one-time share functionality.
2. Visualises and selects the health data available to share and creates a static document.
3. (optional) Configures the xShare Yellow Button share options:
    a. Data transformation: anonymisation, translation, and digital signature.
    b. Data format: EEHRxF and the original data in human readable format.
4. Selects the authorised data recipient: specific healthcare organisation, trusted one, or an xShare labelled app (using the qualified endpoint to send to shared data or link to them).

5. Clicks on the Share/Accept button (the user of the app is informed of interoperability and its effects and provides explicit consent).
6. The health data is available for retrieval by the selected data recipient or app.

Flow according to the authorised data recipient:

- *Healthcare organisation:*
  - (optional) The authorised recipient is notified regarding the data availability from a specific citizen.
  - Authorised recipient (document recipient) authenticates in the organisation portal (authorisation client).
  - Document recipient requests and accesses/visualises the data and is able to store in the organisation health system.
- *Trusted one:*
  - Authorised recipient (document recipient) accesses a link/portal (authorisation client) and authenticates itself (e.g., MyHealth@EU, eIDAS).
  - Document recipient accesses/visualises the data with option to save locally.
- *App:*
  - (optional) The authorised recipient is notified regarding the data availability from a specific citizen.
  - Authorised recipient (document recipient) authenticates itself the app (authorisation client).
  - Document recipient accesses/visualises the health data in the app.

The one-time share functionality follows a consent approach, where the citizen consents that their data is shared with a trusted one or an institution. This consent functionality would also allow to restrict the access to specific person (under EHDS article 8).

3.2.3 Linked Options

The linked options (subscription) functionality ( ) enables the citizen to authorise a subscription and share their health data (in the EEHRxF) with a click-of-a-button, from a health provider portal/app to a trusted one (e.g., healthcare provider, relative, clinical trials, research institutions) for a period of time, according to the following workflow:

Same as one-time share but when new data is available or data is updated, the data recipient can request or be notified and receive the new data or a link to the new data from the data responder.

The linked options functionality follows a subscription approach, where the citizen authorises that their data is subscribed by a trusted one until the subscription ends (or is cancelled).

3.3 Aligning business use cases framework with SDOs

The overall description of the work to be done in the xShare adoption sites are linked to the health business and user needs and requirements.

A Business Use Case (BUC) template from previous projects and initiatives was used to derive the template to use in xShare. In particular, the ones proposed and used in Antilope, eStandards, MyHealth@EU, and X-eHealth. The template was then further “enriched” in a co-creation approach.

A BUC is a complete, meaningful and from the point-of-view of Health professional, citizen, patient or relatives in some role or roles in relation to a system and that embodies the purpose or intentions underlying interactions.

In eStandards a BUC repository was developed by IHE Europe. In xShare, IHE Europe will extend the BUC repository with new functionality and include “old” and new BUCs from the xShare Adoption Sites and the open call winners from WP3, WP4, and WP5.

The BUC prepared by the Adoption Sites has been done in co-creation with stakeholders. The co-creation process is very important to get the end-users (patients, citizens, health professionals) involved from the beginning. This will allow feedback to the industry implementing the format and SDOs and the EC shaping the EEHRxF standards and associated implementation acts.

In terms of Maturity, a first assessment was made using the TRL scale and considering a combination of the usage of the format and of the xShare Yellow Button as a mechanism for providing data to citizens/patients. Under the following rationale it was assessed the degree to which:

- For the format: data is made available by IT systems and is possible to collect it in a machine-readable format.
- For the button: provision of data to citizen/patients in digital formats (even if in PDF).

The BUC repository will be linked to the Hub and allow public access to the BUCs and associated assets and X-Bundles. The Hub will provide the most updated information regarding the Adoption Sites and open call winners link to BUCs repository. Standardised BUC metadata may be leveraged as a basis for searching and access to relevant information in the BUC repository. The BUC metadata attributes are:

- Author
- CreationTime
- EEHRxFCode
- HealthCareFaciliyTypeCode
- HIDCode
- InfrastructureCode
- ReferenceArchitectureCode
- ScaleCode
- TechnologyReadinessLevel
- Title
- Version
- X-BundleCodeList
- YellowButtonMaturityCode

The full metadata description and additional details of the BUCs alignment is available on D2.3 *Business Use Case Registry* (M10).

3.4 xShare Adoption Sites analysis

With the obtained results we performed an analysis of the Adoption Sites BUCs in the following areas: actors, USs per actors, HIDs per AS, as shown in the following subsections.

3.4.1 Adoption Sites Actors

This section provides an overview of the actors' list across all Adoption Sites and present in the USs. These actors were chosen based on the UCs definition workshops (under T3.1). Hence the primary list of possible actors, as well as the Adoption Sites in which these actors are present is presented in Table 2.

Actor	**Adoption Site #**								**USs per actor**
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	
Citizen/Patient	7	3	10	8	8	6	6	9	57
Health Care Professional/Provider		2	3	11	3	6			25
Pharmacist			2						2
Clinical Investigator								5	5
Research Team								3	3
ICT		1		1					2
USs per Adoption Site	*7*	*6*	*15*	*20*	*11*	*12*	*6*	*17*	*94*

Table 2. Identified actors in each AS USs.

3.4.2 Adoption Sites HIDs

During the BUCs and USs workshops it was analysed which HIDs and xShare Yellow Button basic functionality each of the Adoption Sites was focusing on. Table 3 provides an overview of the HIDs per Adoption Site. As can be observed, the main focus of the Adoption Sites is the Patient Summary Download.

HID	Adoption Site #								AS per HID
	1	2	3	4	5	6	7	8	
Patient Summary	⬇	⬇	⬇ ☁ 🔗		⬇	⬇ ☁		⬇ ☁ 🔗	6
Electronic Prescription	⬇	⬇	⬇ ☁ 🔗	⬇	⬇				5
Electronic Dispensation	⬇	⬇	⬇ ☁ 🔗		⬇				5
Medical image and image report	⬇	⬇		⬇	⬇	⬇ ☁			5
Laboratory Results	⬇	⬇		⬇	⬇	⬇ ☁			5
Discharge Report	⬇	⬇		⬇	⬇	⬇ ☁			5
Telemonitoring									0
Care Plan			⬇ ☁ 🔗				☁		2

⬇ Download

☁ One-time share

🔗 Linked options

Table 3. Overview of the basic scenarios of the xShare Yellow Button in the Adoption Sites.

Following the new HIDs regulation, these tables will be revised with the new naming of the HIDs. Additionally, the telemonitoring and the care plan HIDs will be developed under T3.4 *xSHARE Care plans and tele monitoring use case*.

3.4.3 Adoption Sites EHDS Article 8 Adherence /Compliance

Table 4 presents the Adoption Sites compliance with EHDS article 8. The xShare Yellow Button is using as legal framework of EHDS more specifically article 8 in the context of cross-border healthcare.

EHDS article 8 legal framework	**Adoption Site #**							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
a) Access PHR	✓	⌛	✓	✓	✓	✓	⌛	⌛
b) Insert info in PHR	✗	⌛	✓	✓	⌛	⌛	⌛	⌛
c) Rectification	✗	⌛	✓	✓	✓	✓	⌛	⌛
d) Data Portability	?	⌛	✓	✓	✓	✓	⌛	⌛
e) Restrict Access	✗	⌛	✓	✓	✓	✓	⌛	⌛
f) Data Access Information	✓	⌛	✓	✓	✓	⌛	⌛	⌛
g) Data Access Services	✓	⌛	✓	✓	✓	⌛	⌛	⌛
h) Opt out in Primary Use	✗	⌛	✓	⌛	✓	✓	⌛	⌛

✓ Yes

⌛ In progress

✗ No

? Unknown at this moment

Table 4. Compliance of the xShare Adoption Sites to EHDS article 8.

3.5 xShare Yellow Button

During a deeper analysis and distillation of the Adoption Sites USs (Appendix 3) there was the need to define reference USs to aggregate the Adoption Sites USs and to have a detailed description of the xShare Yellow Button functionalities (section 3.5.1). Then, based on the reference USs, the xShare Yellow Button requirements were elicited and the MVP defined (section 3.5.2). Lastly, the xShare Yellow Button main components were identified (section 3.5.3).

3.5.1 Reference User Stories

The reference USs were defined based on the Adoption Sites USs and the foreseen functionalities of the xShare Yellow Button. Table 5 details the reference USs and its corresponding Adoption Sites USs (when existing). Table 6 presents the out-of-scope reference USs that derived from the Adoption USs and the reasoning to be out-of-scope.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Adoption Sites USs
US1	Data owner	Have the xShare Yellow Button in my healthcare institution portal or app	I want easy access to my health data in EEHRxF (8a & 8d)			
US2	Data owner	Visualise the xShare Yellow Button functionalities	I can easily select the appropriate one			
US3	Data owner	Visualise the list of options (anonymisation, translation, sharing-period, password)	I can select the most appropriate ones			
US4	Data owner	Visualise the list of all operations made with the xShare Yellow Button	I can be fully informed what I have done with my health data			
US5	Data owner	Visualise the available health information per HIDs (e.g., PS,	I can select the appropriate health			AS1_US1, AS1_US2, AS1_US3, AS1_US4, AS1_US5, AS1_US6, AS1_US7. AS2_US1, AS2_US4, AS2_US5, AS2_US6.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Adoption Sites USs
		ePrescription) organised in a tree structure	data to download or share			AS3_US1, AS3_US2, AS3_US3, AS3_US4, AS3_US5, AS3_US6, AS3_US7, AS3_US12, AS3_US14, AS3_US15. AS4_US1, AS4_US2, AS4_US3, AS4_US4, AS4_US5, AS4_US19. AS5_US1, AS5_US2, AS5_US3, AS5_US4, AS5_US5, US5_US9, AS5_US10, AS5_US11. AS6_US1, AS6_US2, AS6_US3, AS6_US4, AS6_US11, AS6_US12. AS7_US1, AS7_US2, AS7_US3, AS7_US6. AS8_US1, AS8_US17.
US6	Data owner	Visualise the available data groups (e.g., Allergy) within one selected HID organised in a tree structure	I can select the appropriate health data to download or share			AS3_US4, AS3_US7. AS4_US1, AS4_US2, AS4_US3, AS4_US4, AS4_US5, AS4_US19. AS5_US1, AS5_US2, AS5_US3, AS5_US5, US5_US9, AS5_US10, AS5_US11. AS6_US1, AS6_US2, AS6_US3, AS6_US4, AS6_US11, AS6_US12. AS7_US3. AS8_US1.
US7	Data owner	Visualise the available data fields or data elements (e.g., Allergy Description) within one selected data group organised in a tree structure	I can select the appropriate health data to download or share			AS3_US4, AS3_US7. AS4_US1, AS4_US2, AS4_US3, AS4_US4, AS4_US5, AS4_US19. AS5_US1, AS5_US2, AS5_US3, AS5_US5, US5_US9, AS5_US10, AS5_US11. AS6_US1, AS6_US2, AS6_US3, AS6_US4, AS6_US11, AS6_US12. AS7_US3. AS8_US1.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Adoption Sites USs
US8	Data owner	Be informed about the reasons in case some data are not available	I know why I cannot access my data digitally			EHDS
US9	Data owner	Select the download functionality	The selected data is automatically stored in my device, and I can share or process them			AS1_US1, AS1_US2, AS1_US3, AS1_US4, AS1_US5, AS1_US6, AS1_US7. AS2_US1, AS2_US5, AS2_US6. AS3_US5, AS3_US14, AS3_US15. AS4_US5, AS4_US19. AS5_US1, AS5_US2, AS5_US3, AS5_US4, AS5_US5, US5_US9, AS5_US10, AS5_US11. AS6_US1. AS7_US2, AS7_US6.
US10	Data owner	My health data to be downloaded in the EEHRxF	I can send my data to any recipient I trust and is ready to receive it properly			AS1_US2, AS1_US3, AS1_US4, AS1_US5, AS1_US6, AS1_US7. AS2_US5, AS2_US6. AS3_US5, AS3_US15. AS4_US5. AS5_US1, AS5_US2, AS5_US3, AS5_US4, AS5_US5, US5_US9, AS5_US10, AS5_US11. AS6_US1. AS7_US2, AS7_US6.
US11	Data owner	My health data to be downloaded in human readable format	I can visualise my health data and share it or send it to any recipient I trust			AS1_US1, AS1_US2, AS1_US3, AS1_US5, AS1_US6, AS1_US7. AS2_US1, AS2_US5, AS2_US6. AS3_US5, AS3_US14, AS3_US15. AS4_US5, AS4_US19. AS5_US1, AS5_US2, AS5_US3, AS5_US4, AS5_US5, US5_US9, AS5_US10, AS5_US11.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Adoption Sites USs
						AS6_US1. AS7_US2, AS7_US6.
US12	Data owner	Establish a consent directive	The party named in the consent directive (person or system) can access the data I have decided to share with them			AS3_US1, AS3_US2, AS3_US3, AS3_US6, AS3_US7, AS3_US12. AS4_US1, AS4_US2, AS4_US3, AS4_US4. AS6_US2, AS6_US3, AS6_US4, AS6_US11, AS6_US12. AS8_US1, AS8_US4, AS8_US5, AS8_US17.
US13	Data owner	Be informed about any operations over my data for sharing purposes	I can understand what happens with my data			AS4_US10. AS8_US4, AS8_US5.
US14	Data owner	Visualise the sharing result	I can know that the sharing was successful or not			
US15	Data owner	Be able to anonymise my data	I can be able to share my data without compromising my identity			AS1_US6, AS1_US7. AS2_US6. AS5_US11. AS8_US1, AS8_US17.
US16	Data owner	Be able get my health data digital signed	I can be able provide provenance over my health data			
US17	Data owner	Be able to password protect my data	The are not unauthorised accesses when stored at my devices			
US18	Data owner	Translate my data to other language	I can show it in another country (e.g., vacations) or a			AS3_US2. AS5_US1.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Adoption Sites USs
			healthcare professional can easily understand it			
US19	Data owner	Have the possibility to opt-out (stop sharing)	I can revoke any established sharing and request deletion of my stored data at the receiving part			AS8_US7.
US20	Data owner	Have the possibility to block access to my health data	I can restrict or deny access of a specific health data recipient			AS8_US7.
US21	Data owner	Select the linked options functionality	I can authorise a health data subscription with a verified trusted recipient or app			AS3_US4, AS8_US11.
US22	Data owner	Have the possibility to generate a QR code with the health data	I can present my consented shared health data upon a QR scan			AS3_US4.
US23	Data owner	Visualise the sharing list	I can verify all my sharing sessions, include the active ones			AS7_US4, AS7_US5.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Adoption Sites USs
US24	Authorised health data recipient	Citizen health data that is shared with me or my organisation to be accessible in my EHR system in EEHRxF	I can be timely and accurately informed when I provide care to my citizen (7a & 8b)			AS2_US2, AS2_US3. AS3_US8, AS3_US9, AS3_US10, AS3_US11. AS4_US12, AS4_US14, AS4_US16. AS5_US6, AS5_US7, AS5_US8. AS6_US5, AS6_US6, AS6_US7, AS6_US8, AS6_US9, AS6_US10. AS8_US11, AS8_US13, AS8_US15.
US25	Authorised health data recipient	Citizen health data that is shared with me or my organisation is translated in my native language	I can easily understand it			AS3_US8.
US26	Authorised health data recipient	Citizen health data that is continuously shared with me to be updated with the new information	I can have the most recent information of my citizen to evaluate its progress and/or have more complete datasets for research organisations			AS3_US9. AS8_US11, AS8_US13, AS8_US15.
US27	Authorised health data recipient	Be informed about any missing/omitted health data shared with me (e.g., specific sections of a Patient Summary are omitted)	I can take an informed decision			

Table 5. Reference USs and its corresponding Adoption Sites USs.

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Comments
US28	Authorised health data recipient	Make available a citizen portal/app	My citizens can have access to their health data.			AS4_US7 This is a xShare Yellow Button pre-requirement, i.e., there must be a citizen portal / app to include xShare Yellow Button.
US29	Authorised health data recipient	Measure and track performance indicators	I can improve resources, clinical quality and efficiency			AS4_US8, AS4_US11 Organisation task, not for the xShare button
US30	Authorised health data recipient	Manage appointment scheduling and reminders	I can reduce administrative burden for staff and improve citizen adherence		-	AS4_US9 Organisation task, not for the xShare button
US31	Data owner	Be able to share my health with a clinical trial eligibility app	I can be informed with new clinical trial that I am potentially eligible for, contact the hospitals with clinical trials matches, get an appointment, etc.			AS8_US2, AS8_US3, AS8_US6, AS8_US8 Must be a 3rd party app / organisation managing clinical trials.
US32	Authorised health data recipient	Be able to contact citizen available for clinical trials	I can be informed with available ones, schedule an appointment, etc.			AS8_US9, AS8_US10, AS8_US12, AS8_US14, AS8_US16 Must be a 3rd party app / organisation managing clinical trials.
US33	Data owner	Report adverse drug reactions to a central repository	I contribute to the monitoring of drug safety and identify potential risks, with an improved medication safety for all citizens			AS4_US6 Institution task not for the button

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related basic Functionality	Comments
US34	Authorised health data recipient	Flag potential medication interactions	Reduce the risk of adverse drug reactions, with an improved citizen safety and medication management			AS4_US13 This task is done on the healthcare institution, not with the button
US35	Authorised health data recipient	Collaborate with citizens on setting realistic and achievable health goals	Increase citizen buy-in and commitment to treatment plans, with an improved treatment outcomes and citizen satisfaction			AS4_US15 Download functionality is only available for the citizen
US36	Authorised health data recipient	Interact with specialist consultations virtually	Access expert evaluations for complex cases and improve citizen care coordination, with a facilitated access to specialized care for citizens, especially in remote areas			AS4_US17 Only citizen can share data
US37	Data owner	Share my anonymised data to advocate for policy changes that promote public health initiatives	I contribute to a healthier community through public health policy changes, with an Improved population health outcomes and disease prevention			AS4_US18

Table 6. Out-of-scope reference USs.

3.5.2 Requirements and MVP

In this section, each one of the elicited requirements (Table 7) is described through the following attributes:

- **ID**: the unique identified of the requirement (used in the previous table to refer to the requirement).
- **Title**: a short description of the requirement.
- **Main actor(s)**: the user that triggers the functionalities described by the requirements or that is the main beneficiary of the functionality.
- **Description**: what is the expected behaviour/action, who triggers the behaviour (a human actor or a system), which are the input data, which are the output data and who will receive them.
- **Related basic functionality**: the xShare Yellow Button that the requirement refers to, i.e., Download ( ), One-time share ( ), and Linked options ( ).
- **F/NF**: Indicates if the description refers to a functional or non-functional requirement. The possible values are:
  - F: Functional requirement, i.e., any action performed by the SW application in correspondence of specific events (including user interactions).
  - NF: Non-functional requirement, i.e., constraint that must be fulfilled by the implementation of several functional requirements.
- **Target**: indicates in which version of the project results the functional requirement or be implemented or specified (xShare Yellow Button MVP). The possible values are:
  - D3.5 *xShare Button Demonstrators - Interim 1* (M18).
  - D3.6 *xShare Button Demonstrators - Interim 2* (M24).
  - D3.8 *xShare Button Demonstrators - Interim 3* (M30).

As for the MVP, the target column indicates which of the requirements the technical teams will be focused on for the three demonstrator releases. It is worth notice that despite the Download functionality is planned for the Demonstrator 1, some Adoption Sites might not be able to provide access to all HIDs at that time. But, for an Adoption Site that all the citizen HIDs are accessible, Demonstrator 1 will allow to download all the HIDs data. As for the other HIDs in that or others Adoption Sites, the HIDs will be provided according to the Adoption Site availability.

ID	Title	Main actor	Description	Related Basic Functionality	F/NF	Target D3.5 (M18) / D3.6 (M24) / D3.8 (M30)
1.1	**Accessibility**	Citizen	xShare Yellow Button must be easily accessible from the healthcare provider's portal/app (user interface)		NF	D3.5
1.1.1	Web/app accessibility of health data	Toolbox	The health data in human accessible form shall comply to web/app accessibility guidelines mandated by the European Commission		F	D3.5
1.2	**Logging**	Citizen	xShare Yellow Button must allow to visualise all operations made by the Citizen		NF	D3.5
1.3	**Function Selection**	Citizen	On xShare Yellow Button press, the citizen must be able to select the appropriate functionality: *Download, One-time share, Linked options*		F	D3.5
1.4	**Data Transformation**	Citizen / Toolbox	The citizen must be able to select a set of transformations to apply to the data being manipulated		NF	D3.6
1.4.1	(Pseudo) Anonymisation	Citizen / Toolbox	The operation will strip the selected data of any identifiable information		F	D3.8
1.4.2	Translation	Citizen / Toolbox	The operation will translate the selected data to a selected language		F	D3.6
1.4.3	Password Protected	Citizen	The operation will protect the selected data with a citizen defined password		F	D3.8

ID	Title	Main actor	Description	Related Basic Functionality	F/NF	Target D3.5 (M18) / D3.6 (M24) / D3.8 (M30)
1.5	**Data Selection**	Citizen	The xShare Yellow Button will be able to display the available HIDs for the citizen		F	D3.5
1.5.1	HID Grouping	Toolbox	The xShare Yellow Button will provide a set of available HIDs to select from		F	D3.5
1.5.1.1	Document Grouping	Toolbox	The xShare Yellow Button will provide a set of available Documents to select from a specific HID Group		F	D3.8
1.5.1.1.1	Document Fields	Toolbox	The xShare Yellow Button will provide a set of available Document Fields to select from a specific Document		F	D3.8
1.5.2	Data Unavailability	Toolbox	The xShare Yellow Button will provide a reason for data that exists on the system but cannot be accessed through the xShare Yellow Button mechanism		NF	D3.8
1.6	**Format Selection**	Citizen	The citizen is able to select the document format: EEHRxF and/or human readable format		F	D3.5
1.6.1	EEHRxF Format	Toolbox	The selected data is transformed into the EEHRxF (experimental or final format)		F	D3.6

ID	Title	Main actor	Description	Related Basic Functionality	F/NF	Target D3.5 (M18) / D3.6 (M24) / D3.8 (M30)
1.6.2	Human Readable Format	Toolbox	The selected data is transformed into a human readable format		F	D3.5
1.6.2.1	EEHRxF Embed	Toolbox	The human readable format can contain the selected data embedded in EEHRxF		F	D3.8
1.6.3	Digital Signature	Toolbox	The selected file format is digital signed		F	D3.8
2.1	**Download**	Toolbox	The citizen must be able to download their health data		NF	D3.5
2.1.1	Store Location	Citizen / Toolbox	The selected data will be stored in the select ed format in a citizen defined location		F	D3.5
3.1	**Sharing**	Citizen	The citizen must be able to share their data with trusted ones or apps		NF	D3.5
3.1.1	Consent	Citizen	The citizen must be able to consent for their data to be shared with trusted ones or apps of their choice		NF	D3.5
3.1.1.1	Revoke Consent	Citizen	The citizen is able to revoke data sharing		F	D3.6
3.1.2	Subscription Authorisation	Citizen	The citizen must be able to enable trusted ones or apps to receive notifications when new data is available		NF	D3.6

ID	Title	Main actor	Description	Related Basic Functionality	F/NF	Target D3.5 (M18) / D3.6 (M24) / D3.8 (M30)
3.1.2.1	Subscription Period	Toolbox	The data owner will define a time period for which new data notifications are active for the data recipient		F	D3.8
3.1.2.2	Revoke Subscription	Citizen	The citizen is able to revoke their data subscription authorisation		NF	D3.8
3.1.3	Authorised Data Recipient	Citizen	The citizen must be able to select the authorised recipient or apps for the shared data		NF	D3.6
3.1.4	Data Sharing Log	Citizen	The citizen has access to every sharing event performed through the sharing mechanism		NF	D3.6
3.1.5	Data Access Log	Citizen	The citizen must be informed about any access to the shared data		NF	D3.8
3.1.6	Restrict Access	Citizen	The Citizen must be able to restrict access to a specific HCP		NF	D3.8

Table 7. xShare Yellow Button requirements and MVP.

The following figures, provide a better understanding and visualisation of the requirements used in each of the xShare Yellow Button basic functionality, i.e., Download (Figure 4), One-time share (Figure 5), and Linked options (Figure 6). The requirements have three colour codes according to their target, namely: light blue (D3.5, M18), blue (D3.6, M24), and dark blue (D3.8, M30).

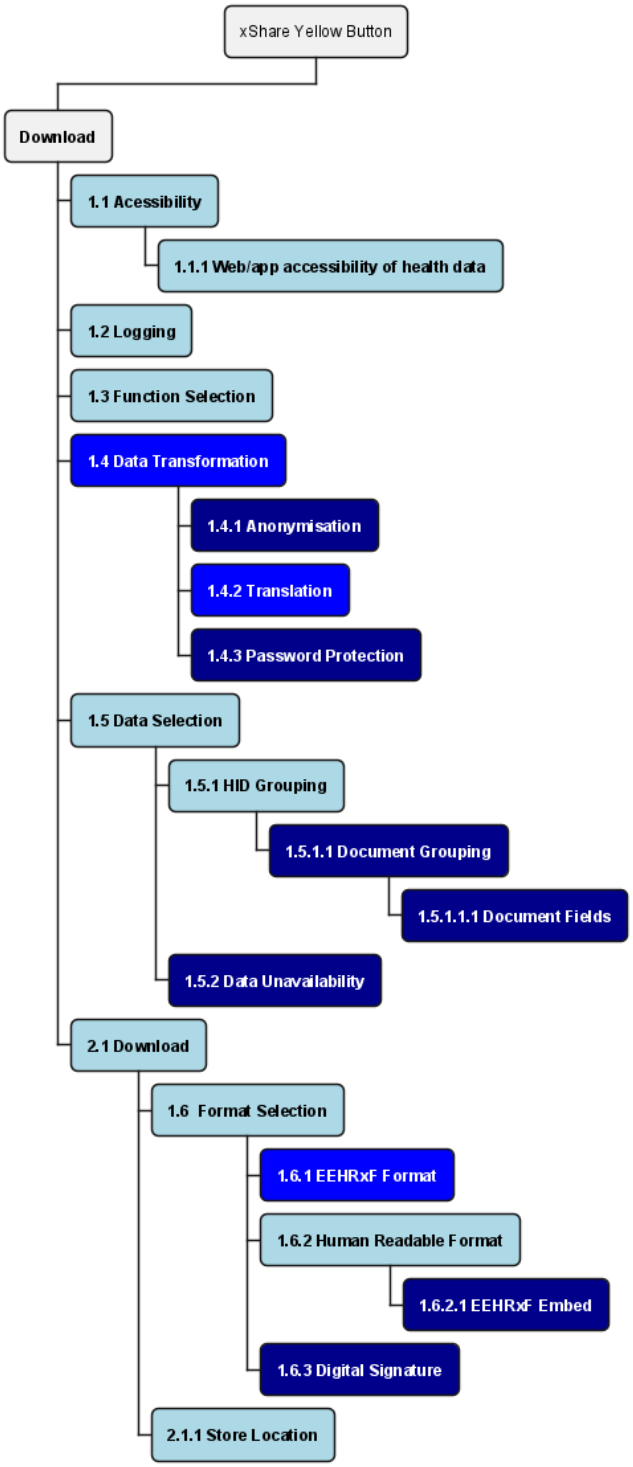

Figure 4. xShare Yellow Button download requirements.

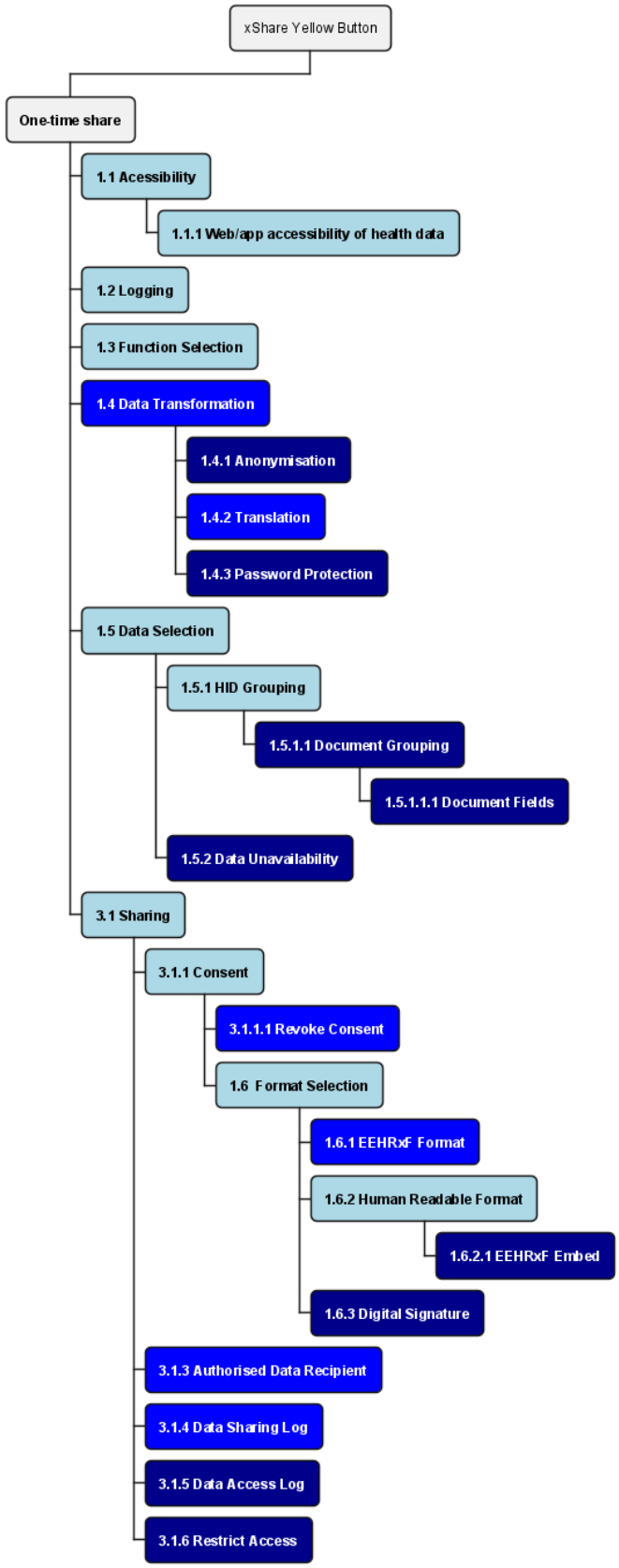

Figure 5. xShare Yellow Button one-time share requirements.

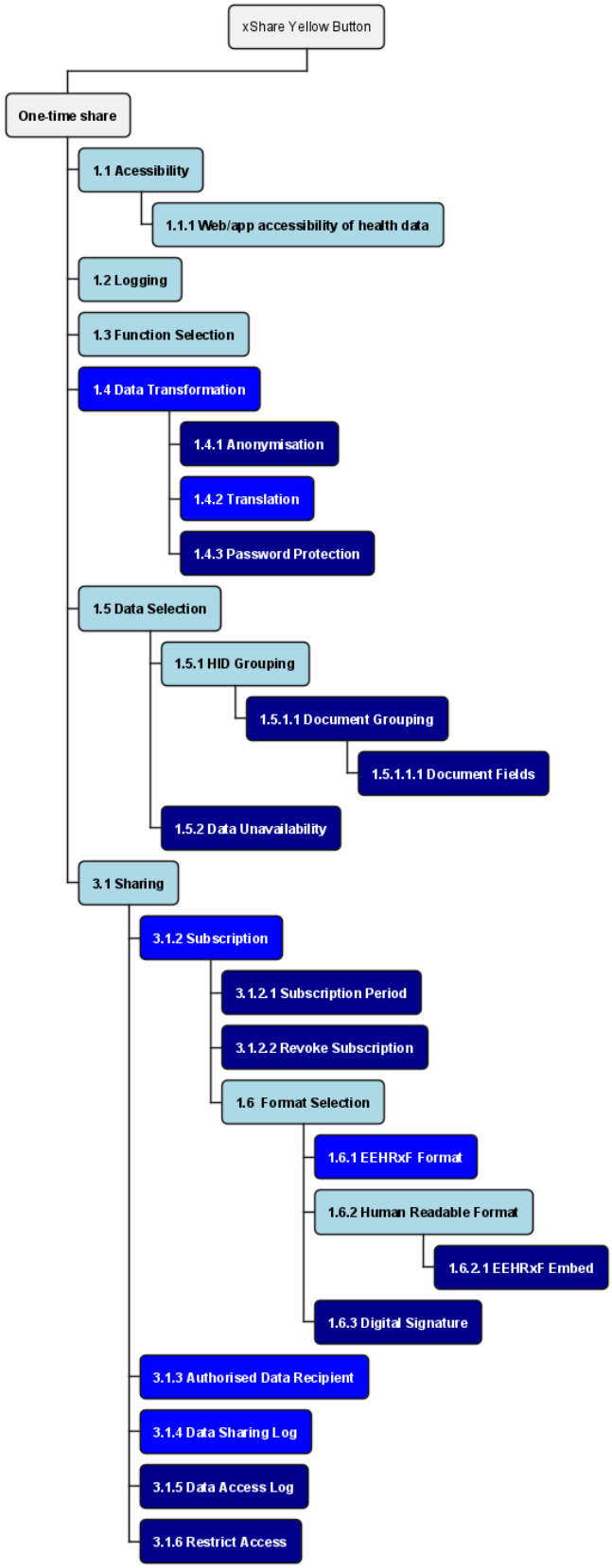

Figure 6. xShare Yellow Button linked options requirements.

3.5.3 Main components

Figure 7 provides an overview of the main components identified based on the reference USs and the elicited requirements. The initial version of the xShare Yellow Button reference architecture and a full description of each of the identified components will be presented in D3.3 *xShare toolbox for data portability under GDPR - Interim 1* (M12). It is worth notice that these components identified in D3.2 result of an initial analysis that will go deeper in T3.2 *xSHARE toolbox for data transformation and data donation* in the upcoming months and can be modified.

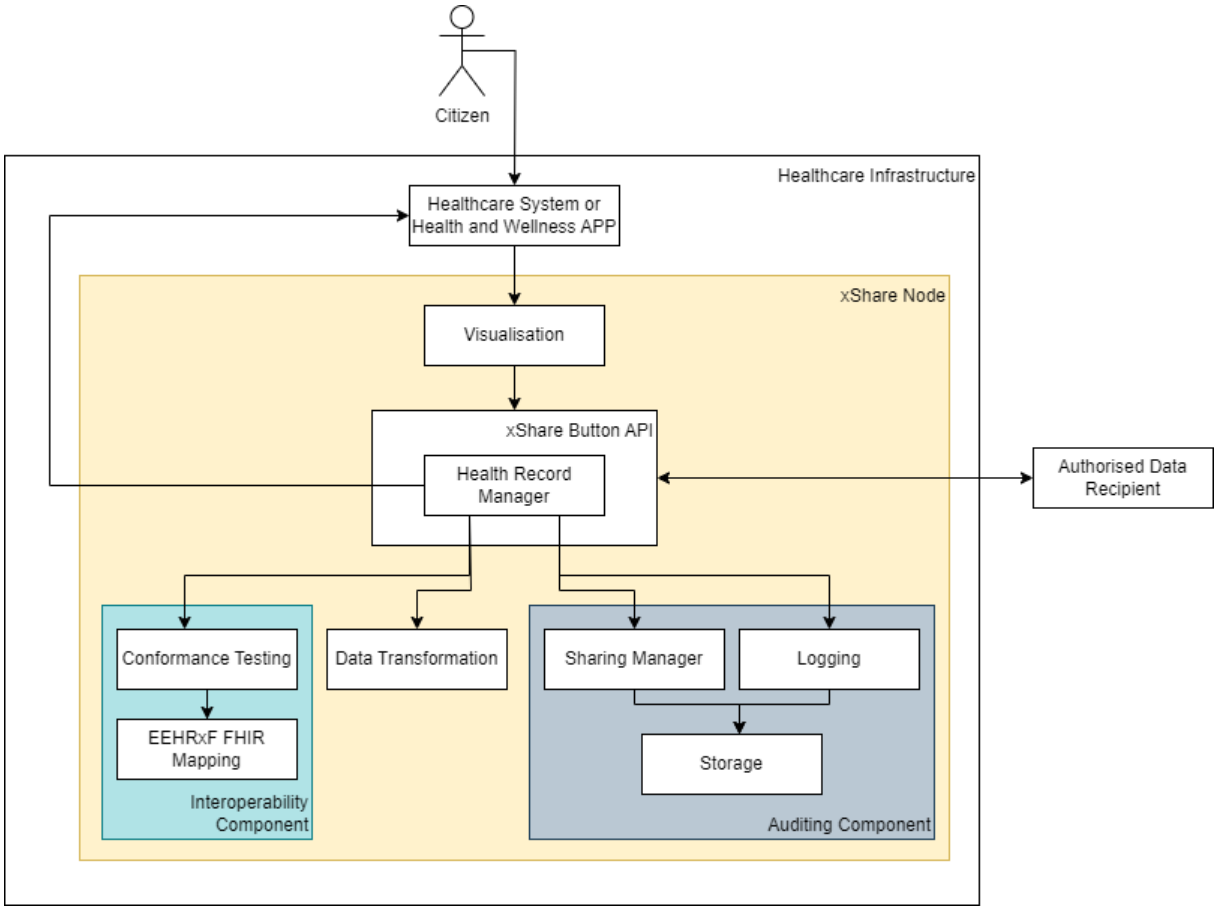

Figure 7. xShare Yellow Button main components identified.

Following is a short description of the main components identified:

- **Healthcare Infrastructure**: The system boundary defining the domain of the healthcare institution.
- **Healthcare System or Health and Wellness APP**: The healthcare institution's own system which is outside the xShare scope or a health and wellness app ecosystem.
- **xShare Node**: The part of the system developed within the scope of xShare and deployed in the Healthcare Infrastructure.
- **Visualisation**: Enables the visualisation and interaction with the xShare Yellow Button
- **Button API**: The components that expose the xShare Yellow Button functionalities to components external to the xShare system. It also exposes the interface that allows and controls the sharing of individual resources with Authorised Data Recipients.

- **Health Record Manager**: Directly accesses a resource in the proposed exchange format (or in a non-EEHRxF format accompanied with a clear specification or implementation guide).
- **Authorised Data Recipient:** The authorised healthcare institution, trusted one, or app, with whom the health data is shared.
- **Data Transformation**: Provides the generally defined functionality for modifying the selected resource format. This includes translation, password protection, and anonymisation.
- **Interoperability Component**: Provide a conversion between the healthcare record's format and the EEHRxF.
- **Conformance Testing**: Tests if the healthcare institution health record is conformant with the EEHRxF FHIR format.
- **EEHRxF FHIR Mapping**: Converts between the healthcare record's "native" format and the EEHRxF FHIR format.
- **Auditing Component**: This component is used to record auditable events.
- **Sharing Manager**: Allows the establishment and revocation of sharing rules within the system. It will also respond to queries regarding a resource sharing status.
- **Logging**: records all the operations executed within the Button API.
- **Storage**: A data storage solution to provide resilience.

4. Conclusions

D3.2 *xShare Data portability business use case, validation process, and localisation requirements – Final* reports the results achieved up to M06 in T3.1 *Business service use cases for continuity of care, under WP3 Patients' Right to Data Portability: the case of continuity of care*.

A detailed assessment on the xShare project Adoption Sites' needs and challenges was performed using a co-creation approach, in the form of Adoption Site-specific BUCs and USs. A total of 94 USs were collected from the 8 Adoption Sites, covering the three xShare Yellow Button basic functionalities (download, one-time share, and linked options).

A set reference USs were defined based on the Adoption Sites USs and the foreseen functionalities of the xShare Yellow Button. Then a set of requirements was defined for the xShare Yellow Button as a result of the reference USs analysis. The MVP was defined by assigning each of the xShare Yellow Button requirements into one of the three releases of the xShare Yellow Button demonstrators (M18, M24, and M30). Lastly, an overview of the xShare Yellow Button main components was identified based on the reference USs and the elicited requirements. The initial version of the xShare Yellow Button reference architecture and a full description of each of the identified components will be presented in D3.3 *xShare toolbox for data portability under GDPR - Interim 1* (M12).

Appendix 1: Madeira Workshop

This workshop was held, pivoting towards a comprehensive discussion on mechanisms for ensuring secure health data sharing, particularly through the adoption of the xShare Yellow Button and how it will contribute to bring EHDS to reality. Also, the session focused on the results achieved within the xShare Adoption Sites, particularly their business use cases, the requirements identified. An open exercise with the audience was operationalised to gather additional requirements. In the end, the results obtained were wrapped up in order to extract concrete conclusions on what are the necessary steps for accelerating the EEHRxF adoption. This workshop was held at the Madeira Digital Transformation Week on June 27th, 2024, in Madeira (Portugal)[4].

A similar session in the scope of XpanDH project was also scheduled, aiming to explore the significance of the EEHRxF as an essential conduit for health data exchange across Europe, underscoring its benefits for citizens and their rights to access their health information. Divided into two distinct segments, the workshop will firstly delve into an introductory exploration of the EHDS, emphasizing the pivotal role of EEHRxF within this framework. This section encompassed an analysis of the associated ecosystem and methodologies for evaluating maturity levels in EEHRxF implementation. In addition, results of adoption efforts made around the EEHRxF in XpanDH were presented and the audience was engaged in an open exercise together to identify further efforts, main challenges and barriers. The agenda for both sessions was as follows:

- **Part I: Xpanding EHRxF**
    - The EHRxF as Building Block for the EHDS
    - How to progress with the implementation ecosystem
    - How to assess maturity and evolve
    - Bubbling around the format: results achieved
    - Open exercise: collecting further efforts, challenges and barriers
- **Part II: Enabling safe share of health data**
    - The xShare Yellow Button for Health data exchange
    - From vision to reality: Adoption sites and overall challenges, aims and requirements
    - Open exercise: confirming requirements and collecting new ones

Part 2 of the workshop started with an introduction to the xShare Yellow Button. Then, the Adoption Sites presented their aim, scenarios (AS-IS and TO-BE), their requirements, and the challenges and barriers for the xShare Yellow Button adoption and implementation. Lastly, an open exercise with multiple questions (using Mentimeter[5]) was carried out to collect the audience feedback regarding the EEHRxF and the xShare Yellow Button.

The participants started by ordering the most important HIDs for health data sharing (Figure 8), followed by the most relevant xShare Yellow Button basic functionality (Figure 9). As can be observed

[4] Madeira Digital Transformation Week [Internet]. mdtweek.digit-madeira.pt. [cited 2024 May 15]. Available from: https://mdtweek.digit-madeira.pt/

[5] Mentimeter. Interactive presentation software [Internet]. Mentimeter. 2019. [cited 2024 August 5]. Available from: https://www.mentimeter.com/

in Figure 9 (and conflicting with the Adoption Sites analysis in section 3.4), linked options was the most selected option, with one more vote than download, while one-time share was less selected option. After some interactions with the participants, the conclusion was that was a misunderstanding regarding the xShare Yellow Button basic functionalities description and they were in fact considering download as the most important basic functionality, followed by one-time share, and linked options as the latter one.

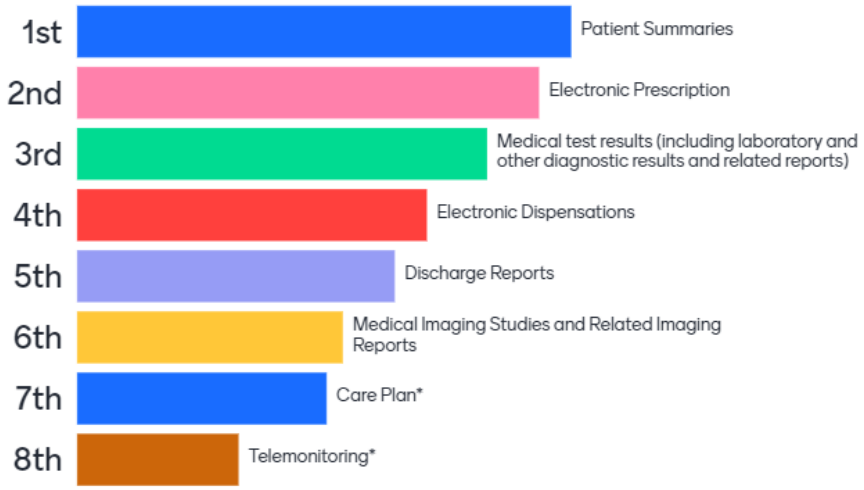

Figure 8. HIDs ordered by importance for health data sharing.

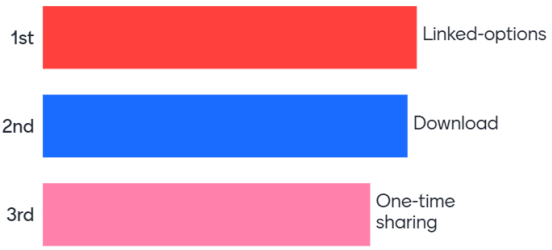

Figure 9. xShare Yellow Button basic functionalities ordered by importance for health data sharing.

The participants also prioritised the xShare Yellow Button requirements that were initially elicited in D3.1 (Figure 10). Then, additionally important requirements were provided by the audience, namely:

- Opt-in and opt-out.
- Semantics integration.
- Give access for next of kin people.
- Provide access to caregivers.
- Security consent.
- Real-time data.
- Expedience.
- Data portability.
- Must be in line with and embedded in EU concepts on health sharing and other services.

- Explanation of storing and responsibility of personal Health Data.
- Revoke sharing.
- Information to patient when data has been used in research.

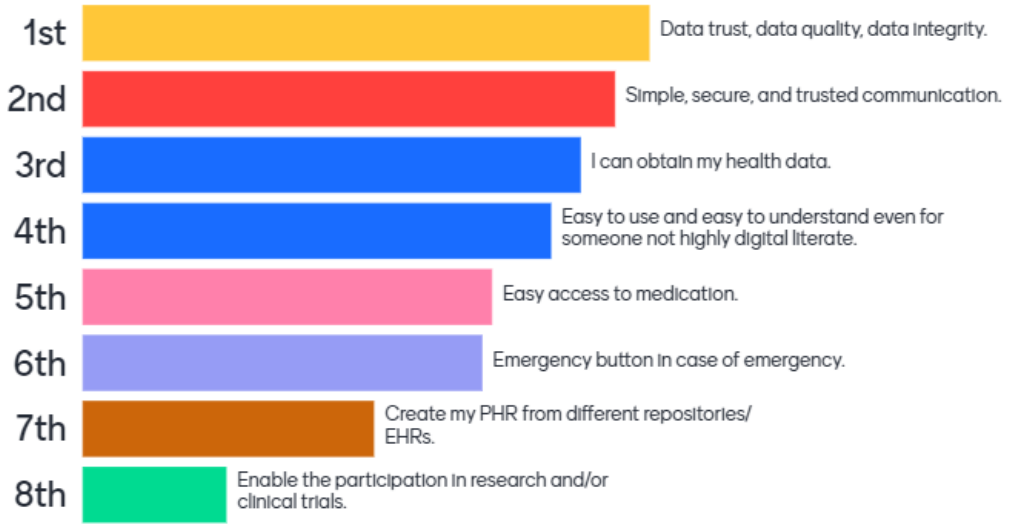

Figure 10. xShare Yellow Button requirements ordered by importance.

A second set of questions where more focused to collect information regarding the HIS known and being used by the audience. From the answers, 50% of the HIS are proprietary, while the other 50% are "home-made". Lastly, the HIS were classified according to their integration levels, divided by intra-organisation, inter-organisation, national level, and cross-border (Figure 11). As can be observed in Figure 11, the wider the healthcare context, the lower level of integration. Both intra- and inter-organisation, there is already some level of integration and even a fully integrated system. As the context wides for national and cross-border, the level of integration starts to decrease.

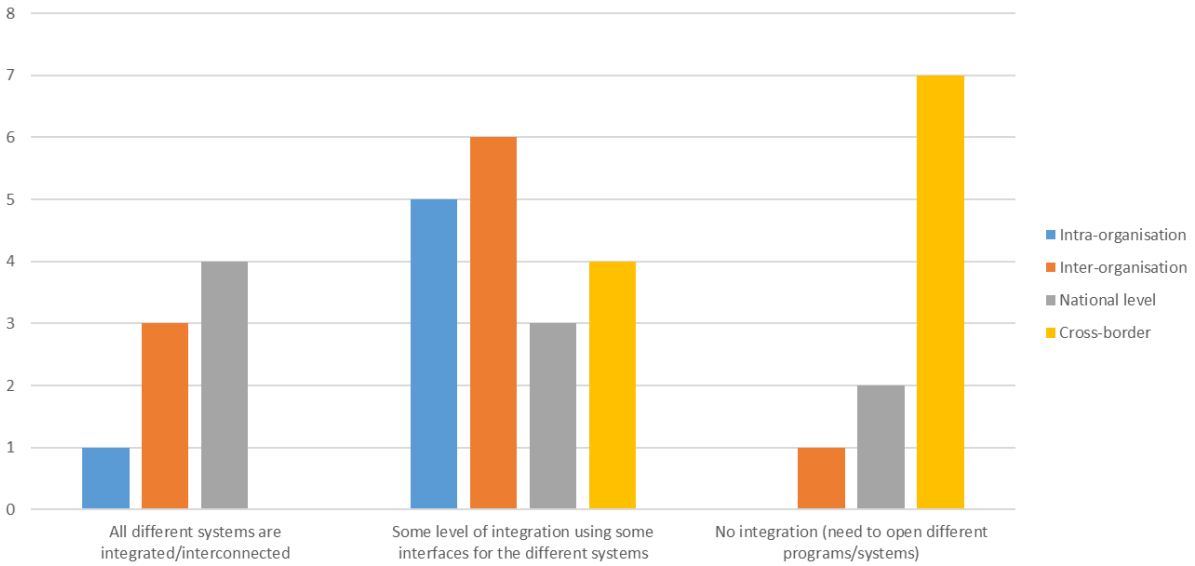

Figure 11. HIS integration levels.

To close the exercise, we asked the participants their organisations and their organisations' countries (Figure 12). The organisations involved in the exercise were:

- **Healthcare institutions and organisations:**
  - ULS Santo António
  - SRS
  - Slovakia National Authority
  - OKFO (National Healthcare Service Centre Hungary)
  - HSE Ireland
  - MedCom
- **SMEs:**
  - Binary scope solutions
  - Telemedicine Technologies
  - Gnomon Informatics
- **SDOs:**
  - IHE Europe
- **Academic:**
  - ISCTE
  - University of Cyprus
- **Research and non-profit organisations:**
  - UNINOVA
  - Empirica Technology Research
  - EHMA (European Health Management Association)

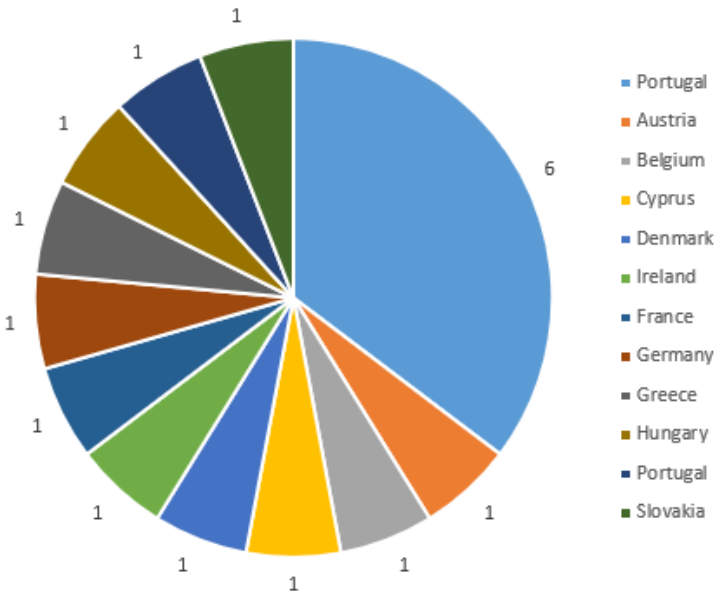

Figure 12. Participants' countries.

As concluding remarks of this open exercise, some “cautions” conclusions might be drawn. As previously observed, the majority of the participants were Portuguese, which might have given Portuguese-biased information. Nevertheless, the open exercise allowed to confirm some of the D3.1 previous findings, eliciting new requirements, and assist in defining the xShare Yellow Button next steps.

Appendix 2: Adoption Sites BUCs description and USs identification

This section provides an overview of the xShare Adoption Sites. Each Adoption Site section provides a short introduction to the Adoption Site, the Adoption Site compliance to EHDS article 8, and lastly their BUCs and US that resulted from the co-creation approach. The Adoption Sites BUCs can be updated during the project lifetime, and it most updated version can be found at the IHE Europe Use Cases Repository[6].

Greece (AS1)

Introduction

Electronic Governance of Social Security and Health Services (IDIKA SA) is a public owned company, supervised by the Greek Ministry of Digital Governance, specialized in IT products for Social Security, Welfare and Health Services. Its main objective is to design, develop, operate, and support IT systems for the Social Security Funds and HealthCare Service Organizations in Greece. Its main activities focus on service-oriented computing, development, maintenance of electronic services in Social Security and Health.

IDIKA is responsible for and operates the largest nation-wide projects in the IT area, such as the National Social Security Number Registry (AMKA), the National ePrescription System in Greece, with 100% coverage of pharmacies and doctors, the National EHR System, the ERP system of 14 public hospitals, the National System for Medical Appointments in Primary Care and the National Registry for Insured Persons and Insurance History and capacity “ATLAS”.

In the cross-border domain, IDIKA acts as both the National Contact Point for eHealth (NCPeH) and Social Security (EESSI Access Point). Through the CEF funding, it has currently implemented the Cross Border ePrescription and Patient Summary scenarios.

In the health sector, in cooperation with the Greek Ministry of Health, IDIKA provides approximately 30 IT systems, including the MyHealth mobile app for citizens, national patient registries, medical certificates, primary health care system apps, hospital information systems and many more. IDIKA’s main Health IT Systems (National ePrescription System and National EHR System) serve:

- ~11 million persons (whole population of Greece)
- 50.000 doctors (all doctors, both in public and private sector)
- 10.500 pharmacists (all pharmacists)

EHDS compliance – Article 8

IDIKA implements eHealth Information Systems on behalf of the Greek Ministry of Health, in accordance with the applicable legal framework and the guidance of the Ministry.

- *Article 8a – Right of natural persons to access their personal health data*

[6] Use Case Repository [Internet]. Ihe-europe.net. 2020 [cited 2024 Sep 4]. Available from: https://usecase-repository.ihe-europe.net/ .

In Greece natural persons have already access to their personal health data electronically, via the following ways:

- National EHR System (web page).
- MyHealth App (mobile application for Greek citizens).
- Submission of an access right request to IDIKA SA.

- *Article 8b – Right of natural persons to insert information in their own EHR*

There is currently no legal framework allowing natural persons to insert data in their own EHR.

- *Article 8c – Right of natural persons to rectification*

Currently there is no possibility for natural persons to request rectification of their own data online. However, a natural person may submit a rectification request to IDIKA and the request shall be examined and processed accordingly.

- *Article 8d – Right of data portability for natural persons*

A doctor providing health services to a patient at a given time already has access to the electronic health data of the patient, on a basis of provision of healthcare services, according to the GDPR, via the:

- National EHR System
- National ePrescription System

However, there is currently no way for a natural person to electronically transmit its own health data.

- *Article 8e – Right of restrict access*

There is currently no legal framework allowing natural persons to restrict all or part of their health data, while accepting healthcare services.

- *Article 8f – Right of obtain information on accessing data*

Currently natural persons can view any accesses to their health data via the logs that are documented in the National EHR system and the National ePrescription System and are accessible in their profile.

- *Article 8g – Electronic health data access services for natural persons and their representatives*

In Greece natural persons have already access to their personal health data electronically, in national level, without charge, via the following services:

- National EHR System (web page)
- MyHealth App (mobile application for Greek citizens)

Representatives can only exercise access rights via submission of an access right request to IDIKA.

- *Article 8h – Right of natural person to opt out in primary use*

There is currently no legal framework allowing natural persons to opt out healthcare professionals from accessing their health data, while providing healthcare services to them.

Person downloading its own health data (AS1_BUC1)

The primary objective of the following BUC is for the natural persons to receive their health data in electronic format, to utilize it for any purpose, both for primary and secondary use.

Overview		
Use Case Acronym	AS1_BUC1	
Document Version	V1.0	
Current situation		
As-Is Situation		
• Persons have access to their own health data through the EHR System and the MyHealth mobile app. They cannot share (in Greece or abroad) or “donate” their data. • Doctors in Greece have access to patient data through the EHR System (web or via API). • Health data are provided for research only in public sector, through Ministry of Health.		
Currently available products/services and its vendors		
National EHR system, MyHealth app		
Which health-related standard does your organisation uses and its alignment to the EEHRxF?		
Application of the EEHRxF to the new National EHR System.		
Use Case		
Actors/Users and their Roles	Patient	Final user: get data in the EEHRxF
	Health Professional, treating the patient	Use patient health data in EEHRxF
	Third Health Professional	Give second opinion on patient health data in EEHRxF

	Pharmaceutical companies, Research & Innovation Organizations, etc.	Uses patient anonymised health data in EEHRxF
	EHR app	Incorporate the xShare Yellow Button in web and API
	MyHealth mobile app	Incorporate the xShare Yellow Button
	Third Party apps	Consume patient data in the EEHRxF

Use Case Description

This is a patient mediated use case, initiated by the patient, following his identification via the national eGOV infrastructure. Patient will receive health data, in a structured coded format, that will be ready to be shared.

When patient view their health data in the EHR System or the MyHealth app, the xShare Yellow Button will be available, for them to get their data. They will be prompted if they need to extract the data or to donate for research etc. In both cases they will also be asked in which sections of data are they interested.

An xShare service will be created, to give patient access, after identification, to EEHRxF enabled EHR data, in a structured format (CDA/FHIR). The service can be integrated in the MyHealth@EU services, to ensure MVC compliance for cross border use in the EU.

User Perspective

Patient will receive health data, in a structured coded format, that will be ready to be shared. Data will also be available in PDF, with QR code.

This is a patient mediated use case, initiated by the patient, following his identification via the national eGOV infrastructure.

System Perspective

When patient view their health data in the EHR System or the MyHealth app, the xShare Yellow Button will be available, for them to get their data. They will be prompted if they need to extract the data or to donate for research etc. In both cases they will also be asked in which sections of data are they interested.

An xShare service will be created, to give patient access, after identification, to EEHRxF enabled EHR data, in a structured format (CDA/FHIR). The service can be integrated in the MyHealth@EU services, to ensure MVC compliance for cross border use in the EU.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary	X			3	6
Electronic prescription	X			3	6
Electronic dispensation	X			3	6
Medical image and image report	X			1	3
Laboratory results	X			3	6
Discharge report	X			3	6
Telemonitoring					
Care plan					

Details

National/regional strategy

The next two years a new National EHR System will be implemented, according to the EEHRxF. There will be available both a web and a mobile application for patient access.

Strategy towards EHDS

The Hellenic Ministry of Health and IDIKA participate to the Actions for Primary and Secondary use of Health Data, as to be aware of the work progress in EHDS and prepare for taking actions to conform the National EHR System to the EHDS Regulation.

Business Goals/Benefits and KPIs

The primary business goal is to empower citizens, by providing them electronic copy of their health data, enabling them to benefit from services outside the national health systems (ePrescription System, EHR System).

KPIs:

- Number of persons that have pressed the xShare Yellow Button and downloaded their data.
- Number of downloads per HID.
- Average downloads per person per year.

Application	In the EHR System and the MyHealth mobile app
Data Preconditions	Coded data in all sections, formatted according to the EEHRxF

System Preconditions	• Security and Privacy Policies will be studied and applied. • For third party patient apps an eGov patient auth service must be available (not yet).
User Preconditions	Patient: • Create awareness of the xShare Yellow Button. • Will patient have to consent for sharing data (despite the patient identification/authorization process)? • Will patient choose where to anonymise data to donate them?
Trigger	Patients need to extract and share their information from a patient triggered event, such as traveling abroad, healthcare visit outside the NHS, participation in research, donation of data, use of health app etc.
Challenges/Limitations	• Following the EEHRxF to format the data (by all stakeholders). • GDPR issues. • Selection of the right interoperability architecture, such as EUDI Wallet, MyHealth@EU. • Transcoding/translation issues, extensions of the MVC.
Involved stakeholders in the BUC definition	Executives of IDIKA and experts were involved. Other stakeholders have not been yet involved, as this was an initial approach of the BUC.
Application of pseudonymisation filters	Yes

Basic Workflow

1. A patient logs in to the NEHR and is well authenticated.
2. He/she selects the xShare functionality and is redirected to the xShare service.
3. He/she selects which of his/her available data to extract, based on EEHRxF specifications.
4. If he/she needs to send his/her data abroad, via the MyHealth@EU service, documents can be translated (when possible) to the select possible language.
5. A transaction is logged in the NEHR infrastructure, and he/she can now download the data in structured format (CDA/FHIR, etc.) and optionally in PDF.
6. On the web browser he/she may download to a preselected folder locally on his/her computer.
7. On a mobile app via the sharing mechanism files can be shared to any application that can process and read EEHRxF enabled document types and optionally in PDF.
8. The xShare service will have a data donation feature logging this action. Data may (or must) be anonymised on request by the xShare tools.

Alternative Workflows

Same as above but the entry point is Portal B of the MyHealth@EU service.

The PATHED architecture and the EUDI architecture will be evaluated as implementable interoperability architectures.

Table 8. Greece: AS1_BUC1.

AS1 USs

The Greek USs can be found in Appendix 3.

Ireland (AS2)

Introduction

The role and function of the Department of Health (DoH) is to provide strategic leadership for the health service and to ensure that Government policies for the health sector in Ireland are translated into actions and implemented effectively. It supports the Minister and Ministers of State in their implementation of Government policy. Key functions of the DoH include the preparation of national health policy based on identified need, the preparation of legislation, planning and monitoring of financial and manpower resource and monitoring the performance of the health services.

The DoH, along with our Health Service Executive (HSE) colleagues, will contribute its expertise in eHealth policies, strategies, interoperability, and patient-centred integrated care. The DoH and HSE are actively involved with the current CEF project - deployment of Cross Border eHealth Services with a patient centred focus of utmost importance.

The HSE is legally mandated to provide public health and social care services on behalf of the Minister of Health for Ireland's population of 5.2 million citizens. The HSE is Ireland's largest organisation of over 114,000 people, whose job is to run all of the public health services in Ireland. The HSE manages services through a structure designed to put patients and clients at the centre of the organisation. The HSE manages 47 public hospitals and a large number of community, secondary and primary care facilities. It is envisaged that the HSE will provide a mobile health app for all citizens in Ireland with the ability to share health information.

EHDS compliance – Article 8

Ireland is fully committed in implementing EHDS compliance and our Health Information Bill (currently being drafted) will address and implement EHDS regulations at a national level. This health information bill addresses legislation on data sharing across borders, consent, primary and secondary use and is available to view on the Irish Government Website[7]. The Health Information Bill is being drafted by DoH and the HSE is legally bound to adhere to all national legislation.

Sharing Health Data in unexpected care or for treatment/procedure (AS2_BUC1)

The BUCs of the HSE is to deliver effective and safe patient care. The DoH and HSE have identified 3 scenarios applicable to the adoption of the xShare project relevant to Irish citizens and aim to benefit from the BUCs cases proposed by our partners and peers in this project. The 3 identified scenarios are:

- **Scenario 1: Sharing Health Data at a Cross-Border Level**

  When an Irish citizen goes abroad within the EU e.g. on holidays, and requires medical attention, they seek medical attention and try to describe their symptoms, diagnoses, and medications to the HP in country of treatment. They have no paper or digital means to show the HP and rely on HP ability to understand patient.

[7] Health Information Bill 2023 [Internet]. www.gov.ie. 2023 [cited 2024 May 27]. Available from: https://www.gov.ie/en/publication/6f6a6-health-information-bill-2023/

- **Scenario 2: Sharing Health Data a Regional Level**

When an Irish citizen goes to another location within Ireland and requires medical attention, they seek medical attention and describe their symptoms, diagnoses, and medications to the HP in region of treatment. They have no paper or digital means to show the HP and rely on HP ability to get the relevant health data on the patient. In many cases, patients, under duress, cannot remember their full medical history, medication lists etc.

- **Scenario 3: Scheduled Treatment at a Cross-Border Level**

An Irish citizen has "Planned Medical Treatment" (scheduled care) either Nationally or Cross Border. On arrival to the selected HP, they have a large paper file (in English) with personal health data. They have no translated digital (translated, if required) means to show the HP and rely on HP ability to understand patient and material in file.

Overview	
Use Case Acronym	AS2_BUC1
Document Version	V1.0
Current situation	
As-Is Situation	
When an Irish citizen goes abroad within the EU or to another location within Ireland, and requires medical attention, they seek medical attention and try to describe their symptoms, diagnoses, and medications to the HP in country of treatment. They have no paper or digital means to show the HP and rely on HP ability to understand patient and get their relevant health data. In many cases, patients, under duress, cannot remember their full medical history, medication lists etc. An Irish citizen can also have "Planned Medical Treatment" (scheduled care) either Nationally or Cross Border. On arrival to the selected HP, they have a large paper file (in English) with personal health data. As stated before, they have no means to show the HP and rely on HP ability to understand patient and material in file.	
Currently available products/services and its vendors	
Acute Hospitals: St. James, Mater and Tallaght, Dublin (different vendors). National systems: Maternal & Newborn Clinical Management System (MN-CMS) in most maternity hospitals and units, roll out to be completed this year. (Cerner). National Integrated Medical Imaging System (NIMIS) – Medical Images (McKesson).	

National Laboratory Information System (MedLIS) – Laboratory Reports and Studies (Cerner).		
Which health-related standard does your organisation uses and its alignment to the EEHRxF?		
Ireland will be using several standards based on the application e.g. HL7 FHIR, HL7 CDA, SNOMED.		
Use Case		
Actors/Users and their Roles	Patients (or their representatives)	• Scenario 1: on holidays and requires medical attention. • Scenario 2: away from home in another part of Ireland and requires medical attention • Scenario 3: scheduled for medical treatment
	Healthcare providers	Assess and provide appropriate healthcare including prescriptions if required
	EHR/SCR systems	Allows access to and provides patient health data in suitable format
	Apps and portals	Mobile Health App or web portal to enable the transfer or sharing of health data
Use Case Description		
• **Scenario 1:** Irish citizen goes abroad within the EU and requires medical attention. The patient can share their own health data (PS) to the HP on their mobile app or web portal using the xShare Yellow Button. • **Scenario 2: Sharing Health Data a Regional Level**: Irish citizen is in another region of Ireland and requires medical attention. The patient can share their own health data (PS) to the HP on their mobile app or web portal using the xShare Yellow Button. • **Scenario 3:** Irish citizen has been scheduled treatment/procedure within the EU. The patient can share their own translated health data (PS) to the HP on their mobile app or web portal using the xShare Yellow Button.		
User Perspective		
Faster assessment and diagnoses by HP. Reduced waiting times and improved patient care resulting in increased patient safety.		

System Perspective

xShare Yellow Button is pressed, SCR system accessed securely and data available for sharing.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary	X			2	4
Electronic prescription					
Electronic dispensation					
Medical image and image report					
Laboratory results					
Discharge report					
Telemonitoring					
Care plan					

Details

National/regional strategy

- Slaintecare -National Strategy, 10-year programme to transform health and social care in Ireland.
- eHealth Strategy – national strategy, to be published May 2024.
- HSE - Reorganising into 6 new Health regions as an important part of Slaintecare strategy
- HSE – Data strategy, to define standards and interoperability.

Strategy towards EHDS

Ireland is fully committed to EHDS and are currently setting up our Health Data Access Body and completing relevant legislation to support EHDS.

Business Goals/Benefits and KPIs

- Faster assessment and diagnoses by HP.
- Reduced waiting times.
- Improved patient care.
- Increasing patient safety.

Application	On a patient mobile app or web portal.

Data Preconditions	Data must be valid, available, and come from NCP as this validates its accuracy and integrity.
System Preconditions	Mobile app/ Web portal must be live and has the xShare Yellow Button integrated.
User Preconditions	• User should be able to access mobile app/web portal and their health data. • Must understand why they can or should do this. • They should also have given prior explicit consent (opted in) in the NCP to enable data sharing "legal requirement".
Trigger	Patient needs medical attention from HP and needs to share their patient summary information
Challenges/Limitations	• Localisation, where required. • Inability to read source language. • Mobile data access. • Ability/process for HP to receive patients' health data.
Involved stakeholders in the BUC definition	Patients or their representatives, and healthcare providers.
Application of pseudonymisation filters	Yes – Secondary data use. No – Primary data use.
Basic Workflow	
Scenario 1: 1. Patient goes on holiday within the EU. 2. Patient is unwell and seeks medical attention. 3. HP requests medical history and current medications. 4. Patient opens App/Portal and views PS information. 5. Patients click on the xShare Yellow Button. 6. Information is translated using MVC (if required). 7. Translated information is then transferred to HP. 8. HP reads health information. 9. HP treats patient as appropriate. **Scenario 2:** 1. Patient goes on holiday within the region. 2. Patient is unwell and seeks medical attention. 3. HP requests medical history and current medications. 4. Patient opens App/Portal and views PS information.	

5. Patients click on the xShare Yellow Button. 6. Information is translated using MVC (if required). 7. Translated information is then transferred to HP. 8. HP reads health information. 9. HP treats patient as appropriate. **Scenario 3:** 1. Patient goes treatment/procedure within the EU. 2. HP requests medical history and current medications. 3. Patient opens App/Portal and views PS information. 4. Patients click on Yellow Button. 5. Information is translated using MVC (if required). 6. Translated information is then transferred to HP. 7. HP reads health information. 8. HP treats patient as appropriate.
Alternative Workflows
N/A.

Table 9. Ireland: AS2_BUC1.

AS2 USs

The Irish USs can be found in Appendix 3.

Cyprus (AS3)

Introduction

The National eHealth Authority (NeHA) is a legal person of public law and has been established under The Electronic Health Law of 2019 (59 (I) / 2019) issued by publication in the Official Gazette of the Republic of Cyprus in accordance with Article 52 of the Constitution, which describes the duties, powers and the authorities. The Authority is managed by and acts through a seven-member board (Executive Chair, Vice Chair, and five members), which manages its assets and resources and carries out its duties, powers, and authorities. The purpose of this Law is to establish a framework for the use of electronic health for the prevention of disease, the promotion of health and the effective and safe provision of health services to citizens, the implementation of the National eHealth Record system for all citizens, the regulation of the storage and use of biomedical information and telemedicine. The National eHealth Authority is also under Article 16 and Article 17 of its legislation the authority for setting standards and specifications for the operation of telemedicine services and National Contact Point for eHealth (NCPeH) for cross-border healthcare defined by EU. Currently in Cyprus we do not have any apps that are used by citizens or hospitals.

In this project NeHA is in close collaboration with the University of Cyprus, a public research university established in Cyprus in 1989. The main objectives of the University are twofold: the promotion of scholarship and education through teaching and research, and the enhancement of the cultural, social, and economic development of Cyprus. The eHealth Lab was established in 1986 under the university, led by Professor Constantinos Pattichis. The objective of the eHealth lab is the development of intelligent medical diagnostic systems integrating a great variety of distinctly different technologies such as signal/image/video acquisition, preprocessing, feature extraction, dimensionality reduction, data mining and risk modelling, clinical decision making, and mobile health support and functionality.

EHDS compliance – Article 8

- *Article 8a – Right of natural persons to access their personal health data*

Cyprus is already focused on the EHDS regulation through the eHealth law 59 (I)/2019 which includes the right of access to the e-Health Record, more specifically article “23. - (1) The following have a right to access the health data in the Electronic Health Record: (a) The citizen who is the holder of the e-health record; ...”. eHealth law is already in accordance with article 8a of the EHDS regulation.

- *Article 8b – Right of natural persons to insert information in their own EHR*

eHealth law 59 (I)/2019 and more specifically to the rights of e-Health record holders section article 24 clearly indicates that “24. - (1) E-health Record Holders are entitled to: ... (e) voluntarily include health data in the e-health record which are not included in the core set of health data;” which is again in total accordance with the EHDS regulation.

- *Article 8c – Right of natural persons to rectification*

eHealth law 59 (I)/2019 and more specifically to the rights of e-Health record holders section article 24 clearly indicates that “24. - (1) E-health Record Holders are entitled to: ... (f) correct and delete

existing non-medical information that they have not registered themselves." which is in total accordance with the EHDS regulation.

- *Article 8d – Right of data portability for natural persons*

eHealth law 59 (I)/2019 and more specifically to the Basic functions of the Single e-Health Records Bank section article 30 clearly indicates that "30. - (1) The Authority shall ensure that the following basic functions are performed in the Single e-Health Records Bank: ... (c) The electronic communication and provision of health data to the authorized users of the e-Health Record; and (d) To ensure the interoperability of the e-Health Record with other e-Health systems." which clarifies the right of data portability for natural persons as in EHDS regulation.

- *Article 8e – Right of restrict access*

eHealth law 59 (I)/2019 and more specifically to the rights of e-Health record holders section article 24 clearly indicates that "24. - (1) E-health Record Holders are entitled to: ... (d) lock specific health data and render this data inaccessible to the healthcare provider;" which is again in total accordance with the EHDS regulation.

- *Article 8f – Right of obtain information on accessing data*

eHealth law 59 (I)/2019 and more specifically to the rights of e-Health record holders section article 24 clearly indicates that "24. - (1) E-health Record Holders are entitled to: ... (a) access and receive electronic information about their health data from their Electronic Health Record or following a letter sent to the Commissioner for the Supervision of E-health Records;" which is in accordance with the EHDS regulation.

- *Article 8g – Electronic health data access services for natural persons and their representatives*

eHealth law 59 (I)/2019 and more specifically to the rights of e-Health record holders section article 24 clearly indicates that "24. - (1) E-health Record Holders are entitled to: ... (c) set the authorization levels for providers by specifying the person who will be partially or totally authorized to access the Electronic Health Record from the Bank's electronic operating system by sending a letter to the Authority in accordance with the decisions issued by the Authority on the activation of the specific rights of the citizen;" which is in accordance with the EHDS regulation.

- *Article 8h – Right of natural person to opt out in primary use*

eHealth law 59 (I)/2019 and more specifically to the rights of e-Health record holders section article 20 clearly indicates that "20. -... (2) The exclusion of a citizen from the Register of e-health record holders may be made at any time in the premises or at the offices for objection filing purposes specified by a decree of the Minister, upon recommendation by the Authority.

(3) Any person who objects to holding an e-health record, either for himself or for his/her minor children, shall sent his/her objection either in writing or electronically.

(4) Where a citizen chooses, either for himself or his children, not to hold an e-health record or requests that he/she or his/her children be removed from the Bank, the Authority shall inform the citizen in writing of any consequences it may have with regard to the future provision of health services both at national and cross-border level." Which clearly is in accordance with the opt out in primary use of the EHDS regulation article 8h.

As you can see above articles 30, 23, 24 and 30 show that NeHA with the eHealth law 59 (I)/2019 is fully compliant to the EHDS regulation specifically to article 8.

Sharing of Medical Information via Mobile (AS3_BUC1)

NeHA's vision is to serve Cypriot citizens, patients, and the healthcare community in its whole as well as decision makers, funding bodies and stakeholders, for the next decades to come. Famagusta General Hospital can be utilized as a BUC. Furthermore, NeHA actively engages in the Xt-EHR and CY-EHDS-2ND projects, facilitating primary and secondary use, respectively, effectively implementing the EHDS regulation.

Overview	
Use Case Acronym	AS3_BUC1
Document Version	V1.0
Current situation	
As-Is Situation	
Project Overview: The project focuses on developing a mobile application designed to provide citizens with access to their International Patient Summary (IPS) and the European Patient Summary (ePS). This initiative aims to enhance healthcare delivery and patient access to medical information, ensuring that critical health data is easily accessible and securely managed. **Development Status:** The mobile application is currently under development, with core functionalities being implemented to enable the display and management of the IPS and the ePS for users. The application is designed to be user-friendly, ensuring that citizens can easily navigate and access their health summaries without technical difficulties.	
Currently available products/services and its vendors	
NCP – National Contact Point managed by National eHealth Authority (HL7 CDA). eHealth4U – Proposed solution for national EHR managed by University of Cyprus (HL7 FHIR).	

Which health-related standard does your organisation uses and its alignment to the EEHRxF?		
HL7 FHIR and HL7 CDA.		
Use Case		
Actors/Users and their Roles	Citizen	Sharing user (IPS + ePS).
	Healthcare provider	Receiving user.
	Mobile Application	Access and Sharing interface.
	Web Application (EHR)	IPS and CDA Viewer.
	FHIR Server	IPS Host.
	NCP	CDA Host for European Patient Summary.
	API Gateway	Intermediary Software for User authentication and authorization. Serves the requested patient summary (IPS FHIR or ePS CDA).
Use Case Description		

1. **User Authentication:**
   - Citizens connect to the mobile application using a combination of credentials such as username and password or biometric data (e.g., fingerprint, facial recognition).
2. **IPS or ePS Sharing Functionality:**
   - Within the application, the "xShare Yellow Button" serves as the mechanism for initiating the sharing of the patient summary.
   - Citizens can customise their sharing preferences in the app's preferences page, including:
     - Expiration Time: Setting a validity period after which the shared IPS link becomes inactive.
     - One-Time Password (OTP): An added layer of security requiring the healthcare provider to enter an OTP to access the shared IPS.
     - Selective Sharing: Choosing specific sections of the patient summary to share, depending on the citizen's privacy preferences.
     - Snapshot and Up-to-date Data: Deciding whether to share a static snapshot of the IPS at the current moment or provide access to up-to-date data.
     - FHIR or CDA: For the Pilot purposes we'll give the choice from the app to select the type of patient summary to be displayed and shared.

3. **QR Code Generation and Sharing Options:**
    - Upon confirming their preferences and pressing the yellow button, the app generates a secure link to the Electronic Health Record (EHR) viewer, presented as a QR code.
    - Citizens have multiple options for sharing this QR code, including displaying it for camera scans or sending it via email to the healthcare provider.
4. **Healthcare Provider Access:**
    - The healthcare provider receives the QR code and, upon scanning or clicking the link, is redirected to an Electronic Health Record (EHR) viewer.
    - By submitting the previously set OTP, the healthcare provider's request is validated through the API Gateway.
    - Upon successful validation, the patient summary document is retrieved from the FHIR/CDA Server, allowing the healthcare provider to review the patient's medical summary.

User Perspective

- **Enhanced User Control and Customisation**: Transitioning from limited control to allowing users to tailor their patient summary sharing preferences, enhancing privacy and personalization.
- **Improved Security and Privacy**: Evolving from existing security concerns to implementing biometric, OTP, and secure QR code sharing, significantly boosting trust and data protection.
- **Ease of Access and Sharing**: Moving from cumbersome sharing processes to a simplified "yellow button" feature, making patient summary sharing straightforward and user-friendly.
- **Better Healthcare Delivery**: Shifting from potential delays in healthcare delivery to ensuring timely access to the patient summary by healthcare providers, leading to improved care and outcomes.
- **Increased User Empowerment**: Progressing from limited user engagement in health management to empowering users with direct control over their health information, encouraging proactive health practices.

System Perspective

The integration of the "xShare Yellow Button", into our existing platforms and systems is envisioned to be seamless and intuitive. The button will be positioned within our application's user interface, ensuring it is easily accessible for users wishing to share their Patient Summary.

This integration is designed to work harmoniously with the application's architecture, leveraging the API Gateway for secure data retrieval and sharing processes. When a user opts to share their patient summary by pressing the xShare Yellow Button, the application will communicate with the API Gateway, which in turn interacts with the FHIR Server or the CDA/NCP Server to fetch the required patient summary data. This data is then securely shared according to the user's preferences, including aspects such as expiration time, OTP for access, and specific sections of the IPS to be shared.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary	X	X	X	3	6-7
Electronic prescription	X	X	X	1	4-5
Electronic dispensation	X	X	X	1	4-5
Medical image and image report					
Laboratory results					
Discharge report					
Telemonitoring					
Care plan	X	X	X	3	6-7

Details

National/regional strategy

Cyprus has the eHealth Law from the National eHealth Authority.

Strategy towards EHDS

Current eHealth Law to be legally revised to be aligned with the EHDS.

Business Goals/Benefits and KPIs

Business Goal: Sharing patient summary data with a click of a button.
KPIs:

User Engagement and Adoption

- **Activation Rate**: Percentage of users who use the xShare Yellow Button after registration.
- **Share Frequency**: Average number of times a user shares their patient summary per month.

User Satisfaction

- **User Satisfaction Score**: User satisfaction with the patient summary sharing process, measured through surveys, system usability scale questionnaire, or feedback forms.
- **Net Promoter Score (NPS)**: Likelihood of users recommending the application to others, indicating overall satisfaction and the app's value.

Security and Privacy

- **Unauthorized Access Attempts**: Number of detected unauthorized attempts to access shared patient summary data.
- **Privacy Settings Utilization Rate**: Percentage of users customising their privacy settings (e.g., setting expiration times, OTP usage).

Health Outcomes and Utility

- **Healthcare Provider Engagement**: Number of healthcare providers accessing patient summary data shared through the application.
- **Impact on Healthcare Delivery**: Qualitative assessments of how the use of shared patient summary data has influenced healthcare outcomes or decisions.

Application	In the patient summary screen of the Mobile Application.
Data Preconditions	IPS data to be hosted in our FHIR server. European Patient Summary data to be hosted in our NCP server.
System Preconditions	xShare Yellow Button technical implementation guidelines.
User Preconditions	User patient summary profile to exists, user account in our backend.
Trigger	Pressing the xShare Yellow Button.
Challenges/Limitations	• No offline functionality • Adoption from citizens. • Countries should upload their MVC in OpenNCP (for translations).
Involved stakeholders in the BUC definition	• Pancyprian medical association. • Pharmaceutical organisations / Pharmacists. • Citizens/patients.
Application of pseudonymisation filters	No

Basic Workflow

1. **User Authentication:**
   - The user opens the mobile application and logs in using their chosen method of authentication (username and password or biometric data).
2. **Accessing the patient summary:**
   - Once authenticated, the user navigates to the section of the app where their Patient Summary (IPS or ePS) is displayed.
3. **Initiating Share:**
   - The user decides to share their patient summary with a healthcare provider and presses the prominently displayed "xShare Yellow Button" to initiate the sharing process.
4. **Customising Sharing Preferences:**
   - The user is presented with options to customise their sharing preferences, including setting an expiration time for the shared link, requiring an OTP for access, selecting specific sections of the patient summary to share, and choosing between a live data link or a snapshot.
5. **Generating QR Code/Link:**
   - After confirming their preferences, the application generates a secure link to the patient summary, presented as a QR code or a direct link, depending on the user's choice.
6. **Sharing the IPS:**
   - The user chooses to share the QR code or link through their preferred method, such as showing it for a camera scan or sending it via email to the healthcare provider.
7. **Healthcare Provider Accesses patient summary:**
   - The healthcare provider receives the QR code or link, scans or clicks it, and is redirected to an EHR viewer where they can access the patient summary.

- If required, the healthcare provider enters the OTP provided by the user to gain access to the information.

8. **Successful Data Retrieval:**
   - The API Gateway validates the request, and it retrieves the IPS document from the FHIR server, making it available to the healthcare provider for review.
   - The API Gateway validates the request, and it retrieves the European patient summary document from the NCP Server, making it available to the healthcare provider for review.
   - Healthcare Provider Reviews patient summary:
   - The healthcare provider reviews the patient's PS, now equipped with the necessary information to provide informed healthcare services or make decisions based on the patient's medical history.

Alternative Workflows

1. **Authentication Failure**
   - **User fails to authenticate**: The user enters incorrect login credentials or experiences a failure in biometric authentication.
   - **Alternative Flow**: The system prompts the user to retry authentication, offering password recovery options or reattempting biometric authentication.
2. **Connectivity Issues**
   - **Poor or no internet connection**: The user attempts to access or share their patient summary without a stable internet connection.
   - **Alternative Flow**: The application displays a message indicating the need for internet access and retries the connection once available.
3. **Preferences Customisation Errors**
   - **Incomplete preference settings**: The user tries to proceed without setting all required sharing preferences.
   - **Alternative Flow**: The system prompts the user to complete all necessary preference settings before proceeding.
4. **QR Code/Link Generation Failure**
   - **System fails to generate QR code/link**: Due to a technical glitch, the application cannot generate the shareable QR code or link.
   - **Alternative Flow**: The system displays an error message and offers the user the option to retry generating the QR code/link.
5. **Sharing Process Interruption**
   - **User unable to share QR code/link**: The user encounters issues while attempting to share the QR code or link (e.g., email or camera function not working).
   - **Alternative Flow**: The application suggests alternative sharing methods or allows the user to save the QR code for later sharing.
6. **Healthcare Provider Access Denied**
   - **Incorrect OTP or expired link**: The healthcare provider enters an incorrect OTP or attempts to access the patient summary through an expired link.
   - **Alternative Flow**: The system notifies the provider of the incorrect OTP or expired link and advises contacting the patient for a new link or correct OTP.
7. **Data Retrieval Failure**

○ **API Gateway - FHIR server – NCP server issues**: There are problems retrieving the patient summary due to API Gateway failures or FHIR Server errors or NCP server errors. ○ **Alternative Flow**: The application notifies the healthcare provider of the issue and suggests retrying later, while automatically reporting the issue for technical support. **8. User Revokes Access Before Provider Uses Link** ○ **User decides to revoke access**: After sharing the patient summary link, the user chooses to revoke access before the healthcare provider uses it. ○ **Alternative Flow**: The system allows the user to revoke shared access at any time, automatically invalidating the shared link and notifying the healthcare provider if they attempt to access it.

Table 10. Cyprus: AS3_BUC1.

AS3 USs

The Cyprus USs can be found in Appendix 3.

Italy (AS4)

Introduction

Monasterio Foundation - Fondazione Toscana Gabriele Monasterio per la Ricerca Medica e di Sanita Pubblica (FTGM) is a public research organization and healthcare provider of the Italian public health service, classified at the tertiary level (the highest) of specialization in cardiac-related disease diagnosis and treatment, including cardiac surgery, for adult and paediatric patients.

FTGM represents the first centre in Italy for volumes of activity in hemodynamic procedures (e.g., PTCA), and an excellence centre for patients affected by chronic heart failure. Their expertise and established collaboration with industries in artificial organs, signal, and image processing, bioengineering and medical electronics add value to the healthcare connected with research use cases and requirements. Spanning its research activities from molecular mechanisms to the organs and the body as a whole, the biomedical staff interacts with non-medical scientists in physics, mathematics, electronics, computer science, chemistry and material science.

Monasterio has an extensive experience in IT research and development, started in 1998 and focused on the continuous refinements of EHR solutions to support both the care of its patients and the many clinical research studies aspects connected to care, with an effective implementation of real-world data approach. The collaboration among the different disciplines of FTGM researchers results in a translational approach for EHR development, starting from the clinical processes to the IT design and development and then translated to the clinical environment experimented at bedside in Monasterio Hospitals, closing the loop with feedback and evolutions back to the IT field.

EHR solutions from Monasterio, certified as software medical devices, are currently used in 17 Hospitals in Tuscany Region, extending to 40 Hospitals within 2024, covering a population of 4.1 million patients.

Main focuses of Monasterio EHR solutions are resilience, ergonomics, and interoperability; in the latter Monasterio gained a large experience in standards usage and development, among the first members of HL7 Italy, member of IHE, and chairing the CoP “Hospitals on HL7 FHIR”, collecting the experience and current level of implementation of HL7 FHIR in European Hospitals.

FTGM was a partner of InteropEHRate EU H2020 project, where it represented the clinical and IT reference partner for user requirements of the EHR interoperability platform, including requirements from citizens, health care operators and scientists’ researchers for all prototyped applications. FTGM was responsible of the WP for the validation of the final InteropEHRate platform, integrating its EHR system with the InteropEHRate platform using HL7 FHIR, assessing all the functional and non-functional requirements. More than 90 people were involved in this validation, deployed in real world operational conditions in 4 countries (Belgium, Greece, Romania, Italy), experimenting their usage in 3 different international scenarios requiring the cross-border exchange of health data to fulfil the requirements of three kinds of users: citizens, healthcare professionals and health researchers. The project produced HL7 FHIR Implementation Guides for Research data definition and collection and another one for cross border data exchange.

EHDS compliance – Article 8

Italy has a national federated public healthcare system, composed of 21 regions, coordinated and supervised by the Health Ministry. A national EHR was established as an IT federated system in 2012 (D.Lgs 179/2012 and update 221/2012[8]) with an evolving framework of national and regional regulations that is now re-designing the overall architecture toward the usage of HL7 FHIR as a national standard for high-level communication[9], in a 2.0 version having an extension of National EHR capabilities, defined in the law FSE2.0 n.23A05829 07/09/2023[10].

The initial scope of the Italian national EHR federated system was oriented to support mainly the collection and consultation of data for the patient subject of care and to allow HCP using its content for the patient care. The second generation of the national EHR plans to empower the role of HCPs, addressing a direct usage of collected information by trusted healthcare providers both of public and private sector, and a secondary usage of health data for research.

The compliance with the future EHDS regulation is based on the connection with the above mentioned National EHR regulations and the national data protection regulations (law 196/2003, law 101/2018), implementing the EU GDPR.

The following articles of EHDS are already included and enforced in the current national regulation for data protection (law 196/2003, law 101/2018, GDPR):

- Article 8a – Right of natural persons to access their personal health data.
- Article 8b – Right of natural persons to insert information in their own EHR.
- Article 8c – Right of natural persons to rectification.
- Article 8d – Right of data portability for natural persons.
- Article 8f – Right of obtain information on accessing data.

While the following articles are connected with Article 11 of FSE 2.0 law:

- Article 8e – Right of restrict access
- Article 8g – Electronic health data access services for natural persons and their representatives

The following article, strictly related to EHDS, is currently not addresses, waiting for the EHDS final enforcement:

- Article 8h – Right of natural person to opt out in primary use

[8] Trova Norme & Concorsi - Normativa Sanitaria [Internet]. www.trovanorme.salute.gov.it. [cited 2024 May 15]. Available from: https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=44151&completo=true
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Discharge and Continuity of Care in Italy (AS4_BUC1)

FTGM general BUC objective is to allow patients to have a direct and real ownership of their data produced during healthcare encounters with Monasterio and, eventually, Tuscany Region Hospitals. This includes also two-ways interaction with the patient, where the patient can send documents and questionnaires to the healthcare structure trough the Monasterio App/portal.

To support continuity of care, special focus was expressed in the discharge report, a document due in the Italian NHS at the end of an encounter, containing the summary of clinical data managed during the care processes (e.g., allergies, patient's history with chronic and acute diseases and related events, current therapy, procedures, instrumental examinations, lab tests, diagnosis, drugs prescriptions and sub-ministrations, etc.; nurses' evaluations, activities and scores, etc.).

Overview	
Use Case Acronym	AS4_BUC1
Document Version	V1.0
Current situation	
As-Is Situation	
A Monasterio Hospital discharges a patient at the end of an encounter, where he/she was diagnosed and treated for a disease. The discharging physician and nurse create on Hospital's EHR (Monasterio C7 ISA) the discharge summary, reporting relevant information about the ward period extracted from the EHR itself: patient history and allergies, physical examination, lab data, administered drugs and therapeutics, procedures reports, instrumental examination reports, diagnostic imaging report, etc. The document also contains prescriptions and indications for the patient to be used at home, and it is intended also for the patient's GP as recipient. The discharging physician digitally sign the pdf version of the discharge document (embedded in a structured HL7 CDA R2) in the EHR platform and print a hard copy for the patient. Before leaving the Hospital, the patient receives a hard copy printed version of the discharge document, while the digitally signed version is available in the App/Portal connected with the Hospital. The patient is capable to view the pdf document in the Monasterio App/Portal, either using credentials assigned by the Hospital or the National eIDAS authentication system.	

<table>
<tr><td colspan="3">From the App/Portal the patient can save the pdf document in the smartphone or computer but cannot use its structured data (HL7 CDA) for any kind of automatic processing, nor send it to another Hospital.</td></tr>
<tr><td colspan="3">Currently available products/services and its vendors</td></tr>
<tr><td colspan="3">C7-ISA EHR system, developed by Monasterio since 1999, medical device. Patient App/portal was developed in 2019 and used since 2020.</td></tr>
<tr><td colspan="3">Which health-related standard does your organisation uses and its alignment to the EEHRxF?</td></tr>
<tr><td colspan="3">Currently using HL7 V2, V3 (CDA), FHIR R4, FHIR R5, SCP, DICOM (Waveform), OHDSI-CDM-OMOP.</td></tr>
<tr><td colspan="3">Use Case</td></tr>
<tr><td rowspan="5">Actors/Users and their Roles</td><td>Patient (caregiver)</td><td>Subject of care</td></tr>
<tr><td>Healthcare provider</td><td>Hospital/other structure entitled of the episode of care</td></tr>
<tr><td>HCP - Healthcare Professional</td><td>Author of report/document</td></tr>
<tr><td>EHR system - Monasterio C7 ISA</td><td>EHR system of the Hospital</td></tr>
<tr><td>PHR: Patient app/Patient portal “Monasterio App”</td><td>IT system used to view a report by patient/caregiver</td></tr>
<tr><td colspan="3">Use Case Description</td></tr>
<tr><td colspan="3">Pre-conditions
A Monasterio Hospital discharges a patient at the end of an encounter, where he/she was diagnosed and treated for a disease.
The discharging physician and nurse create on Hospital’s EHR (Monasterio C7 ISA) the discharge summary, reporting relevant information about the ward period extracted from the EHR itself: patient history and allergies, physical examination, lab data, administered drugs and therapeutics, procedures reports, instrumental examination reports, diagnostic imaging report, etc.
The document contains also prescriptions and indications for the patient to be used at home, and it is intended also for the patient’s GP as recipient.
The discharging physician digitally sign the pdf version of the discharge document (embedded in a structured HL7 CDA R2) in the EHR platform and also print a hard copy for the patient.</td></tr>
</table>

- Before leaving the Hospital, the patient receives a hard copy printed version of the discharge document, while the digitally signed version is available in the App/Portal connected with the Hospital.
- The patient is capable to view the pdf document in the Monasterio App/Portal, either using credentials assigned by the Hospital or the National eIDAS authentication system.
- The patient can save the downloaded document in the smartphone or computer.

Scenario

The patient has an "xShare Yellow Button" in his/her PHR (Monasterio App) and clicking on it, he/she can download the structured content of the discharge summary, in EEHRxF format, locally in the smartphone or computer.

Post-conditions

- Now he/she can use the downloaded content for automatic processing or import it into another application (certified as standard compatible), and can send it to another Hospital, of his/her preference, capable to receive the data package (FHIR document/message) in a safe and reliable way and selected from a list of certified Hospitals.
- The patient can also send the content to a research centre supporting a medical study that involves his/her condition, supported by a tool for anonymisation.

User Perspective

Patients users

- The advantage is the new capability to export a whole set of structured data, contained in a report/summary, and provide this content to another PHR/App/Patient-portal system of their choice (according to the availability on the market of new interoperable systems), or to provide the downloaded content to another healthcare provider of their choice, also in another country, with the possibility to exchange it without an internet connection but directly and simply using Bluetooth/NFC connection with the new provider, just like the usage of a smartphone in a financial transactions.
- The patient can also create a backup copy of some document, to be safely stored in a system of his/her preference.
- The patient can donate his/her data to support a medical study.

Physicians/Nurses users (HCP)

- The advantage is to be sure of the usage of data not only as readable document but as structured dataset potentially importable in EHR systems of other providers; this last feature saves a lot of time and potential errors of HCPs when patients' data are directly imported into the Hospitals' EHR system. HCP can also check if the documents are unaltered, and trace their provenance, authors, and versions.

Researcher

- The researcher/research organization can receive health data voluntarily donated by the patients, following the current regulations (patient's consents, anonymisation, storage, etc.) and if authorized by the ethical committee, where applicable.

System Perspective

The patient should be uniquely identified in a clear, safe, and easy way. This can include authentication processes provided by centralized regional/national platform, as well as distributed systems (digital ID card).

To provide the maximum flexibility of the button, it can be associated to a single or multiple documents to be exported: a discharge summary, a set of diagnostic report, an IPS or a whole EHR.

The existing platform should embed the xShare Yellow Button in a clear a visible way, standardized in the format, colour and description text and referenced to the dataset or document to be exported.

The behaviour of the button should trigger the creation of a standardized set of resources in HL7 FHIR containing the document associated to the button.

The EHR is developed by FTGM since 1998, and now based on DB modelled on HL7 V3 and FHIR data model. The C7 ISA EHR is certified as medical device by TUV class IIa. The C7 ISA EHR is the regional system used by all the Hospitals in Tuscany region, with 4 million patients.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary					
Electronic prescription	X*				
Electronic dispensation					
Medical image and image report	X*				
Laboratory results	X*				
Discharge report	X			4	7
Telemonitoring					
Care plan					

*Included in the Discharge Report

Details

National/regional strategy

Considering the Italian healthcare federated model, the national EHR (FSE 2.0) is created as a virtual network of regional EHR, relying on FHIR usage.

Strategy towards EHDS

Contribute to EHDS with Real World Data (RWD) coming from healthcare processes, telemedicine processes, clinical studies. To be evaluated constraints emerging from the application of national GDPR law.

Business Goals/Benefits and KPIs

The use case is executed to:

- Support data portability (GDPR art.20).
- Fill the gap created by the lack of direct connection (no network connection, no trusted communication channels) between potentially interoperable systems, connecting two systems supporting the same integration standard through the exchange of the (file) exported dataset.
- Support data exchange in air-gapped systems.
- Support digital data backup, according to patient's preferences.
- Support the control on data flow, allowing the patient to restrict sections on data exchange considered sensitive by the patient (with exposure to medical errors in presence of incomplete information).

KPIs:

- Evaluation of Post Study System Usability Questionnaire (PSSUQ), pre and post xShare Yellow Button usage, by patients: expected rate > 50/100.
- Number of downloaded datasets: > 20.

(note: total number of FTGM patients in C7 ISA EHR = 462,000 patients spanning in a 25-year period, see ARCA in OHDSI registry for updates).

Application	• The xShare Yellow Button will be implemented in the user interface of the patient's personal private section of the Monasterio App/Portal. • The Monasterio App/Portal is integrated with the Hospital's EHR (C7 ISA).
Data Preconditions	• All data coming from a healthcare provider must support medico-legal validity. • The PHR/App/Portal is connected to the EHR system of a healthcare provider, or to a network of providers, or to a regional/national EHR system. • Data stored and visualized in the App/Portal must be safe and unaltered and resilient to cyberattacks. • All the information is related to its source/producer/author, where source is the person (including the patient) or organisation

	that provided the info (not necessarily the original author/producer) and takes (i.e., is accountable) of the information content; Producer organisation is the organisation that the author belongs to; Author is the person (or device, in case of automatic production) that produced and validate the information. • All the exchanged health information related to its producer/author, is versioned, timestamped. • The Healthcare provider cannot repudiate the produced health information. • Structured data use common vocabularies when expressing concepts, and, if local vocabulary is used, exist a translation in the common vocabularies.
System Preconditions	• The Patient owns a smartphone/tablet/PC and installs the App/Portal on it. • Each healthcare organization involved has a digital identity that may be represented within the PHR/App/Portal and is trusted by the PHR/App/Portal (e.g., The Healthcare Organization is registered in eIDAS as an Entity). • The data integration platform is available to support the conversion and translation of structured and unstructured information, and it is configured for the healthcare provider and its local vocabularies and their translations in common vocabularies.
User Preconditions	• The Patient gave his/her approval to the App/Portal to store and manage his/her personal health data and to share them only with people explicitly authorized by the patient, and for periods authorized by the patient. • The Patient had a previous encounter with the Healthcare Organization supporting the Standard, for remote access to the patient's health records maintained by the Organization. • Every action performed on health data by means of the PHR/App/Portal is registered (logged) and associated permanently with the unique identification of the involved patient and (HCP or patient) author/actor. • The patient can configure on his/her PHR/App/Portal the data he/she desires to hide/avoid in the data export of xShare Yellow Button. A disclaimer warns the patient in the risks that this action could produce in his/her care.

Trigger	After the patient discharge and the creation of a discharge summary, the patient pushes the xShare Yellow Button to download the discharge summary (/a set of information of his/her preference).
Challenges/Limitations	• The medical data might need translation/representation in a different language, in cross border care: unstructured data should rely on a certified tool to translate correctly medical data in the EU natural languages. Common dictionaries should have official translations of codes in all the EU natural languages. The lack of these features might hamper continuity of care in a cross-border scenario. • The data contained in the EHR and PHR/App/Portal are safe and unaltered and represent a legal ground on which HCPs (and patients) rely for diagnosis/treatment/prognosis/prevention. • The HCP can verify the origin and validity of the information shared by the patient. • How to support a reliable data exchange without a strong patient authentication/identification (no EIDAS). • How to support data download/exchange made by a patient's caregiver (e.g. parent). • How to support data download for large medical image (CT scan, FMRI, etc). • How to support GENERIC data donation for medical research with xShare (ALL data, incl. imaging, needs to be anonymised or pseudonymised). • How to implement partial data export, selected by the patient or defined by a study.
Involved stakeholders in the BUC definition	Patients, Physicians, Nurses, ICT.
Application of pseudonymisation filters	According to the defined/approved clinical study.
Basic Workflow	
Workflow Precondition: 1. The patient owns a set of credentials to access his/her App/Portal. 2. Patient is ready for discharge. 3. The author HCP creates the Discharge Summary in the EHR. 4. The author HCP signs digitally in the EHR the Discharge Summary. 5. The HCP prints a paper copy of the discharge summary. 6. The patient receives the paper copy of the discharge summary. 7. The patient accesses the App/Portal using his/her personal credential. 8. The App/Portal visualizes the list of documents and data available, including the last Discharge Summary produced.	

9. The patient selects the Discharge Summary on the App/Portal. **Workflow:** 1. The patient clicks on the xShare Yellow Button. 2. The PHR asks a confirmation on the download location. 3. Upon confirmation, the App/Portal invokes the EHR service for the creation of the Discharge Summary in the EEHRxF format and receive the structured data. 4. The App/Portal writes the EEHRxF data in the location selected by the patient, with a timestamp and provenance description. *5.* The App/Portal signals to the patient the completion of the xShare Yellow Button operation.
Alternative Workflows
N/A.

Table 11. Italy: AS4_BUC1.

AS4 USs

The Italian USs can be found in Appendix 3.

Spain (AS5)

Introduction

Fundació TIC Salut Social (FTSS) is a public agency within the Catalan Ministry of Health, established in 2006 with the primary objective of facilitating and promoting the advancement and evolution of health and social care frameworks through innovative utilization of ICT. The agency serves as a dedicated observer of trends, innovations, and emerging initiatives in the health and social care areas. FTSS, as an entity within the Catalan Ministry of Health will provide its experience in understanding the complexities of public healthcare systems in integrating new technologies and processes into established healthcare frameworks.

FTSS areas of expertise include Artificial Intelligence; m-health and digital assets for the citizenship; digital skills for healthcare professionals; personalized attention solutions General Data Protection and more. By carrying out projects financed with competitive funds, FTSS creates synergies with organisations in different European Union member states. FTSS contributes to position the Catalan Health System as a model for technological innovation and digital transformation applied to social welfare and the provision of health services.

TIC Salut Social plays a central role within the Catalan public healthcare system, operating under the decentralized structure of healthcare administration in Spain. In Catalonia, the Department of Health supervises the region's healthcare system, with the Catalan Health Service (CatSalut) acting as its primary administrator. CatSalut is responsible for managing public health initiatives and healthcare provision across Catalonia, organizing a diverse array of services including primary care, specialized care, mental health, and addiction services. To facilitate this, CatSalut employs three main service provision models, collectively forming the Comprehensive Public Health System of Catalonia (SISCAT).

The Catalan Healthcare Model is characterized by its tax-funded nature, with co-payment for pharmaceutical products, ensuring universal coverage and free access to a wide range of public healthcare services. These services are primarily provided in public facilities, under a multi-provider model integrated into a single public network, comprising over 160 providers with more than 28 HIS. The Catalan Public Healthcare system serves a significant population, providing to 8,005,784 citizens as of November 2023, with an average life expectancy of 83 years and a birth rate of 7.2. Its infrastructure includes 377 Primary Care Centres, 98 Intermediary Care Centres, 130 Mental Health Centres, and 67 Hospitals within the SISCAT network.

La Meva Salut is the main public PHR App and web portal, a digital health platform in Catalonia that allows the 8M Catalan citizens to interact remotely with the public Health System. Users can access clinical reports, diagnoses, test results, and medication plans, and request primary care appointments. Non-face-to-face services include eConsultation for medical inquiries and administrative tasks. Parents or guardians can request access for minors. The platform is accessible via website or app. LMS is open to all citizens possessing an Individual Health Card and serves as the primary gateway to Catalonia's digital health landscape. Furthermore, the portal seamlessly integrates with all SISCAT centres, ensuring universal access to a comprehensive range of healthcare services across the region.

EHDS compliance – Article 8

- *Article 8a – Right of natural persons to access their personal health data*

Catalan citizens can access to their personal health data through La Meva Salut app/portal (MyHealth). LMS is a personal digital health space that allows the citizens of Catalonia to interact with the Catalan Health System in a non-face-to-face manner.

La Meva Salut enables the citizen to access your health information, consult with professionals, and perform procedures in an easy, secure, and confidential manner.

- *Article 8b – Right of natural persons to insert information in their own EHR*

Currently, this feature is not available. One of the future objectives considers the possibility of including and upload functionality so that citizens can directly upload their IPS to the portal/app, and additionally, information collected from other sources such as health applications or wearables. Currently, citizens who want to insert information or results into their EHR must open an e-consultation service (available in LMS) through which they transmit the information to their GP that manually enters the data.

- *Article 8c – Right of natural persons to rectification; Article 8e – Right of restrict access; and Article 8h – Right of natural person to opt out in primary use*

Catalan citizens have the right to obtain information about whether the Catalan Health Service (CatSalut) is processing personal data concerning them or not.

As interested parties, Catalan citizens have the right to access their personal data, as well as to request the rectification of inaccurate data or, if applicable, request its deletion, among other reasons, when the data are no longer necessary for the purposes for which they were collected.

They can request the limitation of the processing of their data in accordance with the conditions established in Article 18 of the GDPR. In this case, data will only be processed to exercise or defend claims or in the protection of the rights of another natural or legal person or for reasons of important public interest. In certain circumstances, Catalan citizens may object, providing reasons for their request, to the processing of their personal data.

- *Article 8d – Right of data portability for natural persons*

The Catalan Ministry of Health has developed a first version of the xShare Yellow Button (temporarily called Blue Button), as a feature of La Meva Salut (LMS). The BB allows a citizen to download their information in accordance with the HL7 C-CDA and Blue Button 2.0 standards and specifications, in conformity with the EU implementation guides certified by the Integrating Healthcare Enterprise (IHE).

The 'Health Data for Sharing-Blue Button' initiative aligns with the principles of the EHDS by providing immediate access to health data, adhering to international standards, and promoting cross-border data sharing. This initiative sets a precedent for the potential widespread adoption of similar practices across Europe to enhance healthcare data accessibility, quality, and interoperability.

Catalan citizens can exercise their rights of access, rectification, deletion, opposition to processing, and request for limitation by submitting a request in paper format to the Catalan Health Service (Edifici Olímpia, travessera de les Corts, 131; 08028 Barcelona), or electronically, through this specific electronic service.

- *Article 8f – Right of obtain information on accessing data*

LMS provides information about who and when has accessed to the EHR of a person. This information is available on the portal and the mobile app.

- *Article 8g – Electronic health data access services for natural persons and their representatives*

This can also be done through LMS app/portal, since parents, legal guardians or responsible individuals can request access to LMS for their children under 18 years of age and those under their legal guardianship, and therefor are able to use the button.

Catalonia Region (AS5_BUC1)

FTSS general BUC objective is to improve and extend the existing Catalan Blue Button tool, now called xShare Yellow Button, within the La Meva Salut (LMS) portal/app. This enhancement aims to improve the access and exchange of health information for Catalan citizens. Specifically, the project aims to:

- Improve the xShare Yellow Button tool by addressing errors, including medication errors, and ensuring compliance with EEHRxF standards.
- Expand the International Patient Summary (IPS) domains to include additional types of medical information such as medical imaging, lab reports, discharge summaries, radiology, etc.
- Implement the xShare Yellow Button in the private sector to facilitate data exchange between the public and private healthcare sectors.
- Enable secondary use of data by allowing citizens to donate their health data for research purposes using intermediary tools/platforms.
- Implement an intermediary tool for citizens that acts as an information viewer and is able to consolidate different IPS downloads into a single document.

Using the template adopted by the xShare project, FTSS has identified 3 scenarios, namely:

- **Scenario 1: Cross-Border Health Data Exchange**

  Catalan citizen vacationing in Madeira who falls ill and needs medical attention. She uses the La Meva Salut mobile app to access her IPS, which contains crucial health information including her chronic illness and medication details. Following a series of steps, she downloads her IPS and shares it with the emergency doctor in Madeira via email, ensuring alignment between her treatment and existing medical conditions.

- **Scenario 2: Private Healthcare Data into Public Health Records**

Catalan citizen undergoes gynaecological treatment at a private hospital, encountering complications during childbirth. Wanting her primary care physician to have access to her medical history, she downloads her IPS from the private hospital's app. Using La Meva Salut's e-consultation service, she shares her IPS with her doctor, enabling informed decision-making for follow-up care.

- **Scenario 3: Health Data Sharing for Clinical Research Participation**

A citizen discovers that he has a rare type of disease. Currently, different research groups are recruiting patients and seeking participants for a clinical study to advance understanding of this disease. The citizen downloads his IPS and uses an intermediate app installed on his personal mobile to check available research projects matching his profile. He securely sends his IPS to participate in a clinical study.

Overview	
Use Case Acronym	AS5_BUC1
Document Version	V1.0
Current situation	
As-Is Situation	
The Catalan Public Healthcare System has developed a tool that affords users the ability to securely download their clinical data for sharing purposes with other healthcare providers. This tool is known as “Blue Button”. Individuals seeking access to this invaluable data can conveniently download the requisite documents in XML format via the 'Personal Data' section within the La Meva Salut (LMS – Personal Health Record) platform. LMS is a digital, non-transferable query space that allows citizens to consult all their personal healthcare information and use it in a secure and confidential manner. In this manner, the functionality of the Blue Button has been integrated into LMS, offering Catalan citizens the opportunity to download their International Patient Summary (IPS). The International Patient Summary is a standardized health document that contains essential patient health information. It is designed to facilitate the exchange of patient information across borders and between different healthcare systems, with the goal of improving the quality and continuity of care for individuals who receive medical treatment in different countries. The collated patient summary comprises critical medical information, including diagnoses, the medication summary, immunizations, surgical procedures, and allergies. In Catalonia, the offering extends to the inclusion of medical discharge reports. The current status of the ePrescription system indicates that the prescriptions are internally stored in a structured format. However, citizens are presently only able to download the active	

prescription in PDF format, while the dispensed prescription remains inaccessible in this format. Looking ahead, there is a consideration to enhance the system so that citizens can download both active and dispensed prescriptions in a structured format or possibly appearing in the respective section of the IPS.

Currently, only iPhone users can access their XML files through the HEALTH app. Unfortunately, there is no intermediary tool available as an information viewer. Regarding the secondary use of data, there is currently no feasible scenario where direct data donation for research is possible using intermediate tools or platforms.

Currently available products/services and its vendors

La Meva Salut is the main public PHR App and web portal with Blue Button integrated.

Which health-related standard does your organisation uses and its alignment to the EEHRxF?

IPS - CDA R2 L3 HL7 XML format.

Use Case		
Actors/Users and their Roles	Citizens	End-users
	La Meva Salut	PHR (Personal Health Record) App and web portal
	EHR systems	Data providers
	Citizen's mobile phone	Communication tool

Use Case Description

The Catalan Public Healthcare System has introduced the initial version of a tool called "Blue Button." This innovative tool is reshaping the European healthcare landscape by enabling citizens to securely access and download their clinical data in a structured XML format.

Despite this first version of the tool, the xShare project will conduct a review of the current state of the Blue Button (BB), and a second version will be implemented, incorporating improvements and expanding its scope.

The business case envisioned for Catalonia includes the following:

- **Evolution and improvement of the xShare Yellow Button tool on the LMS portal/app**: This involves improvements (like the ones needed for the medication summary section) and all the required modifications to ensure that the generated IPS is compliance with EEHRxF.
- **Expansion of IPS domains to the maximum extent**: Including laboratory results and medical imaging with the corresponding reports.

- **Implementation of the xShare Yellow Button in the private sector**: Allowing the generation of the IPS by private healthcare providers, and the exchange of this data with the public ones.
- **Secondary use of data**: Proposing a scenario where direct data donation for research is possible (using intermediate tools/platforms).
- **Implementation of an intermediate tool for citizens**: That serves as an information viewer and allow merging different downloaded IPS into a single screen.

User Perspective

This innovative tool redefines the European healthcare landscape by empowering individuals to securely access and download their clinical data. It not only grants citizens control over their health data but also fosters cross-border collaboration through the International Patient Summary.' This unique initiative sets new standards by enabling the seamless exchange of medical information across borders, bridging language barriers, and ensuring efficient, patient-centric healthcare services in collaboration with multiple European nations. It represents a groundbreaking leap towards the realization of the European Health Data Space's (EHDS) vision, embodying the ideals of data accessibility, privacy, and interoperability.

From the perspective of the users, there will be several outcomes:

- **Enhanced Patient Empowerment**: Citizens now have immediate, easy, and electronic access to their health data, granting them unprecedented control over their medical information.
- **Improved Healthcare Delivery**: The exchange of IPS enables healthcare professionals to make informed decisions, especially when treating patients from different countries, thereby enhancing the quality and continuity of care.
- **Mitigated Allergy-Related Risks**: With access to critical medical data, including allergies, the risk of allergic reactions during treatment is significantly reduced.
- **Language Barrier Overcome**: The tool addresses language barriers by providing standardized patient health information for healthcare professionals.
- **International Collaboration**: The IPS collaboration with other European countries, and plans for future expansion, demonstrates Catalonia's commitment to pioneering cross-border healthcare data sharing.
- **Legal and Ethical Compliance**: The initiative adheres to the GDPR and aligns with the EHDS standards and specifications, ensuring ethical and legal compliance.

System Perspective

For both public and private initiatives, the xShare Yellow Button will be included in the citizen's application/portal frontend. In the case of private ones, this button will use a function of the corresponding backend that will consume a web service published by an integration engine. This integration engine will obtain all the IPS' data from the database of the provider, and it will transform it into the IPS specification format. Then, the generated IPS will be returned to the application/portal, where the download will start. The backend of the xShare Yellow Button, the integration engine and the provider's database will be on the same provider's intranet, for security reasons.

In the case of LMS (aka the public scenario), the button is already available, and all the communication is done within the Catalan Healthcare Intranet (known as Anella Sanitària). Al the

public healthcare providers are publishing its clinical data to the Public Catalan EHR System, called Història Clínica Compartida de Catalunya. They use web services and CDA R2 HL7 formatted documents to provide this information. This structured information provided by public healthcare entities is the base used to generate the LMS' IPS document.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary - public	X			7	8
Patient summary - private	X			1	7
Electronic prescription	X			2	5
Electronic dispensation	X			2	5
Medical image and image report	X			1	5
Laboratory results	X			1	5
Discharge report	X			1	5
Telemonitoring					
Care plan					

Details

National/regional strategy

Catalonia's strategy involves continuous improvement of the healthcare organization through the intensive use of ICT, ensuring data ownership, data portability and interoperability.

Strategy towards EHDS

Empower citizens with control over their data to securely access and download their data. Foster cross-border collaboration through the IPS, ensuring data accessibility, privacy, and interoperability. Promote the participation on the citizen on the secondary use of data.

Business Goals/Benefits and KPIs

Catalonia has been carrying out a digitization process in the healthcare sector for over 40 years. During this time, there have been changes in legislation (such as the law on a single medical history created 20 years ago), and new needs have been identified due to the health emergency (such as the COVID-19 pandemic). Experts, researchers, healthcare professionals, and patients advocate for

the existence of quality healthcare continuity: that my information be available to those who need to attend to me or wish to generate knowledge for the benefit of all.

Despite this need, currently in Catalonia, personal social and health information from the private sphere is not available. This is why there is a need to create a new scenario in which the citizen is at the centre and resolves this issue, exercising their right to own and share their health data as they see fit.

Additionally, the xShare Yellow Button initiative aligns with the principles of the EHDS by promoting immediate access to health data, adhering to international standards, and promoting cross-border data sharing. This initiative sets a precedent for the potential widespread adoption of similar practices across Europe to enhance healthcare data accessibility, quality, and interoperability.

Access to the IPS is typically granted to authorized healthcare providers and organizations involved in a patient's care. The primary goal of the IPS is to facilitate the exchange of essential health information across different healthcare systems and settings. On the other hand, the xShare Yellow Button promotes the secure sharing and access to personal health information by patients. It allows individuals to have easy and convenient access to their PHR and health-related data. The xShare initiative has been developed to empower patients and promote patient engagement in their own healthcare.

In this way, Catalonia is committed to digital portability based on international standards, allowing citizens to move towards control of their health data: immediate, easy, free, and in an electronic, structured, and reusable format. This initiative is in line with the GDPR and advances toward what is established in the EHDS.

- KPI1: Number of citizens downloading IPS from LMS >250
- KPI2: Number of IPS download from private healthcare providers systems > 30
- KPI3: Private Healthcare organizations involved and informed (not piloting) =350
- KPI4: Private Healthcare organizations piloting =2
- KPI5: Number of healthcare professionals involved on the piloting =150

Application	The xShare Yellow Button will be integrated on La Meva Salut portal/app. Additionally in the case of private sector, it will be integrated on the portal/app of private health providers
Data Preconditions	As a data precondition, it is necessary that private healthcare providers have in their systems all the data set that conforms the obligatory sections of the IPS definition. This data needs to be available in a structured format, and it also needs to be mapped to the controlled vocabularies indicated in the IPS specification.
System Preconditions	As a system precondition, it is necessary that private healthcare providers have a mobile application or a portal where patients can

	consult their medical data. This tool needs to be integrated, using secure web services, with the EHR system of the provider.
User Preconditions	The user must be registered on La Meva Salut portal/app, as well as in the portal/app of the corresponding private healthcare provider.
Trigger	The user needs to have his health data to share it in different scenarios: 1. Share his health data with other medical professionals to ensure continuity of care. 2. Provide data for research. 3. Receive cross-border medical assistance or in emergency medical situations. The user accesses the health portal, uses the xShare Yellow Button, and downloads their IPS to share it with whoever he chooses.
Challenges/Limitations	**Citizen Utilization:** The adoption and usage rate of the Blue Button tool among citizens, signifying the extent to which individuals are empowered to manage their health data. **Cross-Border Collaboration**: The extent of collaboration and adoption of the International Patient Summary among European member states. **Adoption of IPS/xShare Yellow Button on the private sector**: IPS has been only implemented and adopted in Public Health Systems, so the private sector would need to adopt it in order to be able to exchange data in the same structured way. **Ease of Use:** The ease and accessibility of the tool for both citizens and healthcare professionals. **Data Security:** The successful safeguarding of patient data to maintain privacy and data security. **Availability of additional or intermediate tools:** like a viewer for the IPS; a tool for merging all IPS onto one single screen; a tool for data cession for secondary use of data; a tool for direct sharing the IPS, etc.
Involved stakeholders in the BUC definition	IT experts, public healthcare administrations, private healthcare associations.
Application of pseudonymisation filters	Yes
Basic Workflow	

Scenario 1: A Catalan citizen has travelled to Madeira. During her vacation, she felt unwell and sought treatment at a health centre. This citizen has a chronic illness and currently takes four different types of medication. To ensure that the emergency doctor treating her in Madeira has all the relevant health information, she accesses to the La Meva Salut mobile application, where she has the xShare Yellow Button available. This button allows her to download her IPS, which she saves on her mobile phone. She emails this document to the doctor in Madeira, ensuring that the treatment she receives aligns with her chronic illness and current medication.

Preconditions:

- The citizen has a Catalan Personal Identification Number (called CIP – Codi d'Identificació Personal).
- The citizen has downloaded LMS in her mobile phone.
- The citizen has access to LMS mobile application.
- The citizen has downloaded an IPS Viewer in her mobile phone.
- The citizen has access to the IPS Viewer mobile application.
- The emergency doctor of Madeira has created an EHR for the Catalan citizen, in the Madeira centre information system.

Steps:

1. The Catalan citizen opens LMS mobile application in her mobile phone.
2. The citizen clicks the access button ("Accedir").
3. The citizen choses the CIP option to authenticate herself.
4. The citizen introduces her CIP and password and clicks the access button ("Accedir").
5. The citizen accepts the welcome message, and access to the main menu.
6. The citizen clicks the profile button to access to a secondary menu.
7. The citizen selects Personal Data on the menu ("Dades Personals") and access to her demographic information.
8. The citizen scrolls down the screen until the data exchange section ("Dades de salut per compartir xShare Yellow Button") and clicks the download option ("Descàrrega").
9. The citizen selects the language of the IPS that she wants to download.
10. The citizen clicks the download option ("Descàrrega").
11. The IPS is downloaded and stored in the citizen's mobile phone filesystem (in CDA R2 L3 HL7 XML format).
12. The citizen opens the IPS Viewer mobile application on her mobile phone.
13. The citizen access to the main menu and clicks the import button ("Importar resum").
14. The citizen clicks on the navigate button ("Selecciona fitxer…").
15. The citizen looks for the previously downloaded IPS.
16. The citizen selects the IPS(s) that wants to import to the IPS Viewer.
17. The IPS(s) is(are) imported to the IPS Viewer mobile application.
18. The citizen returns to the IPS Viewer mobile application main menu.
19. The citizen clicks the sharing button ("Compartir resum").
20. The citizen sees a list with all the available IPS.
21. The citizen choses one or more IPS.
22. The citizen clicks the mail sending option "Compartir resum(s) per correu electrònic".

23. The citizen introduces the mail of the emergency doctor that is attending her.
24. The citizen clicks on send button (“Enviar”).
25. The emergency doctor receives the IPS via email.
26. The doctor downloads the IPS(s) file(s) into his or her computer filesystem.
27. The doctor imports the downloaded IPS(s) to the EHR of the Catalan citizen.
28. The doctor reads the incorporated information and can align the new treatment with the current medications that the citizen is taking for her chronic disease.

Scenario 2: A Catalan citizen has been undergoing specific gynaecological treatment at a private hospital in Catalonia. She experienced a severe complication during childbirth, leading to surgery and subsequent treatment follow-up. CT scans and blood tests have been conducted, and she has been prescribed medication. Since her case was handled in a private centre, her primary care physician lacks information about everything that has happened to this citizen. The citizen, wanting her medical information in her public healthcare EHR (Electronic Health Record), downloads her IPS from the private hospital app and sends it to her doctor through La Meva Salut's e-consultation service.

Preconditions:

- The private healthcare provider has a PHR mobile application for its patients.
- The citizen has downloaded the PHR application in her mobile phone.
- The citizen has access to the PHR mobile application.
- The citizen has downloaded the IPS Viewer in her mobile phone.
- The citizen has access to the IPS Viewer mobile application.
- The citizen has a Catalan Personal Identification Number (called CIP – Codi d’Identificació Personal).
- The citizen has downloaded LMS in her mobile phone.
- The citizen has access to LMS mobile application.
- The e-consultation functionality of LMS is integrated in the primary care EHR system.

Steps:

1. The Catalan citizen opens the PHR mobile application in her mobile phone.
2. The citizen introduces her National Identifier and password and clicks the access button (“Accedir”).
3. The citizen access to the main menu.
4. The citizen clicks the personal data button ("Dades salut”).
5. The citizen access to the sharing data screen ("Dades de salut per compartir - xShare Yellow Button”)
6. The citizen selects the language of the IPS that she wants to download.
7. The citizen elects the language of the IPS that she wants to download.
8. The citizen clicks the download option ("Descàrrega”).
9. The IPS is downloaded and stored in the citizen’s mobile phone filesystem (in CDA R2 L3 HL7 XML format).
10. The citizen opens the IPS Viewer mobile application on her mobile phone.
11. The citizen access to the main menu and clicks the import button ("Importar resum”).

12. The citizen clicks on the navigate button (“Tria un fitxer…”).
13. The citizen looks for the previously downloaded IPS.
14. The citizen selects the IPS that wants to import to the IPS Viewer.
15. The IPS is imported to the IPS Viewer mobile application.
16. The citizen returns to the IPS Viewer mobile application main menu.
17. The citizen clicks the sharing button ("Compartir resum”).
18. The citizen sees a list with all the available IPS.
19. The citizen choses one or more IPS.
20. The citizen clicks the mail sending option “Compartir resum(s) per correu electrònic”.
21. The citizen introduces the mail of the primary care doctor that is attending her.
22. The citizen clicks on sending button (“Enviar”).
23. The primary care doctor receives the IPS via email.
24. The doctor downloads the IPS file into his or her computer filesystem.
25. The doctor imports the downloaded IPS to the EHR of the Catalan citizen.
26. The doctor reads the incorporated information.

Scenario 3: A citizen discovers that he has a rare type of disease. Currently, different research groups are recruiting patients and seeking participants for a clinical study to advance understanding of this disease. The citizen downloads his IPS and uses an intermediate app installed on his personal mobile to check available research projects matching his profile. He securely sends his IPS to participate in a clinical study.

Preconditions:

- The citizen has his IPSs downloaded in his mobile phone filesystem.
- The citizen has downloaded an intermediate mobile application to share his data with research projects.
- The citizen has access to the intermediate mobile application to share his data with research projects.

Steps:

2. The citizen opens the intermediate app on his mobile phone.
3. The citizen introduces his user and password into the corresponding fields.
4. The citizen clicks the access button ("Accedir”).
5. The citizen accesses to the main menu of the intermediate app.
6. The citizen clicks the clinical trial button ("Assajos clínics”).
7. The citizen sees all the available clinical trials.
8. The citizen clicks on one specific clinical trial.
9. The citizen sees the detail of the information of the clinical trial (like name, participants, responsible organization, dates, objective, etc.).
10. The citizen clicks on the sharing data button “Compartir dades de salut”.
11. The citizen clicks on the navigate button (“Tria un fitxer…”).
12. The citizen looks for the previously downloaded IPS.
13. The citizen selects one or more IPS.
14. IPSs are shared with the clinical trial in an anonymised manner through the intermediate app.

Alternative Workflows
Scenario 1: • 3.a.1 The citizen choses the National Identifier option to authenticate himself (“DNI, NIE o passaport”). • 3.a.2 The citizen introduces her National Identifier and password and clicks the access button (“Accedir”). • 3.a.3. The flow continuous in step 5. • 3.b.1 The citizen choses the option fingerprint authentication (“Accedir amb empremta”). • 3.b.2 The citizen uses the mobile phone fingerprint recognition capabilities to access. • 3.b.3 The flow continuous in step 5. **Scenario 2:** • 10.a.1 The Catalan citizen opens LMS mobile application in her mobile phone. • 10.a.2 The citizen clicks the access button (“Accedir”). • 10.a.3 The citizen choses the CIP option to authenticate herself (see scenario 1 for alternative authentication methods). • 10.a.4 The citizen introduces her CIP and password and clicks the access button (“Accedir”). • 10.a.5 The citizen accepts the welcome message, and access to the main menu. • 10.a.6 The citizen clicks e-consultation button. • 10.a.7 The citizen clicks the primary care e-consultation button. • 10.a.8 The citizen indicates that is attaching her IPS in the corresponding fields ("Motiu consulta” “Descripció” “Adjuntar fitxer 1”). • 10.a.9 The citizen clicks on the navigate button (“Tria un fitxer…”). • 10.a.10 The citizen looks for the previously downloaded IPS. • 10.a.11 The citizen selects the IPS(s) that wants to import to the IPS Viewer. • 10.a.12 The citizen clicks the sending button (“Enviar”). • 10.a.13 The primary care doctor receives the IPS(s) via the e-consultation functionality, which is integrated in the EHR system. • 10.a.14 The primary care doctor incorporates the received IPS(s) into the EHR of the citizen. • 10.a.15 The flow continuous in step 26. **Scenario 3:** • 8.a.1 The citizen clicks on the return option, so he returns to the list of clinical trials. • 8.a.2 The flow continuous in step 7. • 6.a.1 The citizen uses the search field to look for a specific clinical trial. • 6.a.2 The citizen sees all the available clinical trials, matching the search criteria. • 6.a.3 The flow continuous in step 6.

Table 12. Spain: AS5_BUC1.

AS5 USs

The Spanish USs can be found in Appendix 3.

Portugal (AS6)

Introduction

Secretaria Regional de Saúde e Proteção Civil (SRS) is the governmental health authority in the Autonomous Region of Madeira, an ultraperipheral region from the EU and the regional policy maker in the health sector and civil protection. SRS is responsible for several entities and services including the Madeira Regional Health Service (SESARAM- E.P.E), the Health Administration Institute (IASAÚDE- IP- RAM), the Regional Directorate of Health (DRS) and the Civil Protection Regional service (SRPC- IP- RAM). Thus, SRS oversees the provision of healthcare and articulates, in a complementary way, primary care centres and hospitals in Madeira, providing healthcare and continued and palliative care through a network of easily accessible services, with a high level of technical and social efficiency that enables health gains. SRS is responsible for resource planning and delivering healthcare to individuals, families, and social groups; developing research and training activities, both in its services and in specific units; and ensuring technical and logistical support for the adequate provision of healthcare. Madeira's Regional Public Health System comprises 3 hospitals, the Dr. Nélio Mendonça Hospital, the Marmeleiros Hospital and the João de Almada Hospital, and 47 Health Centres within the islands of Madeira and Porto Santo. These health infrastructures comprise about 1,000 beds and an annual average healthcare of 80,000 emergency episodes, 250,000 medical consultations, 110,000 nursing consultations and around 10,000 surgeries. A new central and university hospital is currently under construction, to be completed in 2027, comprising 607 additional beds. This new unit follows new guidelines for health units, favouring outpatient care, day hospitals, fewer inpatient beds, and associated home hospitalisation.

Through SRS and the involvement of health care infrastructures, workforce and regional partners, digital health has been strongly supported, developing new technologies to provide citizens access to their health information, support patient monitoring and increase interoperability and use of platforms dedicated to the user. Since 2003 the Madeira Health Service has been developing its own HIS, SEIS-RAM (acronym for Electronic Health Information System of the Autonomous Region of Madeira) in which each patient has a unique EHR, featuring all medical records and social clinical data within the public health sector. Following, in 2022 one app was developed as an alternative communication channel for patients. This solution integrates an application ecosystem connected with the patient portal and the institutional portal, which connects all public health services available in the region, including hospitals and health centres, to provide digital services and useful, up-to-date, and personalised health information to users in a close and real-time manner.

EHDS compliance – Article 8

- *Article 8a – Right of natural persons to access their personal health data*

SRS has been developing and working to ensure an adequate level of coordination of health information, maximising the sharing of information and knowledge to support decision-making and monitoring of health surveillance actions focused on the EHDS regulation. Empowering individuals to take control of their EHRs and facilitating the exchange of data for the delivery of healthcare through the various digital solutions developed, namely the patient portal and app.

- *Article 8b – Right of natural persons to insert information in their own EHR*

The app and the patient portal from SRS allow the user to insert information in its own EHR, namely prescription requests and medical or nursing consultations requests. SRS is currently studying other solutions that would enable users to include other information in their EHR, nevertheless, this needs to be further analysed to be clearly distinguishable as inserted by the natural person or by his or her representative and not interfere with information provided by health professionals. As stated in article 8b "*Natural persons shall not have the possibility to directly alter the electronic health data and related information inserted by health professionals*".

- *Article 8c – Right of natural persons to rectification*

At the moment SRS, through the Regional Health Service, offers various online communication channels providing a possibility for natural persons to easily request rectification of their personal data online as a way to exercise their right to rectification under Article 16 of Regulation (EU) 2016/679.

- *Article 8d – Right of data portability for natural persons*

The app and the patient portal from SRS allow the user to download information from its own EHR in PDF format. Enabling the user to give access to all or part of their electronic health data to another healthcare provider of their choice immediately and free of charge, in accordance with point 1 of this article. SRS is currently working in transmitting the data in the European electronic health record exchange format referred to in Article 6 through the cross-border infrastructure as referred to in Article 12.

- *Article 8e – Right of restrict access*

The user from the Madeira Regional Health System can declare whether or not they want to restrict access of health professionals and healthcare providers to all or parts of their personal EHR as referred to in Article 8a. When exercising this right, users are aware that restricting access may impact the provision of healthcare provided to them with specific safeguards regarding such restriction mechanisms, also this information is not visible to healthcare providers in accordance with Article 8(e).

- *Article 8f – Right of obtain information on accessing data*

All access to a personal electronic health data stay recorded on file in the exact EHR. Thus, any access to the user's personal electronic health data through the health professional access service made in the context of healthcare, including access provided in accordance with Article 4(4), is available upon request. SRS is still working in including automatic notifications, on any access to the user's personal electronic health data in the context of healthcare.

- *Article 8g – Electronic health data access services for natural persons and their representatives*

In the Madeira Regional Service there are two established electronic health data access services at regional level (app and patient portal). Additionally, as Portuguese citizens, Madeira citizen's also have two electronic health data access services available at national level (app and patient portal).

These enable people to access their personal electronic health data, and the exercise of rights referred to in Articles 8a to 8h. These services are free of charge for the natural persons and their representatives ensuring that one or more proxy services are established as a functionality of health data access service in accordance with 2aa). SRS is currently working in 2a) in implementing acts and lay down the technical specifications to ensure the interoperability of the proxy services of the Member States to transmit data in the European electronic health record exchange format. Furthermore, SRS is very committed in providing easily access for persons with disabilities, vulnerable groups and particularly persons with low digital literacy as mentioned in point 2b.

- *Article 8h – Right of natural person to opt out in primary use*

SRS provides citizens the right to opt out from the access to their personal electronic health data registered in an EHR system through the electronic health data access services referred to in Articles 7b and 8g. In such cases, ensuring that the exercise of this right is reversible at any time. Specific safeguards regarding such objection are applied, in particular the impact in the provision of healthcare provided in cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679, even if the patient has exercised the right to opt out in primary use.

EHR Sharing in the Madeira Region (AS6_BUC1)

SRS general BUC objective is to meet the needs of healthcare professionals and users by empowering healthcare institutions with innovative solutions based on healthcare provision, thus acquiring knowledge, intelligence, and interoperability. It is also about improving the quality of healthcare, guaranteeing patient safety and optimising resource management, providing users and the community with information that enables them to make better health decisions. Ensuring an open health system focussed on people and community, offering transparency, proximity and a response to their needs and expectations.

Using the template adopted by the xShare project, SRS has identified 3 scenarios in which the adoption of the xShare Yellow Button will be paramount, namely: when there is the need for the user to access personalised health data to be more aware/knowledgeable of their health status (no trigger involved); when the user needs to share personalised health data with the private/public health sector (continuity of care/seeking a second opinion/medical emergency) and when there is the need to share health data across border (continuity of care/seeking a second opinion/medical emergency).

The scenarios identified by this adoption site will be further presented and adapted to different actors involved.

Overview	
Use Case Acronym	AS6_BUC1
Document Version	V1.0
Current situation	
As-Is Situation	

With the Madeira Health Service own HIS, SEIS-RAM, each patient has a unique EHR, featuring all medical records and social clinical data within the public health sector. This system aggregates more than 500,000 EHR and ensures interoperability with several external services such as the National User Registry (RNU), the communication and image archiving system (PACS), the Modulab, the National Cancer Screening System and Madeira's Medical Emergency Register (REM RAM). SEIS-RAM comprises a dashboard where doctors, nurses and health professionals can manage and monitor provided health care services throughout public health facilities, as this system establishes communication between hospitals and health centres in the Madeira Archipelago.

Following this system, a patient portal was set up in which patients from the Regional Health Service have access to their patient summary in SEIS-RAM, namely: ID and demographics; allergies and intolerances; immunizations; history of appointments; medical reports; diagnostic results; surgery reports and emergency discharges. Health data featured on this portal can be exported in PDF format thus allowing patients from the public sector to share their health data with external health care providers e.g. private health sector. Additionally, a mobile app was also developed allowing the same functionalities of the previously described patient portal.

Previously, by taking part in Smart4Health project, also some additional work aiming health data portability was done in SEIS-RAM. Data from EHRs in SEIS-RAM (demographics, allergies and intolerances, diagnoses, and clinical exam reports) was mapped and sent in HL7/FHIR standards to the Smart4Health platform upon user request. Further enabling health data portability while seeking private/public care and eHealth tourism.

Due to a cyber-attack occurred on the SEIS-RAM system in August 2023, both structures mentioned above (app and portal) are not currently active as since then their security was compromised.

All efforts have been made to resume its operation according to GDPR and it is expected to be soon reactivated for patients.

Currently available products/services and its vendors
In-house HIS (SEIS-RAM), Regional patient portal, and Regional APP.

Which health-related standard does your organisation uses and its alignment to the EEHRxF?
Previously some work aiming health data portability was done within the Smart4Health project in which data from EHRs was mapped and sent in HL7/FHIR standards upon user request.

Use Case		
Actors/Users and their Roles	Local patient (user 1)	Can access and share EHR data via the xShare Yellow Button in different scenarios: • Scenario 1: the user wants to access health data to be more

		aware/knowledgeable of their health status (no trigger involved). • Scenario 2: the user needs to share health data with the private/public health sector (continuity of care/seeking a second opinion/medical emergency). • Scenario 3: the user needs to share health data across border (continuity of care/seeking a second opinion/medical emergency).
	Tourist (user 2)	Shares EHR data with health authorities in Madeira in different scenarios: • Scenario 1: the user needs to share health data with the local health sector (continuity of care/seeking a second opinion/medical emergency) • Scenario 2: the user needs to share cross border health data with the local health sector (continuity of care/seeking a second opinion/medical emergency)
	Health professional (medical doctors and nurses) (user 3)	Receives EHR data via the xShare Yellow Button in different scenarios: • Scenario 1: the user needs to access health data from user 1 (continuity of care/seeking a second opinion/medical emergency) • Scenario 2: the user needs to access health data from user 2 (continuity of care/seeking a second opinion/medical emergency)
	IT professional	Developer/tester- develops and tests the xShare Yellow Button within the SEIS-RAM app/ patient portal.
	Smart4Health platform	Source of information and knowledge as a pre-existing health data sharing system

		for smart guidelines and medical tourism.
	SEIS-RAM system	EHR data source.

Use Case Description

The Madeira use case will implement the xShare Yellow Button allowing portability of the EHR from SEIS-RAM for patients from the Regional Health System in Madeira, and for tourists to share EHR data with local health authorities. The patient summary data (patient ids, demographic, allergies and intolerances, immunizations, history of procedures, clinical reports, diagnostic results, discharge reports, appointments, and surgeries) is stored in the SEIS-RAM system. The SEIS-RAM system communicates with the digital solutions previously developed, i.e. the patient portal and the mobile app from SEIS-RAM allowing patients to access this data upon registration and authentication. Both the patient portal and the mobile app require a 2-point authentication according to data register upon the Regional Health System registration, thus GDPR compliant.

The xShare Yellow Button will be installed on the patient portal and the mobile app, allowing the EHR to be accessed, downloaded, and then shared.

Once the user presses the xShare Yellow Button, the EHR is download and the patient can share their health data in the different scenarios described.

The button should offer two options for downloading health data, in a format that is readable by the user (e.g. pdf) and in an EU standardised format that complies with standards i.e. with language and coding required by health institutions. By having access to their health data in a standardized format, the patient can then share it with a health institution or health professional of their choice and even across borders. Also, the readable format for the user is of most importance, to encourage and motivate the use of the button by the user, thus additionally increasing knowledge of their health and well-being.

The possibility of placing the button in the app allows patients to always have access to their health data and the ability to share it at anytime and anywhere.

The ability to share the EHR will enable better management of health resources, more personalised healthcare and better preparedness and resilience within health population.

User Perspective

When using the xShare Yellow Button the local patient/user 1 will be able to download the EHR from the Regional Health service and access and share health data with public or private health institutions and across border since the EHR information will follow common standards in order that it can be read and interpreted externally, thus allowing better health care with less time and associated costs.

From the collected testimonies, this was presented as a major benefit when compared to the current situation. Having a quicker way to access health data was also emphasised by user 1, as well

as the fact that the button will make it easier to consult medical second opinions whether inside or outside Madeira.

Also, the ability to interpret health data was also emphasised by user 1, so that besides allowing the portability of health data in standard format, the button should also allow access to this information in a user-readable way for patients. In this regard, it was suggested that data should be structured by medical speciality (e.g. cardiology, neurology, and others) and not by medical procedure.

Health care in Madeira Island will be facilitated for tourist/user 2 who visit Madeira to carry out medical and wellness care or unplanned care during their holidays since it will enable tourists to share their health information with the local health sector, thus allowing better health care in a timely manner. This situation has been highlighted by user 2, particularly in the event of a medical emergency in which no health data is known about the patient.

The xShare Yellow Button will allow the health professional/user 3 to provide better medical care and save time and delays in the provision of health care, allowing a more personalised response to health care and not duplicating resources, thus saving available resources (e.g. medication, lab and imaging exams).

User 1 and user 3 were unanimous that the best place for the button to be presented would be in the SEIS-RAM app and the user portal, thus allowing the use of known structures to these players, with easier access to health data. Also, the app was considered the best site of the two, due to the possibility of accessing it via a mobile system such as a smartphone.

Another situation that was reinforced by the boards of directors consulted was the benefits that can be provided by the xShare Yellow Button in standardizing provided health services and their personalization. It is a real fact that duplication of health examinations occurs countless times between health institutions (public and private), often taking consequences for the patients and their wellbeing, such as increased exposure to ionizing radiation, such as x-rays and gamma rays. The xShare Yellow Button and the sharing of health data will help resource management allowing a more personalized healthcare.

System Perspective

The existing portal/app from SEIS-RAM will enable the xShare Yellow Button to download EHRs in HL7/FHIR format and in PDF format. The implementation of the xShare Yellow Button will benefit from these pre-existing digital solutions to the extent that they can enable downloading information from the EHR once the patient has been registered and thus in accordance with GDPR. The full implementation of the xShare Yellow Button and the fulfilment of cross-border standards requires a clear definition of protocols and guidelines to be used in mapping and structuring of the local HIS.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary	X	X		6	9
Electronic prescription					
Electronic dispensation					
Medical image	X	X		2	8
Image report	X	X		3	9
Laboratory results	X	X		4	8
Discharge report	X	X		5	9
Telemonitoring					
Care plan					

Details

National/regional strategy

- Allow people to exercise their **data portability** rights under GDPR with emphasis in **medical tourism** and the **public/private** sector **continuity of care**.
- **Empower individuals** to control their health data and ensure **interoperability** and **security** within health care providers between public and private health sectors, **fostering** a single market for **digital health services** and products.

Strategy towards EHDS

- Improve quality of care, guarantee patient safety, optimise costs **providing individuals** and **communities** with information to make better health decisions.
- **Ensure** an adequate level of coordination of **health information.**
- **Maximise** the **sharing** of information and **knowledge** to support decision making.
- and monitor health surveillance actions.

Business Goals/Benefits and KPIs

The xShare Yellow Button to be featured in MADEHRAS will allow people to exercise their data portability rights under GDPR in a regional network with emphasis in medical tourism and for the public/private sector continuity of care. This will empower individuals to control their health data and ensure interoperability and security within health care providers between public and private health sectors, fostering a single market for digital health services and products.

The xShare Yellow Button will be employed to facilitate continuity of care in Madeira within citizens and tourists.

• KPI 1: Number of patient/users downloading the EHR through the xShare Yellow Button (1-2% of the Madeira Regional Health Service patients, users 1 and 2). • KPI 2: Number of sharings via xShare Yellow Button (50% of EHR data sets download through the xShare Yellow Button). • KPI 3: Number of EHR data sets download through the xShare Yellow Button (200-500 data sets) • KPI 4: Number of tourist/users sharing EHR data with local health authorities in Madeira (1-2% of user 2, seeking medical care in the Madeira Regional Health Service).	
Application	The xShare Yellow Button will be integrated in the App from SEIS-RAM and in the Patient Portal from SEIS-RAM. Enabling the identified HIDs to be shared in the EEHRxF. These HIDs can be shared separately upon selection.
Data Preconditions	Before this use case can start it should be established a common standard and mapping for the HIS from the Regional Health Service. Training for the IT professionals is in need to establish the correct mapping of the local HIS.
System Preconditions	SEIS-RAM must have the patient's health data within its records. Given that at the moment whether the SEIS-RAM app, whether the patient portal is not available, these must be restarted before the starting of this use case. Also, it should be harmonized the underlying specifications for the EEHRxF.
User Preconditions	Patient/tourist/health professional user need to present digital literacy. All users need to have access to IT resources, computer, phone or tablet. Patient/user needs to be register in the patient portal and/or the mobile app from SEIS-RAM. Patient/user must be an active user of the Regional Health System.
Trigger	Patient and tourist/user seek a second medical opinion outside the public health sector or across borders. Tourist/user needs planned and/or unplanned care during their holidays.
Challenges/Limitations	• Currently inaccessible digital structures (mobile app and patient portal). • xShare Yellow Button location and patient summary requirements.

	• Lack of FHIR standards and FHIR mapping establishment including common content specifications, HL7 FHIR implementation guides.
Involved stakeholders in the BUC definition	• **Local patient** (user 1) – 3 persons. • **Tourist** (user 2) – 2 persons. • **Health professional** (user 3) – 3 persons. • **IT professional** – 2 persons. • **Local authorities** - board of directors for the Health Administration Institute (IASAÚDE- IP- RAM) and the board of directors for Madeira Regional Health Service (SESARAM).
Application of pseudonymisation filters	To be assessed. The implementation of the xShare Yellow Button will benefit from pre-existing digital solutions to the extent that they can enable downloading information from the EHR once the patient has been registered. These require a 2-point authentication according to data provided upon the Regional Health System registration
Basic Workflow	

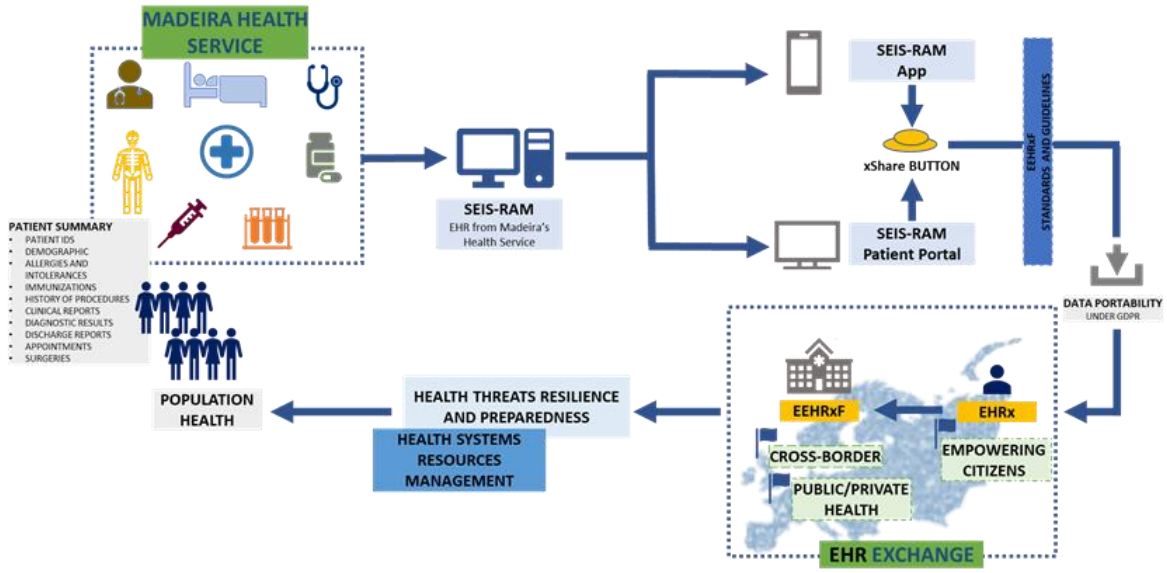

Image: EHRs in the SEIS-RAM health information system from the Madeira Health Service is connected to the SEIS-RAM app and the SEIS-RAM patient portal enabling citizen's access to their personalised health data. The xShare Yellow Button will be implemented in these pre-existing digital solutions to the extent that they can enable downloading information from the EHR once the patient has been registered in the Madeira Health Service. The existing portal/app from SEIS-RAM will enable the xShare Yellow Button to download EHRs in the EEHRxF according to standards and

guidelines. The EHR exchange will foster a genuine single market for electronic health record systems providing a consistent and efficient system to increase health systems resource management and surmount health threats by increasing resilience and preparedness in healthcare.
Alternative Workflows
Select only one digital solution to present the xShare Yellow Button, the mobile app or the patient portal. Select specific and the most important health data from the patient summary (e.g. immunization, clinical reports, etc.) to be download in HL7/FHIR format when using the xShare Yellow Button.

Table 13. Portugal: AS6_BUC1.

AS6 USs

The Portuguese USs can be found in Appendix 3.

Denmark (AS7)

Introduction

The Danish National Authority are running the program “A Patient Comprehensive Overview” which develops solutions for better coordination, collaboration and overview for patients, relatives and health-professionals. The program works on four areas: sharing of appointments, sharing of patient master card, sharing of Care Plans and the patient goals,

The Regions' Salary and Tariff Board and the Practitioners' Organization entered into an agreement on implementation in the collective agreement period 2018-2020. With the agreement are allocated funds for technical development, dissemination and operation of Care Plans. Care Plans are intended to give patients a better overview of their treatment. Care Plans are maintained by the patient's own doctor and aims to contribute to strengthening the patient's self-care and control of their own illness.

MedCom is on behalf of the Ministry of Health responsible for running a project for implementing Care Plans for COPD, diabetes type 2 and heart failures in all primary care clinics (appx. 1.700) in Denmark. Care Plans have been in daily operation 5-6 years. In 2023 the primary care clinics created or updated appx. 175.000 Care Plans. In total appx. 300.000 patients have one or more Care Plans. The initial aim for introduction of the Care Plans in primary care was a digital dialog tool between the primary care doctor and the individual patient.

In 2020 a technical test was launched for sharing Care Plans for COPD with hospitals and social care. The pilot test showed that it was possible to share the information via the XDS-based national infrastructure and a HL7 CDA profile for Care Plans. An evaluation confirmed that the sharing had potential benefits for the cross-sector treatment of a patient as the Care Plans from primary care had very useful information.

In 2023 it was agreed to share the Care Plans for COPD, diabetes type 2 and heart failures via the national infrastructure. A patients Care Plans can be accessed at the Danish portal Sundhed.dk by the patients, their relatives and all health care professionals. According to the Danish health law a health professional may access relevant patient clinical information if there exist a treatment relation. “

All access to a patient clinical information is logged and the patients can in that way see who has viewed their data.

EHDS compliance – Article 8

At the moment, no decisions regarding EHDS and Care Plans have been taken. This relation will be discussed during the xShare project. MEDIQ will facilitate a process with the Danish Health Data Authorities and MedCom.

Care Plan (AS7_BUC1)

In relation to sharing Care Plans from primary Care via the national infrastructure MEDIQ have a number of roles:

- Technical project manager for the Care Plan solution in Primary Care.

- Preparing the Danish HL7 CDA profile for sharing the clinical content for a Care Plan (DK CPD).
- Preparing test-protocols for sending and receiving HL 7 CDA (DK CPD).
- Preparing test-protocol for upload/download of XDS-metadata.
- Test & certification with MedCom of 6 EHR systems and Sundhed.dk (DK CPD + XDS metadata).
- Preparing specification for presentation of the clinical content at Sundhed.dk.

Overview	
Use Case Acronym	AS7_BUC1
Document Version	V1.0
Current situation	
As-Is Situation	
The sharing will be done via the Danish National Infrastructure using a Danish profile HL7 CDA. The Regions' Salary and Tariff Board and the Practitioners' Organization entered into an agreement on implementation in the collective agreement period 2018-2020. With the agreement are allocated funds for technical development, dissemination, and operation of Care Plans. Care Plans are intended to give patients a better overview of their treatment. Care Plans are maintained by the patient's own doctor and aims to contribute to strengthening the patient's self-care and control of their own illness. Digital Care Plans have been developed and put into operation for 3 chronic disease areas (COPD, diabetes type 2 and heart failure). The Care Plans are available in all general practice medical systems in Denmark. By February 2024, 30.000 Care Plans are developed or updated every month. The Care Plan steering board have in 2023 decided that the Care Plans shall be shared with the entire health care sector. The sharing will be done via the Danish National Infrastructure using a Danish profile HL7 CDA.	
Currently available products/services and its vendors	
National Care Plan service, integrated to all GP EHR, Sharing via Danish National Infrastructure.	
Which health-related standard does your organisation uses and its alignment to the EEHRxF?	
HL7 CDA for sharing Care Plans.	
Use Case	

Actors/Users and their Roles	Ministry of the Interior and Health of Denmark *https://ism.dk/english*	Steering group and funds the project.
	MedCom *www.medcom.dk*	Project management and for the Care Plan project. Responsible for the Danish profile HL7 CDA (DK CPD).
	The Danish Organization of General Practitioners *www.laeger.dk*	Safeguards the professional and financial interests of general practitioners. Enters into collective agreements and agreements on behalf of the general practitioners.
	MEDIQ A/S *www.mediq.dk*	Technical project management of the Care Plan project. Assistant to MedCom in development of HL7 CDA (DK CPD). Assistant to the Danish Health Data Authority for sharing Care Plans from primary care via the national infrastructure.
	Suppliers of EHR systems *https://pl-forum.dk/hvem-er-vi/*	Implementing Care Plans in EHR systems for general practitioners. In Denmark we have 6 EHR systems used in primary care.
	The Danish Health Data Authority *https://sundhedsdatastyrelsen.dk/da/english*	Responsible for the National Infrastructure (XDS Document Sharing) and responsible for the Care Plan sharing project.
	PLSP	The General Practitioner Service Platform are responsible for sharing the Care Plans via the national infrastructure.

	https://www.plsp.dk/	
	Sundhed.dk https://www.sundhed.dk/	The Danish Health Portal (Sundhe.dk) are responsible for portal where patient and health professional can search and view Care Plans.

Use Case Description

During 2024, patients Care Plans can be viewed on the Danish health portal Sundhed.dk by patients, relatives, and all health professionals. An evaluation of the sharing is planned. The Care Plans will also be available in the app “Mingle” (English: MyDoctor).

Regarding xShare the plan is to document to Danish use case for Care Plans in the EEHRxF and prepare a first draft for a X-Bundle for Care Plans.

Expressing the Care Plan in the EEHRxF and X-Bundle will be useful to validate how the specifications can be used regional, national and European. The work will also be used as a case to show how future national and cross border projects can be documented – from the initial ideas to full deployment.

The aim is to share the next version of Care Plans on national level in Denmark by using the EEHRxF.

The work will also consider how the xShare Yellow Button can be adopted. A possible first solution is to use the xShare Yellow Button, so the patients can download their own Care Plan and share with health professionals (e.g. specialist for a second opinion, multimorbidity management or social care) and/or informal carers so that family and friends can help them manage their condition.

The implementation cost of the xShare Yellow Button is not financed. The plan is to involve Danish vendors to submit a request for the xShare open call in 2025.

User Perspective

The health care professionals in Denmark will not achieve benefits for using the EEHRxF and the X-Bundle. Also, they will not benefit from the xShare Yellow Button as access to a patient’s data is permitted by law and does not require consent from the patient.

When a Danish citizen travel in Europe the xShare Yellow Button may be useful, but this must be analysed and compared with the current situation where the patient can look-up his own health-data on his own mobile.

With the button the patients can download their own Care Plan and share the data content in a structured format which can be used for further analyses and learning on how to be healthier.

The Danish vison and expectation to the EEHRxF and the X-Bundles is that it can decrease the time for developing new eHealth services including national deployment. This process will indirect be a great advantage for the users – both health professionals and patients.

System Perspective

At the moment, this is difficult to estimate as the EEHRxF and xShare Yellow Button is not described with enough details. However, if the EEHRxF and xShare Yellow Button will be accepted and adopted across Europe – the suppliers themselves will implement it.

Now this is difficult to estimate as the EEHRxF and xShare Yellow Button is not described with enough details. It is important to find technical solutions for the "receiver" of data shared with the xShare Yellow Button and in the EEHRxF format. Today's standards (e.g.: CDA and FHIR) are complex and requires many resources to implement. Most of the standards are also regional or national profiles, which challenges a European implementation and cross border sharing of data.

It is a must that the EEHRxF is built by generic components and supported by applications to be used by the recipient so they can access the data.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary					
Electronic prescription					
Electronic dispensation					
Medical image and image report					
Laboratory results					
Discharge report					
Telemonitoring					
Care plan		X		1	6-7

Details

National/regional strategy

- National eHealth strategy to share more data from GP clinics.

• Strategy for further development/sharing of Care Plans 2023 +5 year.
Strategy towards EHDS
Regarding EHDS Patient Summary is being implemented in 2024 and 2025 in Denmark At the moment no decisions regarding EHDS and Care Plans have been taken. This relation will be discussed during the xShare Project. MEDIQ will facilitate a process with the Danish Health Data Authorities and MedCom.
Business Goals/Benefits and KPIs
The Yellow Button will allow patients to access their own Care Plans in a structured format (EEHRxF) so they can do own and more detailed analysis. The structured data will make it possible for a patient with diabetes to follow how food, medication, exercise and smoking will affect and control the disease.

Application	Candidates are Sundhed.dk and Mingle app.
Data Preconditions	Data for Care Plans is available. We need the EEHRxF and button specification to launch dialog with the vendors.
System Preconditions	Same as data preconditions.
User Preconditions	No identified precondition at the moment.
Trigger	The patient presses the xShare Yellow Button in order to get access to own Care plan in a structured format (EEHRxF).
Challenges/Limitations	• Resources for the implementation of the xShare Yellow Button and a clear description of the EEHRxF and the Button. • By sharing: clinician is not allowed to persist patient data.
Involved stakeholders in the BUC definition	• MedCom. • Ministry of Health. • Health Data Authority. • GP Doctor association. • Hospitals, municipalities, GP clinics (doctors, nurses, ...). • Patients and relatives.
Application of pseudonymisation filters	No
Basic Workflow	

All General Practitioner Clinic (appx. 1.700) have functionality to create and modify Care Plans for patients with COPD, diabetes type 2 and heart failures. All relevant data for the Care Plans are synchronized to a central Care Plan database at PLSP. In April 2024 more than 300.000 patients have one or more Care Plans, worked out by their General Practitioner. Care Plans for COPD, diabetes and heart failures was launched as a digital dialog tool between the patient and the doctor. However, in 2023 it was decided to connect the Care Plan database to the national infrastructure with the aim to give access to view content to all health care professionals and the patient's relatives. To Care Plans are shared via a national XDS services and using a Danish HL7 CDA profile (DK CPD). The existing sharing is not described in detail in this business use case. The aim of the business use case is to give the patient and their relatives access to Care Plans in structured format (EEHRxF) via the xShare Yellow Button. A patient can via button download and print a Care Plan. A new xShare Yellow Button will be developed which will download the Care Plan content to the patients PC or mobile. This new functionality is planned to run in a pilot with appx. 100 patients. After the pilot the new functionalities will be evaluated.
Alternative Workflows
N/A.

Table 14. Denmark: AS7_BUC1.

AS7 USs

The Danish USs can be found in Appendix 3.

France (AS8)

Introduction

Telemedicine Technologies (TTSA) is a French company provider of e-health solution operating in more than 43 countries, involving over 20 000 research centres, with more than 3 million patients in their data base and 50,000 users worldwide. The fields of expertise are divided in five key domains: real world evidence and registries, patient pathway, data services, AI and data visualization, and investigator site management with site solutions.

The sites solutions are designed to meet the challenges faced by investigation sites, hospital, private clinic, and health centre involved in patient recruitment for clinical trials. Indeed, about half of clinical trials are delayed due to recruitment difficulties. In light of this, an innovative digital solution called CT-SCOUT has been developed. The goal of this product is to simplify and speed up the process of identifying studies for which a patient could be eligible, based on their health status. In other words, the goal is to optimise patient pre-screening for a clinical trial.

EHDS compliance – Article 8

In France, the context is favourable to a digital development aligned with the legislation “loin informatique et liberté” and the application of the GDPR. The arrival of the EHDS represents a major project that has been integrating into national work since 2018.

TTSA adheres to the regulation applied in France and also covers its activities in adequation with the health data hosting standard. The health data hosting certification ensures that health data is managed securely and in compliance with current legislation, while safeguarding the confidentiality of patients’ personal information.

xShare Yellow Button for patients pre-screening in clinical trial using “Mon espace santé” health data (AS8_BUC1)

At the national level, there is a space that allows everyone to store and share their data, such as their health documents, securely. This is the “Mon espace santé” platform. As for it, the patient pre-screening process with CT-SCOUT involves entering patient data into the application by a research team member to evaluate compatible studies. These data are retrieved from the medical record or during a consultation with the patient. The link between these existing data in “Mon espace santé” and a digital solution such as CT-SCOUT, would improve patient accessibility to clinical studies.

TTSA general BUC objective is to demonstrate the interest of the xShare Yellow Button applied to “Mon espace santé” and patients pre-screening with CT-SCOUT.

Overview	
Use Case Acronym	AS_BUC1
Document Version	V1.0
Current situation	

As-Is Situation		
Patients have access to their health data through the “Mon espace santé” (My health space) application. The “Mon espace santé” is a patient owned healthcare record and provides to patients and healthcare providers mechanisms to store and maintain data. Through “Mon espace santé” patients can share their data. Data is shared with healthcare professionals. • Healthcare professionals in France have access to patient data through their own systems and through the DMP (dossier médical partagé, shared medical record). • Data are in CDA and/or FHIR format. There are no mechanisms to enable patients to “donate” their data for secondary use. CT-SCOUT is a pre-screening tool used by HCPs at site, which consists in answering a short medical questionnaire filtering automatically the right clinical trials according to the patient profile. The pre-screening performed by CT-SCOUT use real world or data from EHR and do not include specific data from research.		
Currently available products/services and its vendors		
DMP (health medical record), “Mon espace santé”, CT-SCOUT		
Which health-related standard does your organisation uses and its alignment to the EEHRxF?		
CDA and FHIR format.		
Use Case		
Actors/Users and their Roles	Patient	Final user via mobile application, beneficiary.
	Healthcare provider	Final user viewing data acquired by patient via button, beneficiary.
	EHR	Integrate with the xShare Yellow Button service via API.
	Patient mobile application	Integrate with the xShare Yellow Button service via API.
	xShare Yellow Button service	Enables the xShare Yellow Button functions via API, benefactor.
Use Case Description		

Patient has access to structured format health data using "Mon espace santé," and will use the xShare Yellow Button service(s) to decide which data points are to be shared with clinical investigator. Data are available in CDA/FHIR formats.

The patient uses the xShare Yellow Button service(s) to decide which data points are to be shared/donated with clinical investigator. And the xShare Yellow Button service(s) will allow patient data conversion/upload/sharing in structured EEHRxF IPS and sending to the clinical investigator pre-screening tool.

A mapping of the IPS data points and answers to the medical questionnaire will be done followed by automatic completion through the pre-screening tool.

According to the available data, answers to the medical questionnaire are automatically fulfilled. The physician reviews the answers provided by the xShare Yellow Button, and answers the questions left without answer, CT-SCOUT indicates the studies for which the patient is potentially eligible to. The physician selects one or more studies for which he wants to refer the patient, and a notification is sent to the study team to facilitate the coordination onsite for future patient inclusion.

User Perspective

Until now, patient screening for a clinical trial is conducted by HCPs on site. The patient is invited to participate once the investigative team has identified their potential eligibility, often during a routine visit. The xShare Yellow Button will empower patients to take a proactive role in their medical journey and influence their medical follow-up. Therefore, it would enable patients to:

- Share a selection of personal health data related to their condition to a clinical investigator so that their eligibility to a clinical trial can be assess.
- Share the full patient summary so their full eligibility to a clinical trial can be evaluated by Clinical investigator/research team.
- Be contacted if a new clinical trial matches their health profile so that a clinical investigator can evaluate their eligibility to the new clinical trial.
- Be able to choose the hospital in which a clinical trial matches their health profile so that a clinical investigator can evaluate their potentially eligibility to a clinical trial in the hospital of their choice.
- Be able to get an appointment at the hospital of their choice in which a clinical trial matches their health profile to assess their full eligibility by a clinical investigator during a medical visit.
- Be informed of the clinical trial matching their health profile and evaluate their interest to participate to the clinical trial.
- Know how their data will be used and exercise their data portability rights under GDPR.
- Know which data will be used and exercise their data portability rights under GDPR.
- Modify/delete the access to their data and exercise my data portability rights under GDPR.

Besides benefits for the patient, the use of the xShare Yellow Button will be beneficial for the clinical investigator and the research team. Properly screening patients for eligibility in a clinical trial

is one of the most challenging tasks. The xShare Yellow Button could potentially simplify this process by facilitating health data sharing, therefore assisting the PI.

System Perspective

The xShare Yellow Button has found its place in the "Settings" and then "Privacy" section of "Mon espace santé", with, for example, a toggle button to consent to data sharing for identifying eligibility criterion with clinical studies. Through IPS, health data can be converted into EEHRxF, and CT-Scout can access data integrated into the IPS and pre-screen patients or clinical trials.

When a patient is potentially eligible for an ongoing clinical trial at the investigation site, they receive a notification and are contacted to schedule a screening visit. Patient pre-screening data are available in the patient management section of the CT-SCOUT application.

Scenarios for the xShare Yellow Button

HIDs	xShare Yellow Button basic functionality			Maturity	
	Download	One-time share	Linked options	Start TRL	End TRL
Patient summary	X	X	X	3	7
Electronic prescription					
Electronic dispensation					
Medical image and image report					
Laboratory results					
Discharge report					
Telemonitoring					
Care plan					

Details

National/regional strategy

The national strategy lead by the French ministry of health with the SUN-ES program aims to contribute to the generalization of fluid and secure sharing of healthcare data, in order to accelerate its use. "Mon espace santé" is a part of this program and the main challenge is to democratize its use by systematically importing healthcare data from hospitals, clinics, laboratories, etc., and enabling patients to empower their data.

Strategy towards EHDS

Health data from "Mon espace santé" will be translated to EEHRxF.

Business Goals/Benefits and KPIs	
The use case is executed to enhance patient inclusion in clinical trials. Indeed, recruitment is one of the most important and challenging aspect of clinical trials. By facilitating patient inclusion, patients can actively participate in their own health within the clinical trial context, which has traditionally been reserved for HCPs. Benefits are for the patient to empower their health with their assessment in clinical trial, for the Clinical investigator and the research team to be able to recruit the right number of patients and for both to advance clinical research. The evaluation can be performed by the following KPIs: • Number of patients with a "Mon espace santé" account activated. • Number of patients using "Mon espace santé" functionalities • Number of patients referred for clinical trial. • Number of patients included in clinical trial.	
Application	Patient mobile app and healthcare provider EHR system.
Data Preconditions	Coded data aligned with EEHRxF.
System Preconditions	FHIR transactions capability and compliant with consent policies.
User Preconditions	Patient: familiarity with the xShare Yellow Button.
Trigger	The patient allows the link through the xShare yellow Button from "Mon espace santé" to CT-SCOUT.
Challenges/Limitations	Collaboration with "Mon espace santé" working team.
Involved stakeholders in the BUC definition	Patient, clinical investigator, research team.
Application of pseudonymisation filters	Patients will have a pseudonymisation number while being pre-screened in the pre-screening tool.
Basic Workflow	
Basic Scenario: A patient has been diagnosis with a new condition and wants to know if he/she can be included in a clinical trial in one of the hospital next to his/her home. **Basic flow Steps:** 1. The patient logs in to "Mon espace santé". 2. The patient authorizes the sharing of their data for evaluating their eligibility for a clinical trial with the xShare Yellow Button. 3. The health data are converted into the EEHRxF/IPS format.	

4. The health data are shared. 5. CT-SCOUT application interprets the data. 6. The results of compatible studies and participating centres are accessible to the patient in “Mon espace santé “ 7. The patient gives consent for their data to be sent to their chosen centre. 8. The centre (Investigator and research team) can contact the patient to finalize the process. 9. The centre receives this information in the patient management section of CT-SCOUT. 10. The centre accesses the patient’s pre-screening data. 11. Finally, the centre contacts the patient to schedule the visit
Alternative Workflows
Alternative N°1: The patient health condition changes and the results of compatible studies in the centres evolve accordingly. **Alternative N°2:** The patient makes an appointment directly with the centre to discuss his/her eligibility, and shares data with the HCP (QR code) via “Mon espace santé”. Specific pre-screening data are available in CT-SCOUT patient management.

Table 15. France: AS8_BUC1.

AS8 USs

The French USs can be found in Appendix 3.

Appendix 3: Adoption Sites User Stories

AS1 – Greece USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS1 - Greece													
AS1_US1	Patient	Obtain my PS	I have a view of my PS	Important US	P1_BUC1	⬇							
AS1_US2	Patient	Get all my health data	I visit a health care professional abroad	Important US	P1_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS1_US3	Patient	Send all my health data to my doctor	my doctor gets a second opinion from colleague	Important US	P1_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS1_US4	Patient	Get all my health data	I feed a personalized health app (e.g. for diabetes)	Important US	P1_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS1_US5	Patient	Get my PS	I send my PS to insurance company	Important US	P1_BUC1	⬇							
AS1_US6	Patient	Get all my health data	I participate in clinical trial	Important US	P1_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS1_US7	Patient	Get PS and dispensations	I participate in clinical research	Important US	P1_BUC1	⬇		⬇					

Table 16. Greece: AS1 USs.

AS2 – Ireland USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS2_US1	Patient	Obtain my PS	I can show all my relevant health data to the treating HP that is attending me (cross border, nationally, or for schedule care nationally or cross-border).	Critical US	AS2_BUC1	⬇							
AS2_US2	Health Care Professional	Access relevant patient data for treatment	I can make informed clinical decisions and provide the best treatment for my patient	Critical US	AS2_BUC1	⬇							
AS2_US3	Health Care Provider	Access relevant patient data for treatment	HP can make informed clinical decisions and provide the best treatment for my patient	Critical US	AS2_BUC1	⬇							
AS2_US4	ICT	Securely access relevant patient clinical data	Verify the of the data as being most recent available and information is translated if necessary	Critical US	AS2_BUC1	⬇							
AS2_US5	Citizen	Access to and obtain all my data	I can be well informed, decide how to use it	Important US	AS2_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS2_US6	Citizen	Obtain all my data	I can be attended by any healthcare provider as required and share with	Important US	AS2_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
			research initiatives as appropriate										

Table 17. Ireland: AS2 USs

AS3 – Cyprus USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS3_US1	Patient	Share Patient Summary	I can be check up by a gastroenterologist after being diagnosed with coeliac disease	Critical US	AS3_BUC1								
AS3_US2	Patient	Share Patient Summary	In a foreign country, a healthcare professional will see the TRANSLATED patient summary, because I have stomachache and need medical attention.	Critical US	AS3_BUC1								
AS3_US3	Patient	Share Patient Summary	I am dissatisfied with the healthcare professional's service, and I sought a second opinion.	Important US	AS3_BUC1								
AS3_US4	Patient	Share Patient Summary	Issue a health card that will present summary upon QR scan	Important US	AS3_BUC1								
AS3_US5	Citizen	Download Patient Summary	I can compare my patient summary with relatives or friends.	Not so important	AS3_BUC1								
AS3_US6	Citizen	Share Patient Summary	I can provide my patient summary to the insurance company.	Not so important	AS3_BUC1								

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS3_US7	Citizen	Share Patient Summary	I can show/share my vital signs to relatives or friends.	Not so important	AS3_BUC1	☁↑							☁↑
AS3_US8	Health Care Provider	Access Patient Summary	HP can have immediate access to the patient's summary in an emergency situation.	Critical US	AS3_BUC1	☁↑							☁↑
AS3_US9	Health Care Provider	Access Patient Summary	I can monitor a cancer patient for evaluation on a weekly basis.	Critical US	AS3_BUC1	🔗							🔗
AS3_US10	Pharmacist	Access ePrescription and Patient Summary	I can check the allergy status to avoid any allergic reactions before administering a vaccination.	Critical US	AS3_BUC1	☁↑	☁↑						
AS3_US11	Health Care Provider	Access ePrescription	I can review the previous medication to prescribe the next dosage.	Critical US	AS3_BUC1		☁↑						
AS3_US12	Citizen	Share ePrescription	I can present ePrescription to get my medication from pharmacy.	Important US	AS3_BUC1		☁↑						
AS3_US13	Pharmacist	Execute eDispensation	I can communicate with the national systems to update the entry.	Important US	AS3_BUC1			🔗					

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS3_US14	Citizen	Download ePrescriptions	I can check my currently available prescriptions to print it.	Not so important	AS3_BUC1		⬇						
AS3_US15	Citizen	Download ePrescriptions	I can arrange my schedule ahead for getting the medication beforehand from the pharmacy.	Important US	AS3_BUC1		⬇						

Table 18. Cyprus: AS3 USs.

AS4 – Italy USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS4_US1	Patient	Share personal history with a new GP/healthcare provider	I can precisely report my history of illnesses and treatments, as collected in my last encounter, leading to an improved precision on history data collection	Critical US	AS4_BUC1						☁		
AS4_US2	Patient	Share drugs' allergies with a new dentist	I avoid harmful prescriptions for painkillers, antibiotics, etc. supporting a Reduced Adverse Events (AE) risks and improved healthcare efficiency.	Critical US	AS4_BUC1						☁		
AS4_US3	Citizen	Share health data with a wellness coach for personalized coaching plans	I receive tailored guidance on achieving health goals, with an improved motivation and adherence to healthy lifestyle changes.	Not so important	AS4_BUC1						☁		☁
AS4_US4	Patient	Share pain management strategies with a physical therapist	Physical therapist can incorporate these strategies into my rehabilitation plan, with an improved pain management and	Important US	AS4_BUC1						☁		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
			functional outcomes for me										
AS4_US5	Patient	Track their own health data trends over time	I can monitor progress towards health goals and make informed decisions about my health, with an increased patient engagement and self-management of chronic conditions.	Not so important	AS4_BUC1						⬇		
AS4_US6	Patient	Report adverse drug reactions to a central repository	I contribute to the monitoring of drug safety and identify potential risks, with an improved medication safety for all patients.	Important US	AS4_BUC1						⬇		
AS4_US7	Healthcare Provider	Implement patient portals for secure communication with patients	Facilitate two-way communication and improve patient engagement, with an increased patient satisfaction and adherence to treatment plans.	Important US	AS4_BUC1						⬇		
AS4_US8	Healthcare Provider	Track resource utilization	Identify areas for cost optimisation and improve resource allocation, with	Not so important	AS4_BUC1						☁⬆		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
		within the organization	an improved healthcare efficiency and reduced healthcare costs.										
AS4_US9	Healthcare Provider	Appropriate appointment scheduling and reminders for follow-ups	Reduce administrative burden for staff and improve patient adherence to the discharge dispositions, with an improved care efficiency and patient satisfaction.	Important US	AS4_BUC1						⬇		
AS4_US10	Healthcare Provider	Implement patient education and communication in multiple languages	Improve communication and understanding of health information for different patient populations, with an improved patient engagement and adherence to treatment plans.	Critical US	AS4_BUC1						⬇		
AS4_US11	Healthcare Provider	Measure and track clinical quality indicators	Benchmark performance against national standards and identify areas for improvement, leading to an improved quality of care within the organization.	Not so important	AS4_BUC1						☁⬆		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS4_US12	Health Care Professional	Patient's history data collection	Evaluate patient's history based on reliable data collected by the patient and other professionals, increasing precision and completeness.	Critical US	AS4_BUC1						☁↑		
AS4_US13	Health Care Professional	Flag potential medication interactions	Reduce the risk of adverse drug reactions, with an improved patient safety and medication management.	Critical US	AS4_BUC1						☁↑		
AS4_US14	Health Care Professional	Access patient medication adherence data	Identify patients with poor adherence and intervene accordingly (with an improved medication compliance it is expected to have an increased overall treatment effectiveness)	Important US	AS4_BUC1						☁↑		
AS4_US15	Health Care Professional	Collaborate with patients on setting realistic and achievable health goals	Increase patient buy-in and commitment to treatment plans, with an improved treatment outcomes and patient satisfaction.	Not so important	AS4_BUC1						↓		
AS4_US16	Health Care	Access patient-reported	Identify areas for improvement in patient	Important US	AS4_BUC1						☁↑		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
	Professional	experience (PRE) data to understand patient satisfaction with care	experience, expecting an improved patient satisfaction and quality of care.										
AS4_US17	Health Care Professional	Interact with specialist consultations virtually	Access expert evaluations for complex cases and improve patient care coordination, with a facilitated access to specialized care for patients, especially in remote areas.	Not so important	AS4_BUC1						☁↑		
AS4_US18	Citizen	Advocate for policy changes that promote public health initiatives	I contribute to a healthier community through public health policy changes, with an improved population health outcomes and disease prevention.	Not so important	AS4_BUC1						☁↑		
AS4_US19	Patient	Share discharge care plan with family members	I involve caregivers/family members in supporting the adherence to the prescribed therapy for the patient at home	Important US	AS4_BUC1						↓		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS4_US20	ICT	Exchange data across different healthcare providers	Application of standardized interoperability EEHRxF facilitate the connection among different EHR systems	Critical US	AS4_BUC1						⬇		

Table 19. Italy: AS4 USs.

AS5 – Spain USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS5_US1	Patient	Obtain my PS	I can show all my relevant data to the emergency doctor that is attending me during my vacations in another country	Critical US	AS5_BUC1	⬇							
AS5_US2	Patient	Obtain my PS	I can show all my relevant data to the primary care doctor that is attending me, including the information collected in other hospitals	Critical US	AS5_BUC1	⬇							
AS5_US3	Patient	Obtain my PS	I can show all my relevant data to the primary care doctor that is attending me, including the information collected in private centres	Critical US	AS5_BUC1	⬇							
AS5_US4	Patient	Obtain my ePrescription list	I can obtain my medication in any city or country	Critical US	AS5_BUC1		⬇						
AS5_US5	Patient	Obtain all my data	I can ask for a second opinion of a concrete diagnosis, process or interpretation	Important US	AS5_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS5_US6	Health Care Professional	Obtain the eDispensations list of a patient	I can follow its treatment having a first indicator of adherence	Important US	AS5_BUC1			⬇					
AS5_US7	Health Care Professional	Access to all relevant data of my patients	I can make better decisions and avoid health errors and additional issues	Critical US	AS5_BUC1	⬇							
AS5_US8	Health Care Provider	Access to all relevant data of patients	I can minimise health errors and additional issues	Critical US	AS5_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS5_US9	Citizen	Access to and obtain all my data	I am well informed, and I can decide how to use it	Important US	AS5_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS5_US10	Citizen	Obtain all my data	I can be attended by any healthcare provider	Important US	AS5_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		
AS5_US11	Citizen	Obtain all my data	I can share it with research initiatives	Important US	AS5_BUC1	⬇	⬇	⬇	⬇	⬇	⬇		

Table 20. Spain: AS5 USs.

AS6 – Portugal USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS6_US1	Citizen	Access my health data in the public health sector	I am more aware/knowledgeable of my health and wellbeing and in fulfilment of my proprietary right to my health data (no trigger involved)	Critical US	AS6_BUC1	⬇			⬇	⬇	⬇		
AS6_US2	Patient	Share my health data from the public health sector with the private health sector	I can pursuit continuity of care, get a second medical opinion, or be assisted in a health emergency situation in the private health sector	Critical US	AS6_BUC1				☁⬆	☁⬆	☁⬆		
AS6_US3	Patient	Share my health data from the public health sector with the private health sector	I can pursuit continuity of care, get a second medical opinion, or be assisted in a health emergency situation in the private health sector	Important US	AS6_BUC1	☁⬆							
AS6_US4	Patient	Share my health data from the public health sector with a cross-border health provider	I can pursuit continuity of care, get a second medical opinion, or be assisted in a cross-border health emergency situation	Important US	AS6_BUC1	☁⬆			☁⬆	☁⬆	☁⬆		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS6_US5	Health Care Professional (private)	Access the patient's health data in the public sector to provide continuity of care, a second medical opinion, or to assist a health emergency	I can provide the best medical care in the shortest possible time to a patient who is not a private health sector patient, optimising resources and prevent repeating unnecessary tests and exams that could ultimately impair the patient's health	Important US	AS6_BUC1				⬇	⬇	⬇		
AS6_US6	Health Care Professional (private)	Access the patient's health data in the public sector to provide continuity of care, a second medical opinion, or to assist a health emergency	I can provide the best medical care in the shortest possible time to a patient who is not a private health sector patient, optimising resources and prevent repeating unnecessary tests and exams that could ultimately impair the patient's health	Not so important	AS6_BUC1	⬇							
AS6_US7	Health Care Professional (public)	Access the cross-border citizen's health data to provide continuity of care or to assist	I can provide the best medical care in the shortest possible time to a cross-border citizen (tourist) who is not a public health sector	Critical US	AS6_BUC1	⬇			⬇	⬇			

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
		a health emergency	patient, optimising resources and prevent repeating unnecessary tests and exams that could ultimately impair the patient's health										
AS6_US8	Health Care Professional (public)	Access the cross-border citizen's health data to provide continuity of care or to assist a health emergency	I can provide the best medical care in the shortest possible time to a cross-border citizen (tourist) who is not a public health sector patient, optimising resources and prevent repeating unnecessary tests and exams that could ultimately impair the patient's health	Important US	AS6_BUC1						⬇		
AS6_US9	Health Care Professional (public)	Access the patient's health data in the private sector to provide continuity of care or to assist a health emergency	I can provide the best medical care in the shortest possible time to a patient, optimising resources and prevent repeating unnecessary tests and exams that could ultimately impair the patient's health	Critical US	AS6_BUC1				⬇	⬇	⬇		

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS6_US10	Health Care Professional (public)	Access the patient's health data in the private sector to provide continuity of care or to assist a health emergency	I can provide the best medical care in the shortest possible time to a patient, optimising resources and prevent repeating unnecessary tests and exams that could ultimately impair the patient's health	Not so important	AS6_BUC1	⬇							
AS6_US11	Citizen	Share my cross-border health data with the public health sector in Madeira	I can pursuit continuity of care or be assisted in a health emergency situation in the public health sector in Madeira while travelling	Critical US	AS6_BUC1				☁⬆	☁⬆	☁⬆		
AS6_US12	Citizen	Share my cross-border health data with the public health sector in Madeira	I can pursuit continuity of care or be assisted in a health emergency situation in the public health sector in Madeira while travelling	Not so important	AS6_BUC1	☁⬆							

Table 21. Portugal: AS6 USs.

AS7 – Denmark USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS7_US1	Patient	Search for my Care Plans	Get a Care Plans overview	Important US	AS7_BUC1								
AS7_US2	Patient	View a specific Care Plan	I can check the health care goals agreed with the doctor	Critical US	AS7_BUC1								
AS7_US3	Patient	Block access for a specific Care Plan	I will not share my Care Plan with a specific doctor or health organisation	Critical US	AS7_BUC1								
AS7_US4	Patient	See who has accessed my Care Plan	I want to check that my data has been used	Critical US	AS7_BUC1								
AS7_US5	Patient	See who has accessed my Care Plan	I want to check who has viewed my Care Plan	Critical US	AS7_BUC1								
AS7_US6	Patient	Download my Care Plan	I want to do my own analysis of the data content, so I better can manage my own health	Important US	AS7_BUC1								

Table 22. Denmark: AS7 USs.

AS8 – France USs

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS8_US1	Patient	Share a selection of personal health data related to my condition to a clinical investigator	A clinical investigator can evaluate if I can be potentially eligible to a clinical trial	Critical US	AS8_BUC1	🔗							
AS8_US2	Patient	Be contacted if a new clinical trial matches my health profile	A clinical investigator can evaluate if I can be potentially eligible to the new clinical trial	Critical US	AS8_BUC1	🔗							
AS8_US3	Patient	Be able to choose the hospital in which a clinical trial matches my health profile	A clinical investigator can evaluate if I can be potentially eligible to a clinical trial in the hospital of my choice	Important US	AS8_BUC1								
AS8_US4	Patient	Know how my data will be used	I can exercise my data portability rights under GDPR	Critical US	AS8_BUC1	☁							
AS8_US5	Patient	Know which data will be used	I can exercise my data portability rights under GDPR	Critical US	AS8_BUC1	☁							

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS8_US6	Patient	Be able to get an appointment at the hospital of my choice in which a clinical trial matches my health profile	My full eligibility can be evaluated by a clinical investigator during a medical visit	Important US	AS8_BUC1	☁↑							
AS8_US7	Patient	Modify/delete the access to my data	I can exercise my data portability rights under GDPR	Important US	AS8_BUC1	☁↑							
AS8_US8	Patient	Be informed of the clinical trial matching my health profile	I can evaluate my interest in participating in the clinical trial	Important US	AS8_BUC1								
AS8_US9	Clinical investigator	Know if new patients are potentially eligible to clinical trial ongoing at my hospital	I can propose them to participate	Critical US	AS8_BUC1	🔗							
AS8_US10	Clinical investigator	Be able to get the patient coming at my hospital	I can evaluate the patient's eligibility during a medical visit	Critical US	AS8_BUC1	☁↑							

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
AS8_US11	Clinical investigator	Be able to find my patient data previously/during the medical visit	I can save time in the patient's eligibility assessment to my ongoing clinical trials	Important US	AS8_BUC1	☁ 🔗							
AS8_US12	Clinical investigator	Be able to refer the patient to my research team	The patient can be followed up for their potential inclusion in the clinical trial	Important US	AS8_BUC1	☁							
AS8_US13	Clinical investigator	Have access to the full patient summary	I can save time in the patient's full eligibility assessment to my ongoing clinical trials	Important US	AS8_BUC1	🔗							
AS8_US14	Research team	Be informed when a new patient is potentially eligible to clinical trial ongoing at my hospital	I can follow up the patient for their potential inclusion in the clinical trial	Important US	AS8_BUC1	☁ 🔗							
AS8_US15	Research team	Have access to the full patient summary	I can save time in the screening process	Important US	AS8_BUC1	☁ 🔗							
AS8_US16	Research team	Be able to get the patient	The patient eligibility can be evaluated during a medical visit	Important US	AS8_BUC1	☁							

US ID	As a (Who – actor)	I want to (What – action)	So that (Why – outcome)	Relevance	Related BUC	HIDs							
						PS	eP	eD	Medical image and image report	Laboratory results	Discharge report	Telemonitoring	Care plan
		coming at my hospital											
AS8_US17	Patient	Share his full patient summary	My full eligibility to a clinical trial can be evaluated by clinical investigator/research team	Important US	AS8_BUC1	☁↑							

Table 23. France: AS8 USs.