XpanDH

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

D6.2 - (D6.1.2) – Published library of documented asset bundles

WP6 – Sustainability and future action

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Authors:

Name	Organisation	Name	Organisation
Dipak Kalra	i~HD		
Zoi Kolitsi	i~HD		
Giorgio Cangioli	HL7 Europe		
Simon Lewerenz	iscte		
Anderson Carmo	iscte		

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What did this document aim to achieve?	It is important for decision-makers at Member State and European levels to be able to adopt with confidence collections of interoperability assets that enable them to achieve the interoperability vision of the EHDS for primary use. This deliverable presents a repository that has been implemented by XpanDH and populated with interoperability assets that can support that vision.
Present the main methodological approaches in bullet point format	Engagement within XpanDH on assets developed and used by WP4 X-Bubbles. Engagement with projects working on different aspects of EHR interoperability
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	An implemented asset repository that may serve as an example to the EC for hosting its endorsed EHDS assets.
Which project stakeholder group would benefit the most from the document and why?	

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

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Acronym	Description
EC	European Commission
EEHRxF	European electronic health record exchange format
EHDS	European health data space
EHR	Electronic health record
eHEIF	European Health Interoperability framework
ICT	Information and communication technology

1 Executive Summary

This deliverable reports on the compilation of an inventory of interoperability assets that have been developed or collected from other developers, and used for interoperability use cases within the project, especially for the adoption domains and the bubbles of WP4. It additionally includes a few interoperability assets that have been developed and used by other projects working in parallel on other use cases that complement and enrich the primary use opportunities of the EHDS.

An online repository has been developed within the project, to host or link to those interoperability assets, and to describe them within asset bundles. This repository is also summarised here.

In contrast to deliverable 6.1.1 which described a top-down methodology for characterising new interoperability assets, placing some obligation for evidence and transparency on asset developers, this deliverable presents assets that had already been developed with “as is” descriptors which are less extensive.

Since XpanDH is now concluding, it is intended for this online asset repository to be handed over to the xShare project to incorporate within the standards hub that it is developing.

2 Introduction

The European health Data Space (EHDS) regulates for, and will orchestrate, the pan European mobilisation of core electronic health record information that can be accessible wherever a European patient needs healthcare within Europe. This core EHR is considered to be an essential subset of the totality of a person's electronic health record information that is sufficient and of important safety and continuity value to enable a person to receive unplanned care, emergency care and to some extent other forms of continuing care. It has been developed on the basis of multiple prior European initiatives that have formalise the data element and clinical document content, and established capabilities at Member State level to be able to communicate this information between European countries.

The EHDS scales up this capability by enriching the information content and by formalising how this information must be exchanged by specifying, and embedding in implementing acts, a European Electronic health Record exchange Format (EEHRxF). In order for this to succeed within and between countries, Member States and developers of their EHR systems (and of interoperable personal health applications) must implement the identical interoperability specifications. It is therefore anticipated that a library of interoperability assets will be maintained at a European level, probably mirrored and supplemented at Member State level, that comprises the various technical assets that are needed to implement this interoperability and which have been verified to correctly represent and communicate relevant parts of the EEHRxF.

The XpanDH project is pump priming candidates for this European library by implementing several of the main exchange format data flows, known as adoption domains, in several European pilots (validation bubbles). The interoperability assets used in these bubbles are expected to be useful as the EHDS primary use cases scale up. The project has therefore established an online repository in which these individual assets, and collections of assets known as asset bundles, can be discovered and accessed.

This online repository is described in the next chapter, including how it was designed. The following chapter lists the assets presently in it. The final concluding chapter explains the planned handover of this repository to xShare project which still has two years to run, and will be establishing a sustainable standard hub to support EHDS implementation. It also offers recommendations to take on board the more comprehensive asset descriptors presented in deliverable 6.1.1.

3 Method and overview of the asset repository

The concept of the X-Bundle[1] extends the essential requirements outlined in Articles 6 and 23 of the EHDS regulation by encompassing a broader set of supporting assets, beyond just technical specifications. An X-Bundle may include not only specifications (e.g., datasets, technical specifications, terminologies) but also reference documentation, tools, and additional supportive materials. These may include sandboxes, testing services, examples, maturity self-assessment tools, educational resources, best practices, reference implementations, guidelines, and more.

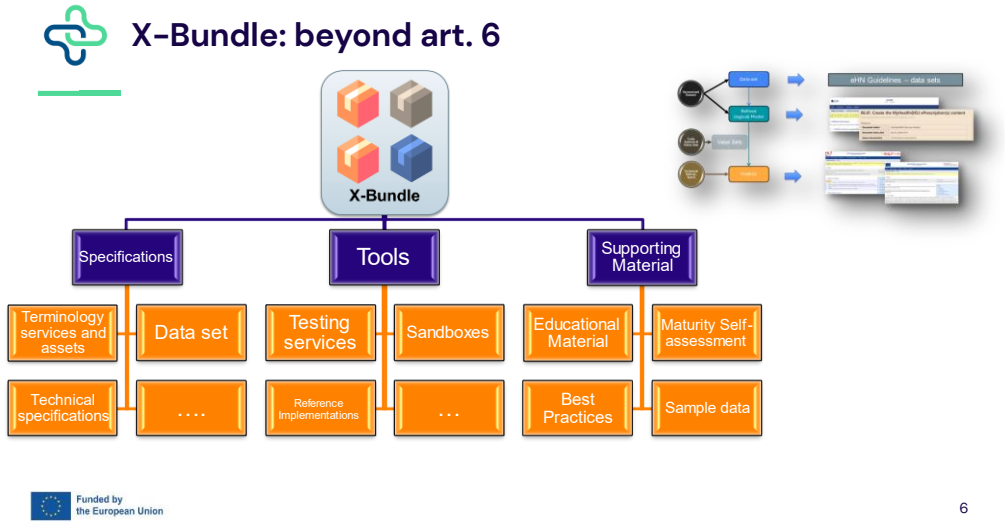

Figure 1 : X-Bundle beyond article 6

This concept, initially introduced by this project and later adopted and further elaborated by the xShare project, was first implemented through the creation of a coherent ecosystem of specifications and supporting materials. These were

[1] "Targeted aggregation of assets (and artefacts) that support the interoperability within and between health systems in different ways, based on European EHRxF specifications. Where, Asset is a standardised specification, tool or supporting material that strengthens the deployment of an interoperability scenario in a real-world implementation. Also called "interoperability asset"; and Artefact is the form in which one or more assets are being made available by any organisation contributing to the European EHRxF, whether a project, an SDO, a government agency or other organisation

provided in the form of a set of HL7 FHIR Implementation Guides, and GitHub repository covering different priority domains (e.g., Laboratory, Hospital Discharge Report). All X-Bundle assets are accessible through a single access point (see https://build.fhir.org/ig/hl7-eu/xpandh/).

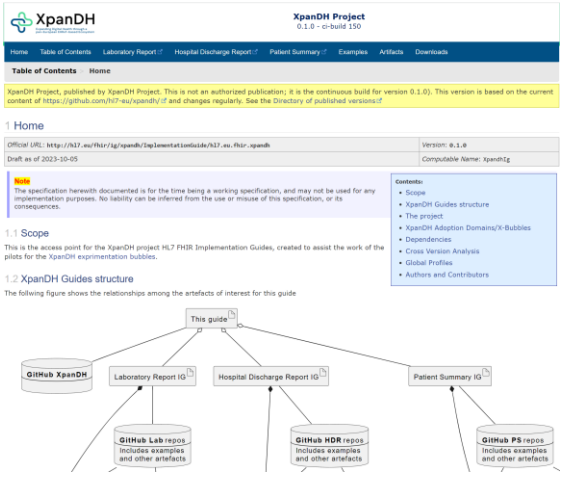

Figure 2: XpanDH assets entry point

The initial practical approach adopted in XpanDH, primarily designed to support the X-Bubbles activities with a focus on content development, has been further elaborated by the xShare project, incorporating inputs from XpanDH WP6.

While the concept of an X-Bundle appears, in fact, simple and straightforward, transforming it into a practical, usable solution is more complex. To achieve this, it is essential to develop a tailored solution that aligns the X-Bundle with specific user needs and requirements, avoiding asset duplication and preventing users from being overwhelmed with unnecessary or irrelevant information. X-Bundles must be organized and made accessible in a way that allows different types of users to meet their specific needs, such as identifying the steps required to implement a patient-mediated service, determining the necessary terminology for generating reports, or understanding the legal prerequisites for cross-border data exchange.

With the support of XpanDH, the xShare project has developed an X-Bundle registry proof of concept (https://x-bundles.ehr-exchange-format.eu/). This registry enables navigation by priority domains or use cases (Figure 3) and organizes artefacts into categories (Figure 4)

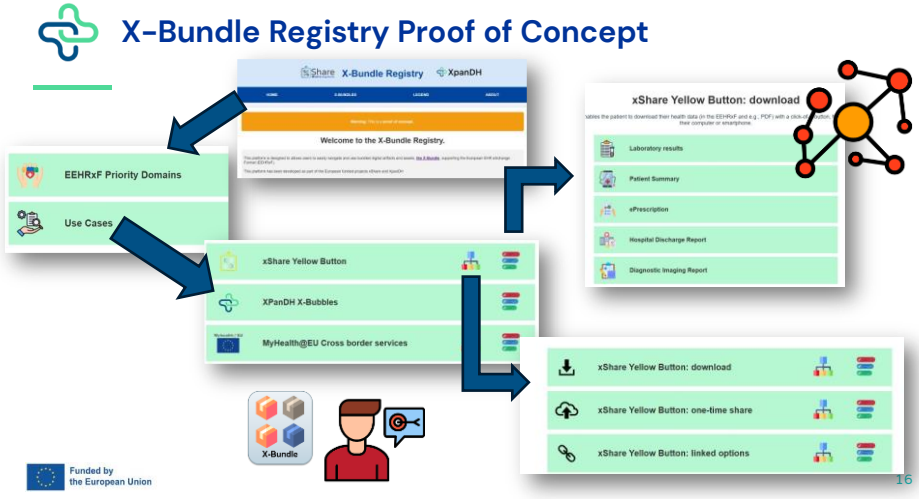

Figure 3: X-Bundle registry navigation

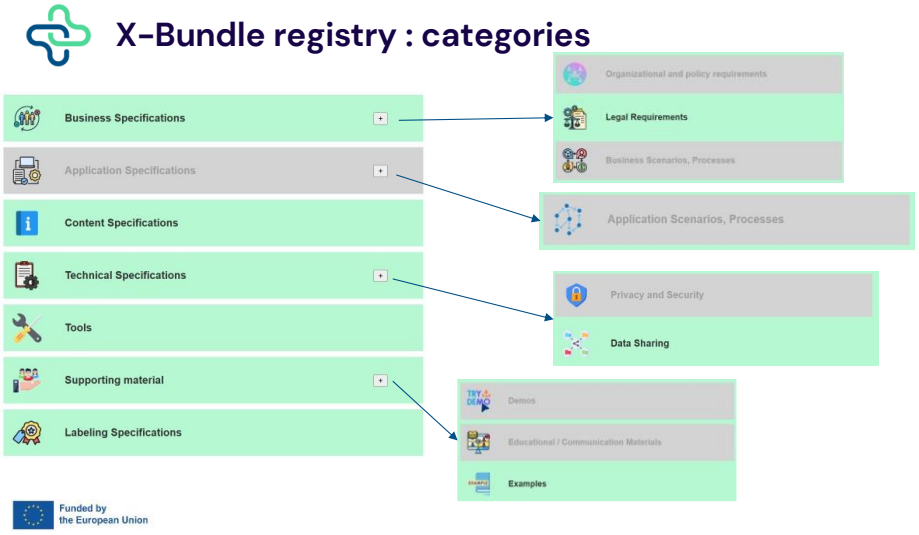

Figure 4: X-Bundle categories

For each category, a list of reference artefacts has been curated, distinguishing between main reference artefacts and other related artefacts that users may find relevant. Metadata sets have been specified for each artefact (Figure 5).

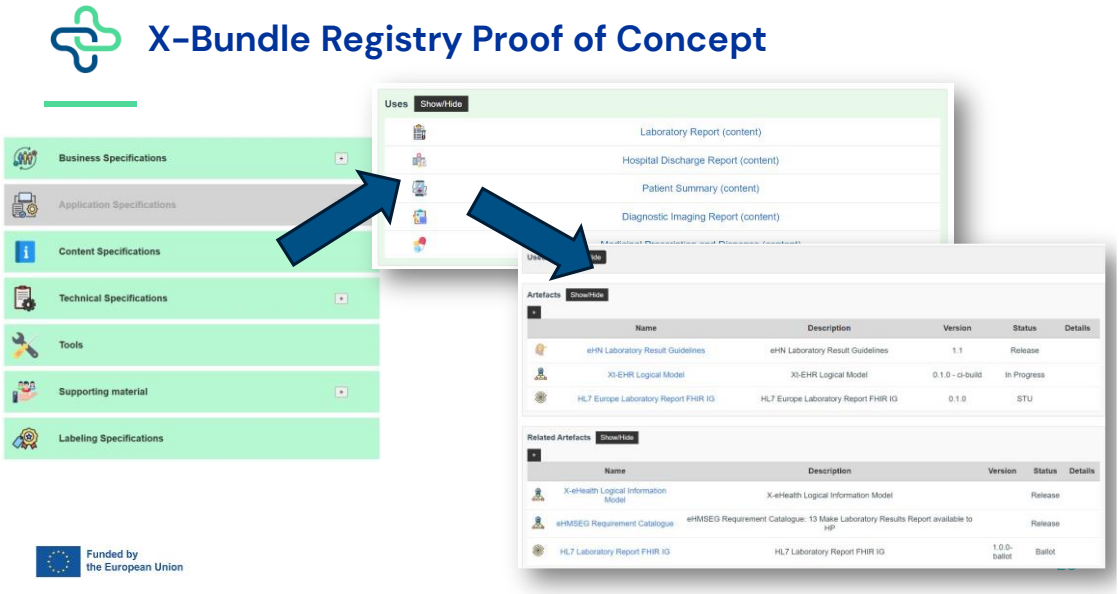

Figure 5: X-Bundle artefacts and related artefacts

X-Bundles have been developed using an iterative and incremental approach, a process that will continue under the xShare project.

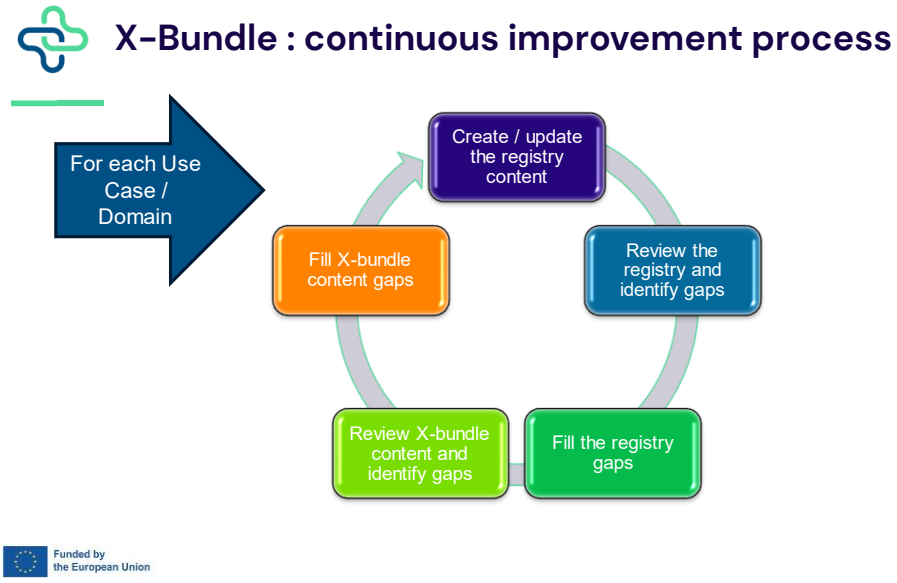

Figure 6: X-Bundle continuous improvement process

Stakeholders directly or indirectly involved in the XpanDH and xShare projects were invited to suggest relevant artefacts to be considered for the registry, categorized by use case, domain, and category. The proposed artefacts were analyzed by the project teams, and a selection was made.

Gaps in the registry and the actual artefact content were identified and will be addressed by the xShare project.

Regarding asset types, the initial focus was on assets related to Articles 6 and 23 of the European Health Data Space regulation, which were later extended to include

additional asset categories. For use cases and priority domains, the starting point was the priority domains documented in XpanDH D2.2.

An iterative and incremental approach was applied not only to the content but also to the actions undertaken, which included:

1. Developing the metadata framework and associated tools for classifying assets (asset matrix),
2. Collecting and processing relevant assets and artefacts, and
3. Actively building the X-Bundles.

The agreed metadata framework was applied to the initial set of selected assets to verify its accuracy and applicability. Feedback gathered during this process was used to refine the framework and finalize the metadata to be used for the X-Bundles.

The selected and classified assets and artefacts served as the foundation for building the first Proof of Concept X-Bundles registry.

4 Overview of the XpanDH asset repository content

The XpanDH interoperability asset repository is online, and being periodically updated. This chapter of the deliverable therefore briefly present the snapshot of content at the time of writing, the end of the official project. As indicated previously, it is to be handed over to xShare, so its content will continue to evolve. This chapter is therefore presented only as an informal indication of the scope and nature of the content so far. The accurate and up to date information, plus details of each asset, can be found online: https://build.fhir.org/ig/hl7-eu/xpandh/

4.1 Overview of the asset inventory

The existing content is summarised as a spreadsheet table on the next three pages. The content is grouped by the sub-sections of the EEHRxF, the name and/or source, an indication of its maturity and also which of the levels of the Refined European Interoperability Framework it aligns with.

The maturity has been specified according to the following levels.

Level 1: Initial (25%)
- Conceptual Phase: the asset is in the earliest stages of development.
- Basic ideas, objectives, and requirements are being defined.
- Preliminary research and planning are underway.
- Limited documentation is available, primarily outlining the scope and purpose.

Level 2: Developing (50%)
- Active Development Phase: the asset is actively being developed with key components being created.
- Significant progress has been made, but the asset is not yet complete.
- Initial drafts, guidelines, or implementation strategies are available.
- Feedback is being incorporated, and iterative improvements are ongoing.

Level 3: Stabilizing (75%)
- Refinement and Testing Phase, Pilot: the asset is nearing completion and is undergoing thorough testing and validation.
- Final adjustments, refinements, and optimizations are being made based on testing outcomes.
- Comprehensive documentation is being finalized.
- Readiness for deployment is being assessed, with any remaining issues being addressed.

Level 4: Operational (100%)
- Fully Mature and Released: the asset is fully developed, finalized, and officially released for use.
- It is actively operational and integrated into relevant processes or systems.
- Comprehensive documentation, guidelines, and support materials are available.
- Ongoing maintenance, updates, and optimizations are in place to ensure continued effectiveness.

EEHRxF category	Name	Asset ID	Asset Project Origin	Maturity of the level	Refined EIF levels
Patient summaries (EUPS - European Pat. Summary)	*eHN Guideline on Patient Summary*	7	Other (pre- or extra-XpanDH)	100%	Legal & Regulatory
	Xt-EHR Logical Model	2	Xt-EHR	25%	Information
	XpanDH EU Patient Summary FHIR IG	8	XpanDH	75%	Information
	ISO 27269:2021 Health informatics — International patient summary	9	Other (pre- or extra-XpanDH)	100%	Care process
	ISO/DIS 27269 Health informatics — International patient summary	10	Other (pre- or extra-XpanDH)	75%	Care process
	X-eHealth Logical Information Model	11	Other (pre- or extra-XpanDH)	100%	Information
	eHMSEG Requirement Catalogue	5	Other (pre- or extra-XpanDH)	100%	Applications
	HL7 International Patient Summary FHIR IG STU 1.0	12	Other (pre- or extra-XpanDH)	100%	Information
	HL7 International Patient Summary FHIR IG STU 2.0	13	Other (pre- or extra-XpanDH)	75%	Information
	Survey - Assessment of practice for production and exchange of Patient Summary		XpanDH	100%	Information
	XpanDH In-Silico Bubble 2	34	XpanDH	75%	
	XpanDH In-Silico Bubble 3	35	XpanDH	75%	
	XpanDH In-Silico Bubble 4	36	XpanDH	75%	
	XpanDH In-Silico Bubble 5	37	XpanDH	75%	
	xShare Business use cases AS1, AS2, AS3, AS5, AS6, AS8		xShare	100%	Care process
	xShare adoption site 1	40	xShare	75%	
	xShare adoption site 2	42	xShare	75%	
	xShare adoption site 3	43	xShare	75%	
	xShare adoption site 5	44	xShare	75%	
	xShare adoption site 6	45	xShare	75%	
	xShare adoption site 8	46	xShare	75%	
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity	15	N/A	%	
Electronic prescriptions & electronic dispensation	*HL7 EU Medication Prescription and Dispense FHIR IG*	1	XpanDH	50%	Information
	Xt-EHR Logical Model	2	Xt-EHR	25%	Information
	ePrescription and eDispensation of Authorised Medicinal Products - Guidelines on the electronic exchange of health data under Cross-Border Directive 2011/24/EU	3	Other (pre- or extra-XpanDH)	100%	Legal & Regulatory
	ISO 17523:2016 Health informatics — Requirements for electronic prescriptions	4	Other (pre- or extra-XpanDH)	100%	Care process
	eHMSEG Requirement Catalogue	5	Other (pre- or extra-XpanDH)	100%	Applications
	IHE Medication Prescription and Delivery (MPD)	6	Other (pre- or extra-XpanDH)	50%	Applications
	XpanDH Deliverable 4.2	25	XpanDH	100%	Care process
	CoD eP/eD/ePI	27	XpanDH	75%	
	xShare Business use cases AS1, AS2, AS3, AS4, AS5		xShare	100%	Care process
	xShare adoption site 1	40	xShare	75%	
	xShare adoption site 2	41	xShare	75%	
	xShare adoption site 3	42	xShare	75%	
	xShare adoption site 4 (eP only)	44	xShare	75%	
	xShare adoption site 5	45	xShare	75%	
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity	8	N/A	%	

EEHRxF category	Name	Asset ID	Asset Project Origin	Maturity of the level	Refined EIF levels
Laboratory reports (is included in the EHDS reg. data category "medical test results")	*MyHealth@EU Laboratory Report FHIR IG*	14	Other (pre- or extra-XpanDH)	75%	Information
	eHN Laboratory Result Guidelines	15	Other (pre- or extra-XpanDH)	75%	Legal & Regulatory
	Xt-EHR Logical Model	2	Xt-EHR	25%	Information
	HL7 Europe Laboratory Report FHIR IG	16	Other (pre- or extra-XpanDH)	75%	Information
	eHMSEG Requirement Catalogue	5	Other (pre- or extra-XpanDH)	100%	Applications
	MyHealth@EU MVC (Master Value Sets Catalogue) v7.2.0	17	Other (pre- or extra-XpanDH)	100%	Legal & Regulatory
	MyHealth@EU MVC (Master Value Sets Catalogue) v8.0.1	18	Other (pre- or extra-XpanDH)	75%	Legal & Regulatory
	MyHealth@EU NCPeH FHIR specifications	19	Other (pre- or extra-XpanDH)	75%	Legal & Regulatory
	HL7 Laboratory Report FHIR IG	20	Other (pre- or extra-XpanDH)	75%	Information
	X-eHealth Logical Information Model	21	Other (pre- or extra-XpanDH)	100%	Information
	MyHealth@EU NCPeH FHIR specifications	26	Other (pre- or extra-XpanDH)	25%	Legal & Regulatory
	Survey - Assessment of practice for production and exchange of Laboratory reports		XpanDH	100%	Information
	Use cases X-Bubbles 1, 2 (XpanDH Deliverable 4.1)		XpanDH	100%	Care process
	State of practice and alignment with the eHN guidelines X-Bubbles 1, 2 (XpanDH Deliverable 4.3)		XpanDH	100%	Information
	XpanDH X-Bubble 1	29	XpanDH	75%	
	XpanDH X-Bubble 2	30	XpanDH	75%	
	Laboratory Report Gap Analysis in-silico bubble 3		XpanDH	50%	Information
	XpanDH In-Silico Bubble 1	33	XpanDH	75%	
	XpanDH In-Silico Bubble 3	35	XpanDH	75%	
	XpanDH In-Silico Bubble 6	38	XpanDH	75%	
	XpanDH In-Silico Bubble 7	39	XpanDH	75%	
	xShare Business use cases AS1, AS2, AS4, AS5, AS6		xShare	100%	Care process
	xShare adoption site 1	40	xShare	75%	
	xShare adoption site 2	41	xShare	75%	
	xShare adoption site 4	42	xShare	75%	
	xShare adoption site 5	43	xShare	75%	
	xShare adoption site 6	44	xShare	75%	
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity	17	N/A	%	
Medical test results, including laboratory and other diagnostic results and related reports (excluding	*(name of asset)*				
	(name of asset)				
	(name of asset)				
	(name of asset)				
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity		N/A	%	

EEHRxF category	Name	Asset ID	Asset Project Origin	Maturity of the level	Refined EIF levels
Hospital discharge reports	*HL7 International Patient Summary FHIR IG STU 1.0*	12	Other (pre- or extra-XpanDH)	100%	Information
	HL7 International Patient Summary FHIR IG STU 2.0	13	Other (pre- or extra-XpanDH)	75%	Information
	Xt-EHR Logical Model	2	Xt-EHR	25%	Information
	eHN guidelines on Hospital Discharge Report	22	Other (pre- or extra-XpanDH)	75%	Legal & Regulatory
	XpanDH Hospital Discharge Report FHIR IG	23	XpanDH	75%	Information
	X-eHealth Logical Information Model	21	Other (pre- or extra-XpanDH)	100%	Information
	Survey - Assessment of practice for production and exchange of Hospital discharge reports		XpanDH	100%	Information
	Use cases X-Bubbles 3, 4, 5, 6 (XpanDH Deliverable 4.1)		XpanDH	100%	Care process
	State of practice and alignment with the eHN guidelines X-Bubbles 3, 4, 5, 6 (XpanDH Deliverable 4.3)		XpanDH	100%	Information
	XpanDH X-Bubble 3	30	XpanDH	75%	
	XpanDH X-Bubble 4&5	31	XpanDH	75%	
	XpanDH X-Bubble 6	32	XpanDH	75%	
	HDR Gap Analysis in-silico bubble 3		XpanDH	100%	Information
	XpanDH In-Silico Bubble 3	35	XpanDH	75%	
	xShare Business use cases AS1, AS2, AS4, AS5, AS6		xShare	100%	Care process
	xShare adoption site 1	40	xShare	75%	
	xShare adoption site 2	41	xShare	75%	
	xShare adoption site 4	42	xShare	75%	
	xShare adoption site 5	43	xShare	75%	
	xShare adoption site 6	44	xShare	75%	
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity		N/A	%	
Discharge reports (other reports besides hospital discharge)	*CoD Teleconsultation Encounter Report*	28	XpanDH	75%	
	(name of asset)				
	(name of asset)				
	(name of asset)				
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity		N/A	%	
Medical imaging studies and related imaging reports	*eHMSEG Requirement Catalogue*	5	Other (pre- or extra-XpanDH)	100%	Applications
	eHN Guidelines on Medical imaging studies and reports	24	Other (pre- or extra-XpanDH)	75%	Legal & Regulatory
	Xt-EHR Logical Model	2	Xt-EHR	25%	Information
	MCWG-Imaging-CoD	27	XpanDH	75%	
	xShare Business use cases AS1, AS2, AS4, AS5, AS6		xShare	100%	Care process
	xShare adoption site 1	40	xShare	75%	
	xShare adoption site 2	41	xShare	75%	
	xShare adoption site 3	42	xShare	75%	
	xShare adoption site 4	43	xShare	75%	
	xShare adoption site 5	44	xShare	75%	
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity		N/A		
Care plans	*xShare Business use cases AS3, AS7*		xShare	100%	Care process
	xShare adoption site 3	45	xShare	75%	
	xShare adoption site 7	47	xShare	75%	
	insert more lines if needed				
	TOTAL of Assets /Aprox maturity		N/A		

5 Conclusions and recommendations

This deliverable has reported on an online repository for EEHRxF relevant assets that is offered to the European Commission (EC) as an indication for how their definitive asset portal might be constructed. It has been agreed that xShare will sustain this, further enhance its features and content, as part of its standards hub.

There are two aspects that this project recommends the portal be taken forward.

Firstly, a wider range of assets should be included. In order for the EHDS to deliver its primary use value, and leverage the exchange format. The relevant clinical information must already exist in EHR systems, in a computable format so that it can be accurately extracted, mapped to the EEHRxF standard and communicated. Then it needs to be received, assimilated into the destination EHR system, its provenance understood and correctly labelled as coming from that source when imported. There is therefore the need for a broad range of sociotechnical assets including education, requirement specifications and evidence of patient care value that should be added.

Secondly, the repository currently has pragmatically obtained descriptors that indicate what the asset is and what function it serves, but not about its quality, reliability or evidence of its adoption and use. Deliverable 6.1.1 provided that comprehensive set of descriptors and it is recommended that the repository be enhanced to include more of those, and that interoperability asset developers be encouraged to adopt a stronger quality approach so that they can actually populate these descriptors.

Finally, of course, the repository of interoperability assets must be promoted and consideration be given to whether the use of assets exclusively from a future EC-endorsed repository like this is made mandatory for EEHRxF certification.