XpanDH

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

D6.1 – (D6.1.1) –Governance and operating model for XpanDH asset bundles

WP6 – Sustainability and future action

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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 efficiently-implemented and smooth-running information exchange that delivers their intended benefits to health systems and patients. This deliverable presents a standardised framework for reporting transparency in the governance that has been applied by the developing organisation for interoperability assets and the characteristics of trust that a potential adopter could look for.
Present the main methodological approaches in bullet point format	Desk research looking into governance frameworks for informatics assets 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?	It presents a quality assessment framework that XpanDH could promote, and use itself, to assess the assets it has developed or is using
Which project stakeholder group would benefit the most from the document and why?	
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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
EEHRxF	European electronic health record exchange format
EHDS	European health data space
eHEIF	European Health Interoperability framework
ICT	Information and communication technology

Executive summary

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 efficiently-implemented and smooth-running information exchange that delivers their intended benefits to health systems and patients. There are many kinds of interoperability asset being developed by standards development organisations, European Commission projects, national programmes and other initiatives. These assets span a rich spectrum from guidance to decision makers, technical standards and specifications for ICT companies and eHealth Competence Centres, procurement recommendations, adoption good practices and educational materials.

Since the potentially necessary interoperability assets could cover many different business and technical functions within the health ICT and health data ecosystem, and be developed by different organisations, it is not practical to impose a single governance model on their development. The approach reported in this deliverable has been to propose a standardised framework for reporting transparency in the governance that has been applied by the developing organisation for each asset and the characteristics of trust that a potential adopter could look for. This deliverable presents a transparency framework that draws on and synthesises work from multiple previous projects.

To this bottom-up transparency-based approach to governance, it is possible to add a simple top-down filtering, based on the anticipated needs of the target users, which in this case is decision-makers about the adoption of interoperability assets. Focusing on those assets which are ready for adoption entails setting minimum criteria for inclusion, based on the proven maturity of the assets including demonstrated use beyond the scale of conventional pilots: successful adoption in a large scale pilot or initial productisation or adoption by a jurisdiction.

Since multiple interoperability assets frequently need to be used together, especially technical ones, an additional aspect of adoption governance is for the decision maker to know which assets are collectively needed to achieve their desired end result on interoperability, and if there is any existing evidence or guidance on how these assets can be used in combination. This is the concept of the asset bundle, also introduced here.

The next step for WP6 will be to populate this asset and bundle transparency framework for the assets developed in XpanDH, to validate the framework and to assess its usefulness to some sample adoption stakeholders. This will be reported in D6.1.2 in December 2024.

It was envisaged in the project that this work package would also seek to establish a new entity or nominate an existing entity to hold and sustain those assets that are not being directly hosted by their developers, and to hold, maintain and promote

asset bundle specifications. It is now becoming clear which existing entities and initiatives are the most likely to prove suitable for this. These options have been outlined in this deliverable, and the definitive plan for asset hosting, promotion and sustainability will be reported in D 6.1.2.

1 Introduction

1.1 Background

There are many kinds of interoperability asset being developed by standards development organisations, European Commission projects, national programmes and other initiatives. These assets span a rich spectrum from guidance to decision makers, technical standards and specifications for ICT companies and eHealth Competence Centres, procurement recommendations, adoption good practices and educational materials. Because these are developed through many different organisations covering different use cases, it is not feasible to apply top down governance to this ecosystem. Instead, it is possible to foster a common approach to transparency about the purpose and scope, quality processes and evidence of use relating to each asset, in order to allow potential future adopters to come to appropriate decisions about which assets to use and how to use them in order to advance their capability for interoperability in their chosen areas.

To this bottom-up transparency-based approach to governance, it is possible to add a simple top-down filtering, based on the anticipated needs of the target users, which in this case is decision-makers about the adoption of interoperability assets. Focusing on those assets which are ready for adoption entails setting minimum criteria for inclusion, based on the proven maturity of the assets including demonstrated use beyond the scale of conventional pilots: successful adoption in a large scale pilot or initial productisation or adoption by a jurisdiction.

This document presents a proposal by XpanDH for:

(i) the basis for selecting interoperability assets to list within a possible platform or catalogue and to include within one or more XpanDH asset bundles (Chapter 2);

(ii) descriptors and metadata that should be used by any hosting platform or asset catalogue to present transparent governance information about interoperability assets and interoperability asset bundles (Chapters 3 and 4);

(iii) an initial options appraisal for the organisations that might be appropriate to take over XpanDH interoperability assets and the specifications of asset bundles (Chapter 5)

1.2 Interoperability asset bundles

An interoperability asset bundle is an organised collection of documents, standards, technical specifications and other resources that collectively can enable a healthcare organisation, region, country, or multinational environment to implement, govern and achieve benefits from greater interoperability of health data for a given purpose (use case) and within a given context.

Individual interoperability assets are usually thought of as published standards, or as technical specifications that profile or tailor a standard to make it most useful to achieve a targeted result. However, it is often necessary for a health system, at any geographic granularity, to enable the real benefits from interoperability not only at a technical level but by acting at multiple different levels including policy, legal, financial, procurement, organisational, capacity building and incentivisation. Not every chosen adoption of an interoperability use case will require changes at all of these levels, which will depend on the level of business process transformation that the interoperability introduces.

As an example, the introduction of a structured (fully computable) laboratory investigation result may not require much change in the laboratory systems generating the structured result because the underlying data is usually already held in well-structured formats, but might require mapping the internally used terminology systems to the ones chosen by a health ministry, for example, to utilise an international terminology standard. The data flow may already be taking place electronically between organisations with an unstructured laboratory result, and these data flows might not need to change, and new legal agreements might not be required. The receiving system might need to be upgraded in order to import computable data, to store it preserving its structure and to be able to present the data in tabular and graphical forms which was not previously possible.

On the other hand, the introduction of a structured electronic referral form from a general practitioner to a hospital specialist to replace an existing paper system may require not only changes in each of the electronic health record systems to be able to generate and import structured and coded data, but may require joint controller agreements to comply with the GDPR, and may require financial incentives or a reimbursement procedure to support the costs incurred at each end because these might be significant, and may require the procurement of new EHR system modules, although probably not the re-procurement of the whole EHR systems.

The adoption of interoperability for a given purpose may therefore require the use of multiple assets of different kinds, or at least to review some in order to verify if they are needed or not. In the case of technical standards and specifications, these are usually developed and published by international organisations and initiatives, and are the predominant kind of asset included in the bundles developed by the XpanDH project. Other kinds of asset, such as legal and procurement instruments, cannot usually be specified internationally, but may at times be guided by internationally developed guidelines or good practice examples. Only a few such examples can be included in the asset bundles produced by XpanDH, but these areas of content might be strengthened in the coming years, post-project, as good practices emerge and are shared.

1.3 Governance considerations

Decision makers such as policy makers and eHealth Competence Centres need to be able to determine the level of trust they should place in utilising the assets listed within a bundle, and on what basis each asset can be used. Chapter 2 of this document summarises the ecosystem in which interoperability assets arise and are initially implemented and tested, before reaching a level of certainty about their quality and utility that could warrant their inclusion in a list of potentially adoptable solutions.

Chapter 3 specifies asset descriptors that focus in particular on asset selection and governance aspects, such as the requirements and stakeholder engagement contributing to the design, the testing and validation undertaken, how the currency of the asset is maintained, the terms and conditions of use and what level of engagement and support for adopting communities is offered.

At present no minimum criteria are being specified to indicate when a described asset should be considered "fit for adoption". Such minimum or filter criteria might be determined later. Perhaps most importantly for decision makers will be the extent of endorsement for the adoption of a particular asset, for example if it has been specified in a European Regulation such as the EHDS, Implementing Acts that will shortly follow this Regulation, in European guidelines endorsed by the eHealth Network, or has been endorsed by other bodies. For this reason, this register of assets is expected to include only assets that are adoption-ready or procurement-ready, which means that they have been tested, piloted and have evidence of large scale use.

Standards and specifications are often developed by different organisations and at different times, and they do not always fit together well, sometimes having overlaps or inconsistencies in various aspects of their data representations. The asset bundle transparency metadata in Chapter 4 therefore also contains an explanation, to the extent known, of how the assets listed in a bundle can be used together. This experience is still emerging and it is not always possible to provide this information.

Many of the asset descriptors in this document are not expected to be included within the published specification or standard containing an asset. Indeed some properties such as implementation experience and endorsement, can only be accumulated after it has been published. Most of these descriptions are therefore intended to be incorporated within the platform or catalogue that hosts or references the assets. This document does not include specifying the functional requirements of platforms that will host and provide discovery of, and access to, interoperability assets and bundles, but it is expected that the specification in Chapters 2 and 3 will inform the development of such platforms, with a focus on the governance and transparency aspects.

It has not yet been determined which organisations will be best placed to sustainably host new assets developed by EC projects like XpanDH. Many of them will be hosted

by their publisher e.g. ISO or HL7 standards. Some interoperability profiles will also be hosted and maintained by their developers e.g. HL7 FHIR profiles, but endorsing organisations (such as the EC) may host a version-specific reference copy as being the one to be used by conforming organisations (for example for use in MyHealth@EU). Chapter 5 of this document outlines some of the hosting body scenarios that are currently being considered.

The second deliverable in this series, due for production in December 2024, will provide completed asset and asset bundle metadata descriptions for the interoperability assets developed by XpanDH project, and a proposal for the organisation(s) and arrangements for their sustainability.

1.4 Methodology for selecting the transparency asset descriptors

The descriptors presented in the later chapters for assets and bundles draw on, synthesise and prioritise prior work to describe various kinds of asset from a quality perspective. These include:

- The PARENT Joint Action project deliverables that specify good practices for registries;
- epSOS framework agreement that characterises interoperability assets, in particular for the cross-border communication of patient summaries;
- The description of heart failure interoperability assets developed by the EC Framework Programme 7 (FP7) SemanticHealthNet project;
- The asset register prototype developed in the EC FP7 EXPAND project;
- The PhD research of Alberto Moreno Conde on quality criteria for clinical information models;
- Deliverable D2.1 Quality Management for Interoperability Testing from the FP7 Antilope project;
- The IMI EMIF and EHDEN catalogues for describing data sets;
- The metadata descriptors used for openEHR archetypes;
- The metadata descriptors used for archetypes in ISO 13606 Part 2;
- Trillium-II Deliverable 5.2 regarding the suggested lifecycle for maintenance of the International Patient Summary;
- Draft Maintenance Agency Terms of Reference for ISO 27269 (the ISO IPS)

A few of these resources contain requirements or specifications that closely relate to the objective of this document. Many others refer to governance expectations or requirements for other kinds of asset e.g. for data sets, from which has been possible to infer relevant transparency requirements that could also apply to this focus on interoperability assets. The resulting superset of adoption assurances were thematically grouped and consolidated into a manageable number of descriptors.

The descriptors in this document are offered largely for free text completion, in the first instance. Once experience has been gained from populating and using them, we can determine if structured responses for some descriptors would be more helpful. We can also determine if some of them should be mandatory to populate.

There is considerable interest in the use of the D-CAT standard for data catalogues, including by the EHDS for the description and discovery of secondary use data sets. This standard does not seem immediately applicable to the asset register being proposed here, but a future evolution of it might align with D-CAT in order to produce a more computable form of asset register. However, it needs to be borne in mind that the target users of this asset catalogue are not data scientist but decision makers, and it therefore needs to remain usable by them.

2 Asset development ecosystem and the basis for determining their suitability for potential adoption

This chapter explores the challenge of improving efficiency in the EEHRxF development processes and explores the governance characteristics that could potentially impact the scalability of the Format itself and through it the EHDS.

The EHDS Regulation has turned two decades of efforts to achieve interoperability of EHR systems in practice and at scale into what promises to be an enabling legal framework. This is not of course to say that the new EHR interoperability landscape, leveraging on the European EHR exchange format (EEHRxF) is unlikely to present the digital health ecosystem stakeholders with new and complex challenges, especially to those responsible for making adoption policy, ICT adoption investments, procurement decisions and for developing large scale eHealth infrastructures. On the contrary, our findings from consultations and surveying current interoperability projects and initiatives indicate that there are several described in D5.2. "Interoperability Enabler Report" indicate that several barriers are hindering adoption and uptake of the Format today. These include factors such as lack of clarity, limited coverage of clinical domains combined with a slow development process of extensions and scaling up as well as lack of information as to the quality and maturity of existing interoperability assets. They are furthermore showing that some of the more important factors preventing us from delivering the several perceived benefits of the Format are the slow and effort demanding process of development of the Format and its constant evolution.

Central to the approach introduced by the EHDS Regulation, is a two layered governance setting clear roles and responsibilities for the EU and national level actors, schematically depicted in Figure 1. Inherent in this approach is the separation between the interoperability policy implementation and enforcement layer, which is regulated in the EHDS and the common specification development layer which is largely governed by the European Health Interoperability framework (eHEIF).

At the interoperability policy implementation level, MS collectively decide upon priority use cases that will be served through extensions of the existing EEHRxF, such that they represent realistic opportunity spaces for national health systems and representing a good fit between health system priorities and existing national preconditions. Through the EU policy co-ordination mechanisms and appropriate funding and co-ordination support the interoperability community is mandated and enabled to deliver what should be implementable common specifications, which should be then become enforceable through Delegated Acts. EHR manufacturers will need to demonstrate compliance to these common specifications, while MS should enforce such compliance including through procurement monitoring and surveillance mechanisms. Where

national extensions or modifications will be necessary for national deployment, it is expected that this will follow a similar cycle.

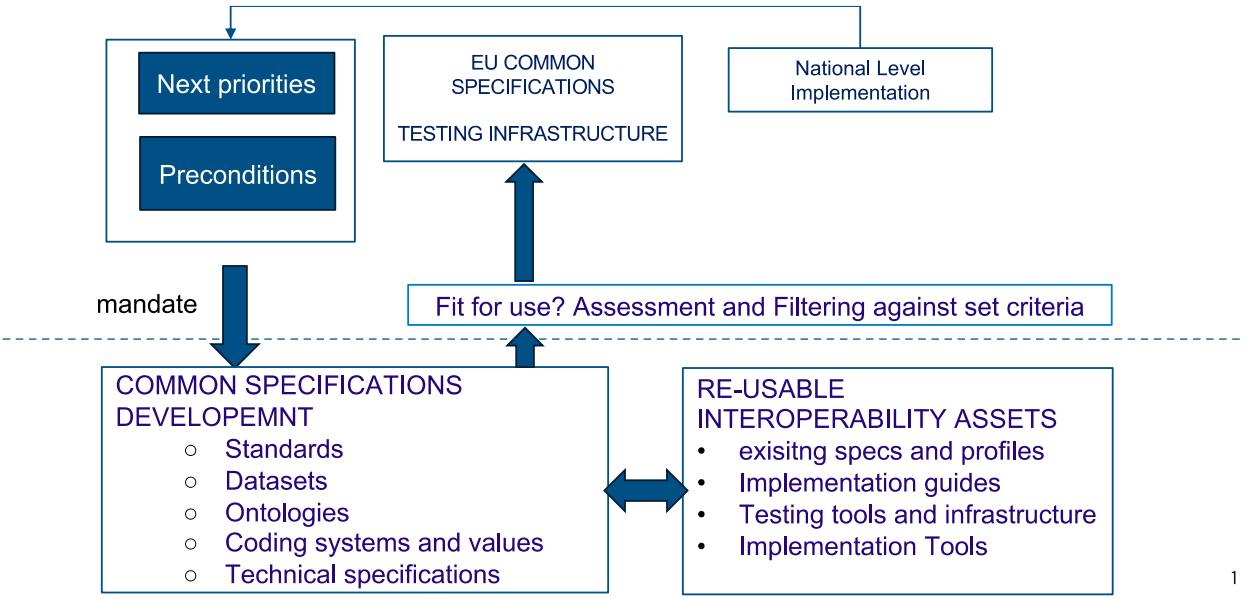

Figure 1: Two Layers of interoperability Governance

At the level of specification development, the European eHEIF sets out the implementation principles; the myHealth@EU governance defines the MS collaboration at the policy and the subject matter expert level. There is also a seasoned multistakeholder community and a mature collaboration, which has proven successful in the implementation of interoperability projects involving the elaboration of technical specifications. This particularly involves the EC, the eHealth Competence Centres, the SDOs and the ICT industry. (End users such as healthcare professionals, patients and citizens largely have weak and indirect influence here.)

Still, however, there are outstanding challenges to improve the adoption and uptake of the Format by the digital health communities, in particular to reach the point of delivering value to the end users of interoperable EHR and personal health systems, as well as the efficiency of the process that would deliver implementable common specifications to the appropriate robustness and maturity to be taken up for implementation by EHR manufacturers and enforced by digital health solution procurers. This is partly attributed to the closed, highly controlled and complex process of developing the Format today.

Early findings from the CapacityHD study (not yet published), which aims to boost digital health capacities in MS through exchange of knowledge across MS, indicate that those MS that are advancing well with the implementation of their digital health strategies have also compartmentalised their national interoperability activities in a similar way as illustrated in figure 2. By separating the demand for specifications supporting their digital health transformation policy activities from the supply of the specifications it is possible to create efficiencies and strategies for scaling up capacity in both areas.

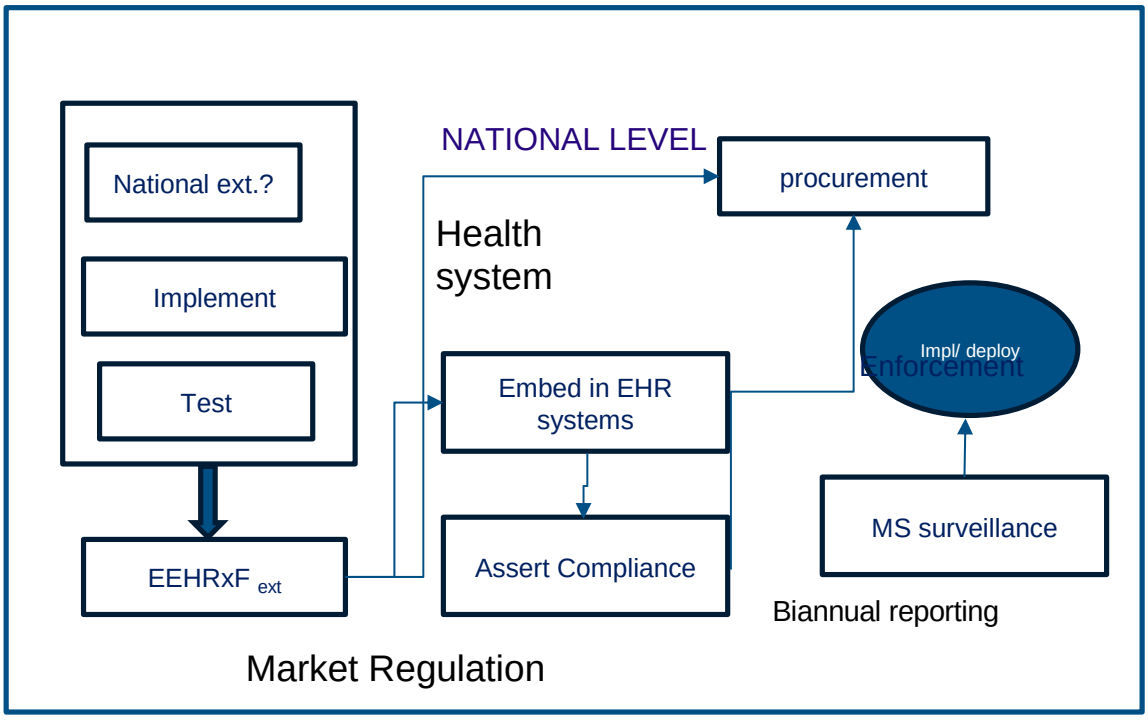

Figure 2: Generic schematic of Member State interoperability activities

On a separate note, a large number of research and innovation projects are today working on a respectively large number of interoperability use cases and delivering standards-based solutions that could potentially be leveraged upon to scale up the EEHRxF. There is a need, an opportunity and eventually an obligation to explore ways that such efforts should also come under a more global governance of interoperability asset development that would minimize the need of duplication of effort and rework when it comes to extending the EHRxF to new domains. Conversely, where such assets are available, it should be possible to assess them as to their appropriateness to be mainstreamed into the elaboration of common specifications, against common criteria.

The next two chapters explore such criteria and – as a first step – a strategy of self-assessment against them, which could possibly inspire a good development practice while create the necessary transparency for considering their further exploitation in the EEHRxF trajectory.

3 Asset selection, quality and governance descriptors

This chapter presents a set of descriptors that should be populated by the developer of an asset, preferably validated by an end user such as a reference site to confirm the validity of the statements made. A self-declaration model is proposed as being the only affordable and scalable approach, in a similar way to the experiences and future intentions for the population of data set catalogues, for example in IHI EHDEN[1] and to be established by EHDS Health Data Access Bodies. It will be important for the organisation hosting an interoperability asset platform to incorporate a mechanism for feedback, from adopting communities, in order to enable these descriptions to be corrected and updated as necessary.

The descriptors are presented here as mind maps, for readability.

[1] The IMI European Health Data and Evidence Network (EHDEN). Please see https://www.ehden.eu

Asset front sheet

These descriptors provide the name of the asset, the organisation and contact details of the party responsible for having developed it, the current version of it that is available and a reference (such as a URL) to the actual asset or a dedicated hosting page.

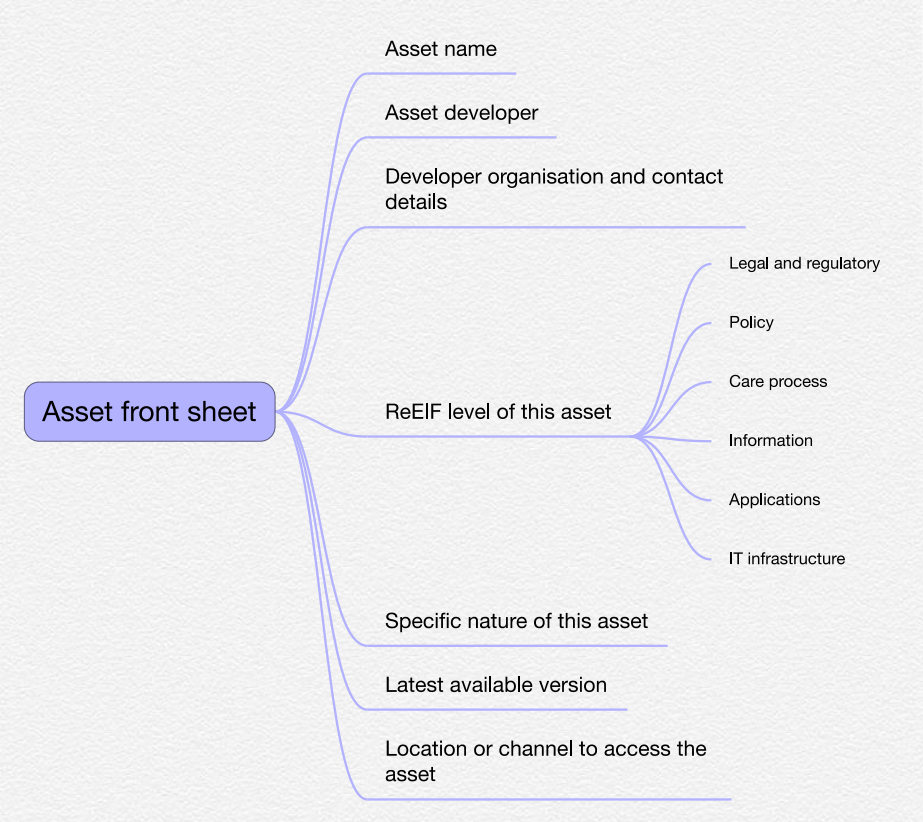

Figure 3: Descriptors for the asset front sheet

Purpose, scope and use cases

Decisions about whether an interoperability asset (or a bundle of assets) is relevant to the area of interoperability, that a health system wishes to advance, might be made at the level of an asset bundle or per individual asset. It is therefore important that information that explains the purpose and scope is available at both levels of granularity: asset and bundle. This chapter, which focuses on assets, therefore includes a set of descriptors for this that are replicated in the next chapter.

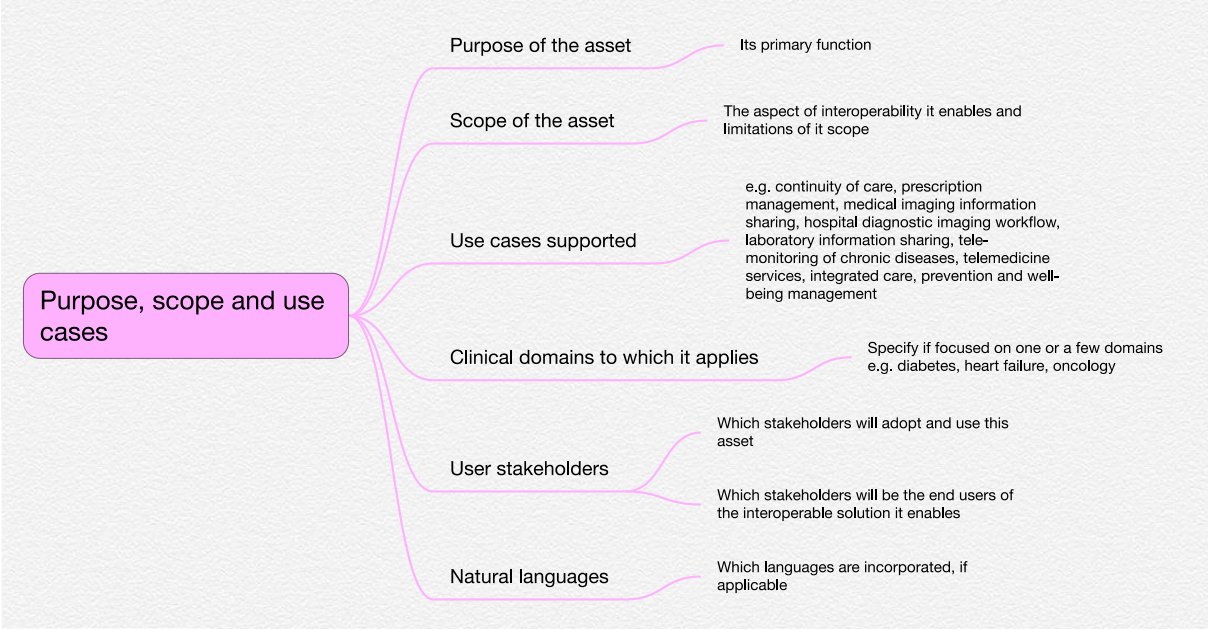

Figure 4: Descriptors for the purpose, scope and use cases

Quality processes adopted for the design and development of the asset

This set of descriptors is intended to give insight to a potential adopting party of the approach and care taken by the asset developer to ensure that it is fit for purpose, that appropriate inputs have been obtained to ensure its design, that an appropriate quality process was adopted during its development and that an appropriate level of testing and evaluation has been performed before this asset has been published.

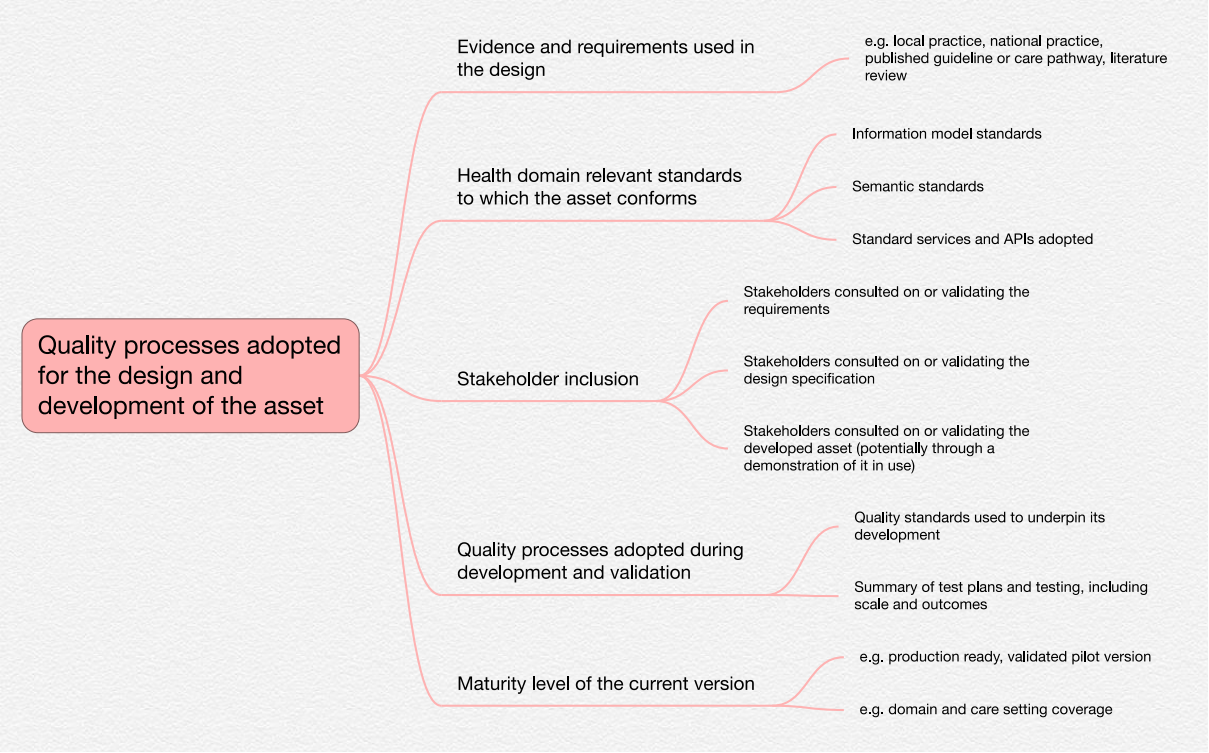

Figure 5: Descriptors for the quality processes adopted for the design and development

Evidence and experience of use, endorsements for adoption of the asset

This set of descriptors provides information about the extent to which the asset has already been used, if there are communities with experience of using it who could support a potential new adopter, and if any organisation or legislation has specified the use of this asset.

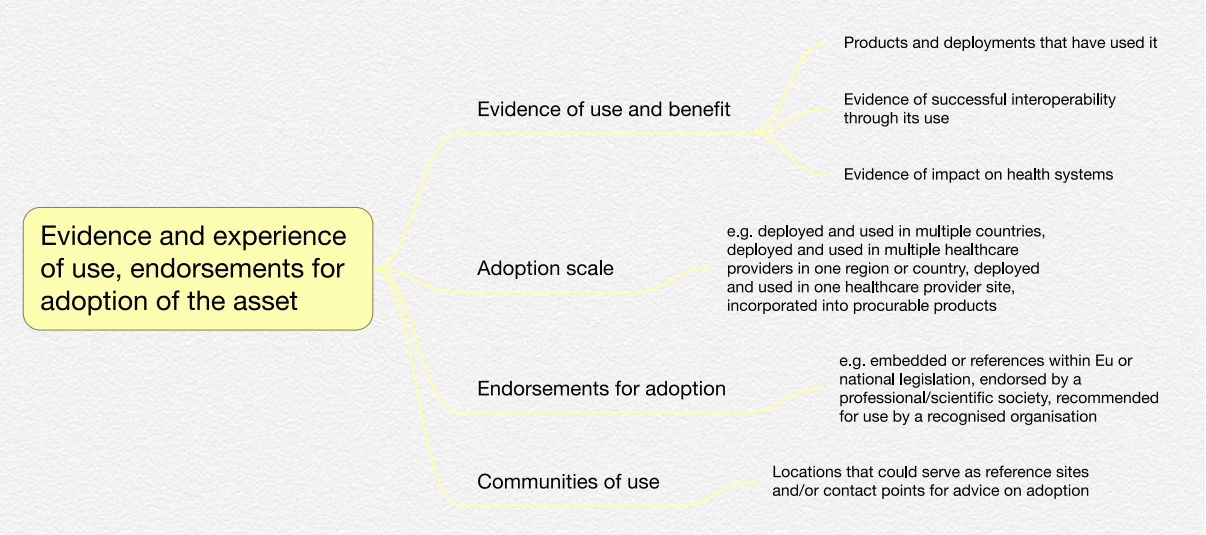

Figure 6: Descriptors for the evidence and experience of use, endorsements

Terms of use and plans for maintenance of the asset

This set of descriptors provides information for a potential user of it about any terms and conditions for its use, such as if there is any license or fee payment requirement, and how the developer commits to keeping it as up-to-date as is appropriate and where to discover information about new versions that have been released. Other aspects of maintenance such as the availability of its textual content in additional languages, could also be provided here.

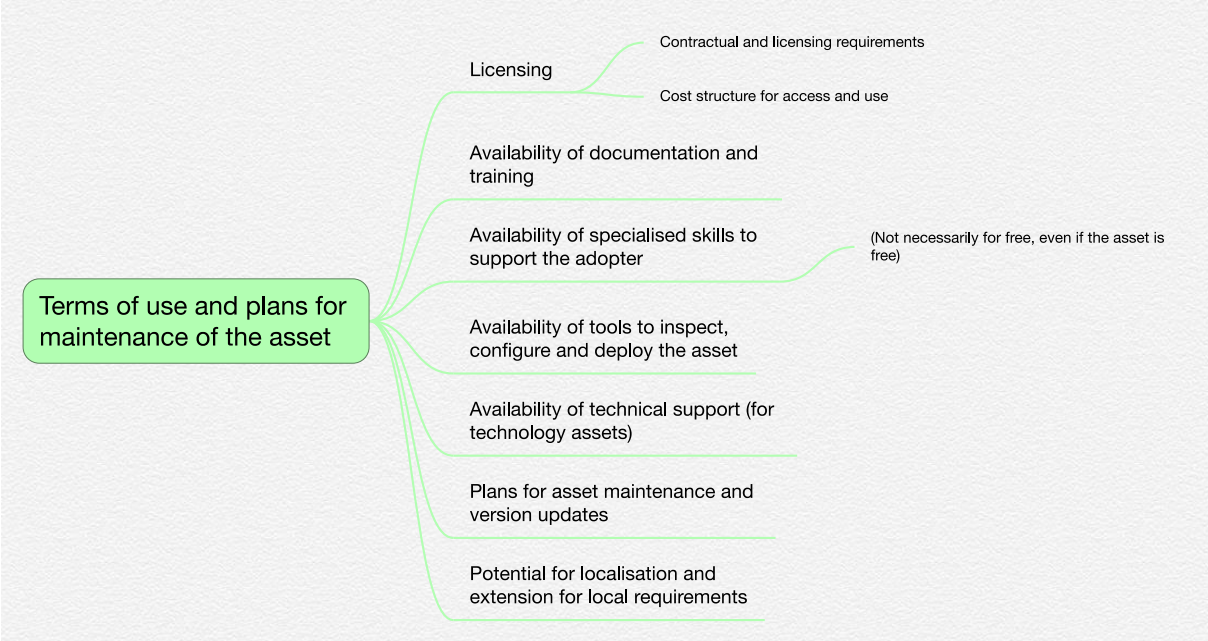

Figure 7: Descriptors for the terms of use and plans for maintenance

Inclusion within asset bundles

It is recommended that any forum hosting interoperability assets and incorporating these descriptors, provides bi-directional links between assets and asset bundles. This section of an implemented platform or catalogue should therefore contain a list of the asset bundles that include this asset.

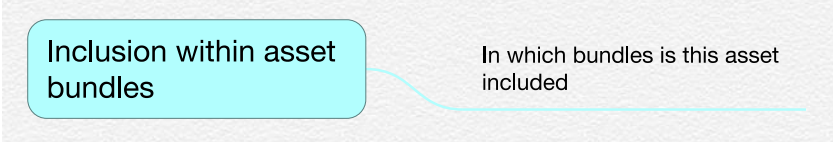

Figure 8: Descriptors for the inclusion of the asset within bundles

4 Asset bundle selection, quality and governance descriptors

An asset bundle comprises an organised collection of interoperability assets that may be useful to different stakeholders involved in putting a new area of interoperability into practice within a health system or network of health systems such as MyHealth@EU. At minimum it could be a labelled list of assets and pointers to obtain them, with just a little information about what each asset contributes and which stakeholders are intended to use it. A richer asset bundle would be more like a playbook, guiding a potential decision maker through the steps needed to achieve their desired interoperability, indicating when and how each of its included assets should be utilised. This chapter lists the main metadata descriptors that should be used to inform a potential user of the asset bundle about its purpose, level of detail, maturity and maintenance. These descriptors have some overlap with the descriptors of the previous chapter, although they are simpler.

Asset bundle front sheet

These descriptors provide the name of the asset bundle, the organisation and contact details of the party responsible for having developed it, the current version of it that is available and a reference (such as a URL) to the actual bundle (which might be a document or a web site).

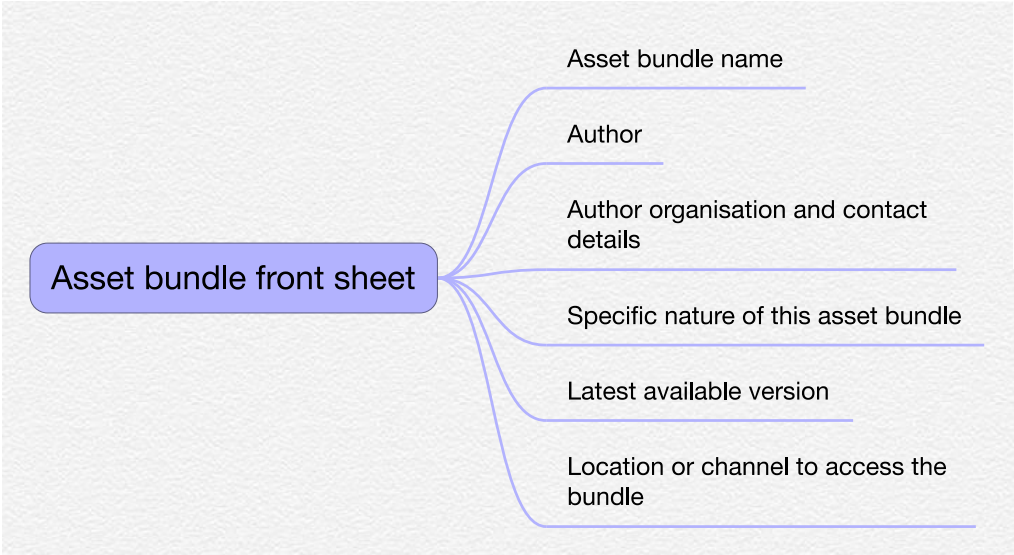

Figure 9: Descriptors for the asset bundle front sheet

Purpose, scope and use cases

This section is nearly identical to the corresponding section in the previous chapter.

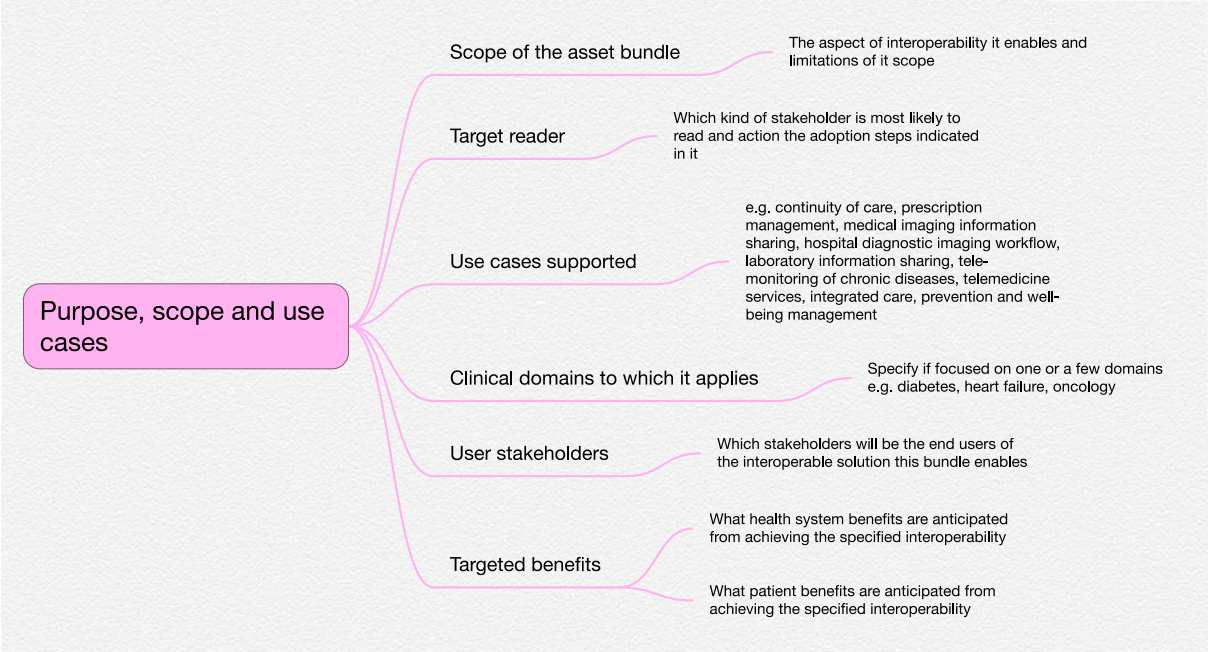

Figure 10: Descriptors for the asset bundle purpose, scope and use cases

Quality process adopted during development

This section is nearly identical to the corresponding section in the previous chapter.

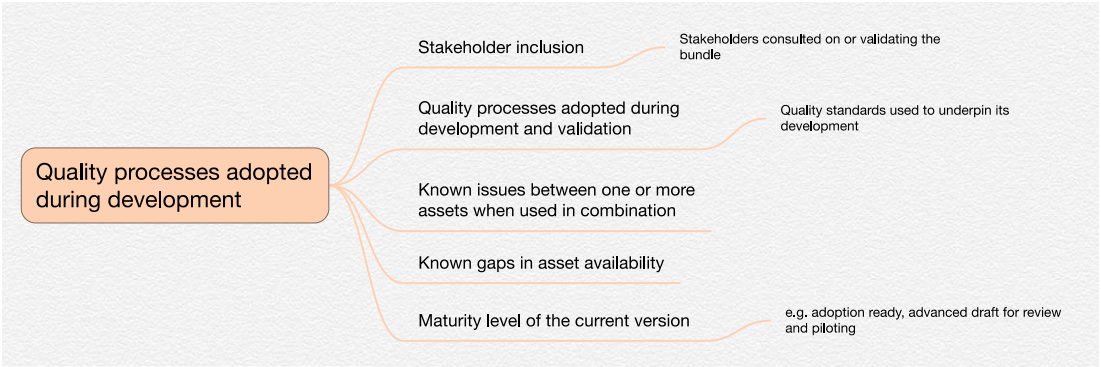

Figure 11: Descriptors of the asset bundle quality process

Evidence and maturity

This section provides the potential user with information about the extent of design, testing and usage experience has provided confidence that the different assets listed in it are relevant to the intended use case, compatible with each other and together provide a complete enough blueprint for achieving the desired interoperability. This section may also include limitations to this confidence, and known gaps for which a suitable asset has not been discovered or developed.

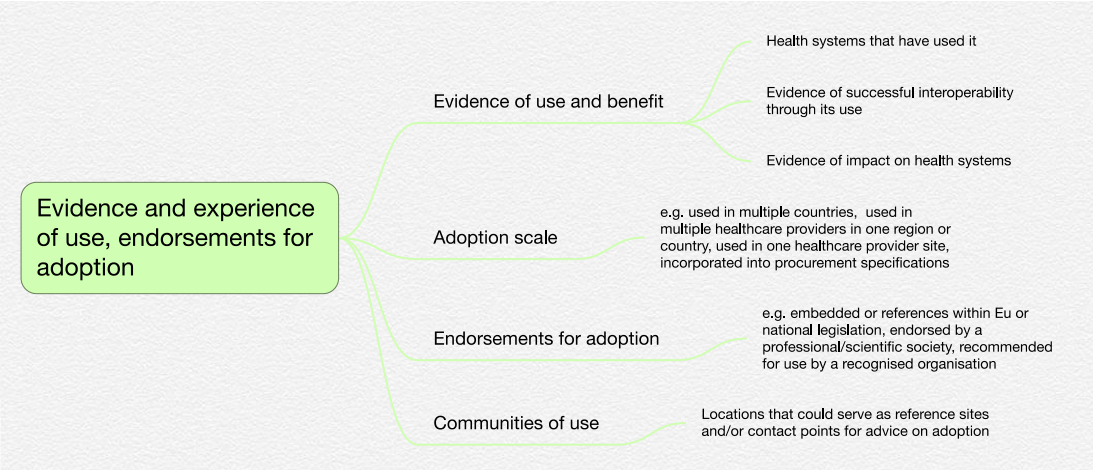

Figure 12: Descriptors for the asset bundle evidence and experience of use, endorsements

Assets included within this bundle

This section provides an inventory of the assets that are referenced within the bundle, to assist with searching and discovery of the bundle.

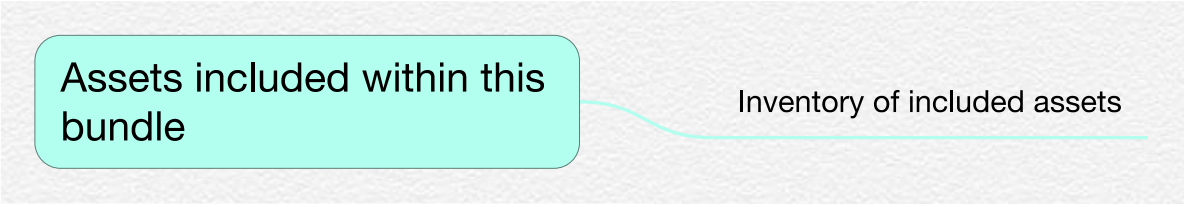

Figure 13: Descriptors for the assets included within an asset bundle

5 Publishing, sustaining and maintaining assets and bundles

Since the XpanDH project it not a permanent structure, and is expected to end in 2024, it is necessary to consider candidates to host interoperability assets and interoperability asset bundles that have been developed specifically through XpanDH. At this stage, these options and organisations are provisional, and no formal agreements have yet been made. An update to this chapter will therefore be provided in the second deliverable in this series from work package 6, in December 2024.

It is clear from the current discussions taking place with EC officials that they will establish the formal curation and maintenance internal body and mechanisms for the interoperability assets that support MyHealth@EU, at a European level and on behalf of Member States. It is possible that the new Joint Action Xt-EHR will act as the intermediary recipient of assets and bundles targeted for MyHealth@EU consideration.

However, the xShare project is presently favoured as the custodian of XpanDH assets since it is developing a hosting platform and has both workplan and budget to continue to refine the XpanDH assets. It may in turn be the feed into Xt-EHR and MyHealth@EU, which has yet to be determined.

Contributing the project asset bundles that enable implementation of the EEHRxF for our chosen adoption domains to the European Commission is therefore the most important exploitation measure to be taken. It is unusual for an exploitation strategy to target a single "customer" and not to be concerned with scalable uptake or with business revenues. However, given the substantial investments and legislative framework intended for the European Health Data Space, this pathway is the logical one for enabling rapid adoption at scale of the XpanDH asset bundles.

5.1 Asset development, testing and adoption lifecycle

The Trillium II project proposed the diagram below to depict the life-cycle for the development and maintenance of interoperability assets, with particular focus on the IPS.

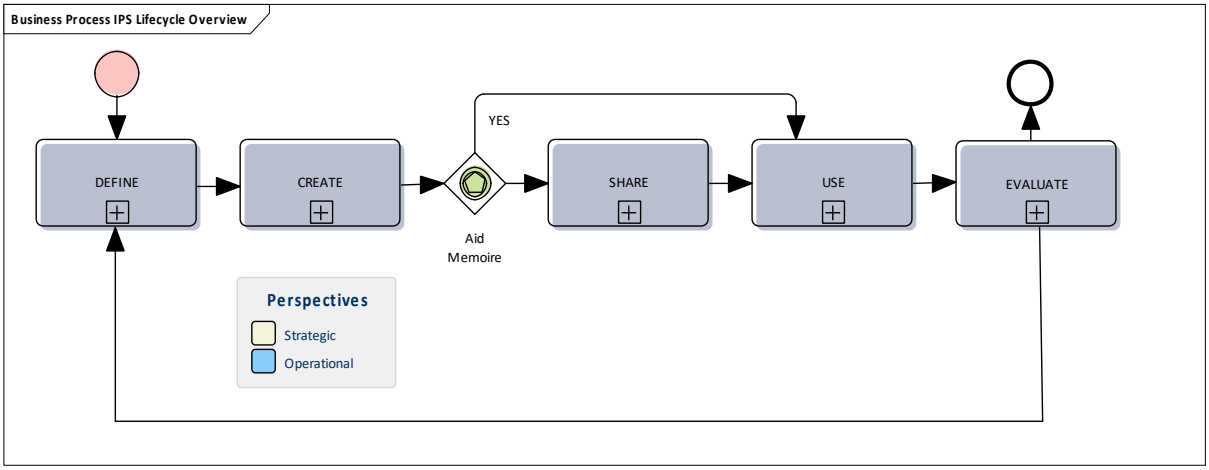

Figure 14: Reproduced from Trillium-II Deliverable 5.2 regarding the suggested lifecycle for maintenance of the International Patient Summary

The figure below applies this high-level life-cycle to the possible future ecosystem EEHRxF, in particular to highlight that new requirements accompanied by capacity pre-requisites will inform the development of new interoperability specifications. These will need initial testing and some real life piloting before they are considered candidates as future extensions of the EEHRxF. Such assets might arise as the outcome of European Commission funded projects such as those that have interacted with this project like the December 2023 Summit. In order to be taken forward for Europe wide adoption by Member States they will need a quality and governance assessment.

Figure 15: Life-cycle of the possible future ecosystem EEHRxF (partial diagram showing the initial development of new assets)

If the assets prove to be of a robust enough quality, they will be documented as such using the descriptors listed earlier in this document, as individual assets and as components of asset bundles.

The figure below shows the ongoing life-cycle towards adoption, as additional proposals for EU level common specifications and then for national adoption by Member States. These EEHRxF extensions will need to be integrated at policy, technical and reimbursement levels and may also be subject to national conformity assessments.

After some period of evaluation it is anticipated that they would become formally adopted as part of the EU common specifications and become published as an updated version of the EEHRxF. Validated specifications will also be candidates for international standardisation.

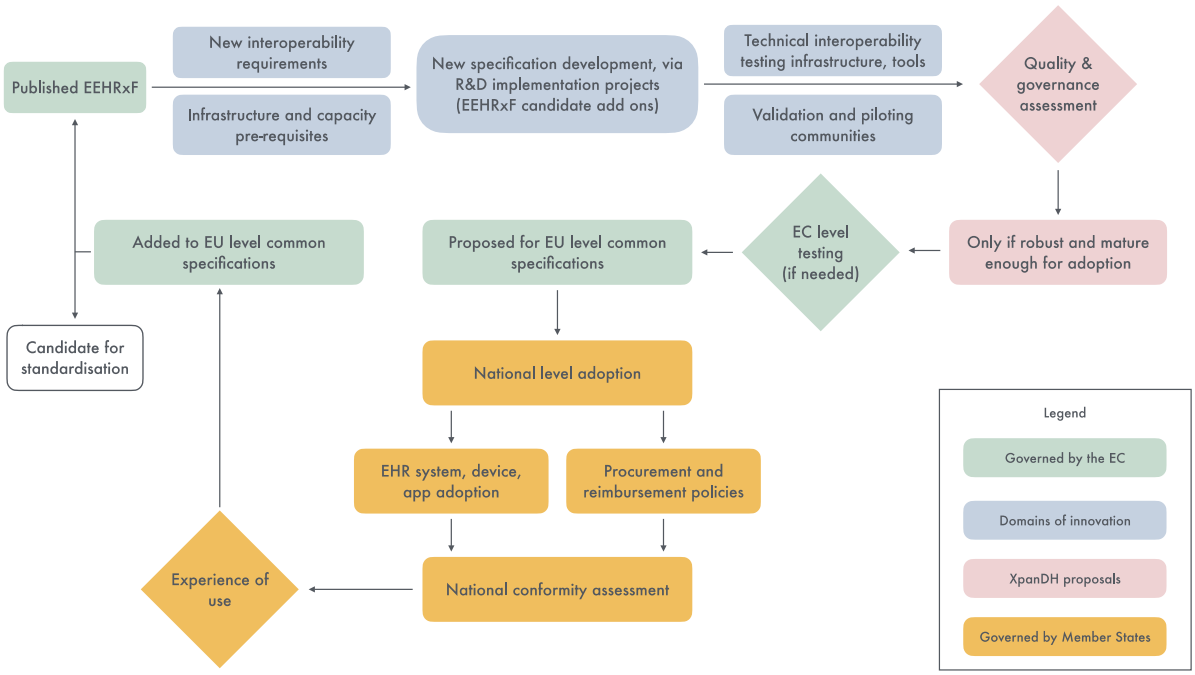

Figure 16: Life-cycle of the possible future ecosystem EEHRxF (complete diagram)

This high-level schema will inevitably have case-by-case variation including some scenarios of fast-track adoption and other scenarios of iterative improvement and piloting cycles before assets are considered ready and have a sufficient adoption business case for Member State use.

6 Conclusions and next steps

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 efficiently-implemented and smooth-running information exchange that delivers benefits to health systems and patients. Since the potentially necessary interoperability assets could span many different business and technical functions within the health ICT and health data ecosystem, and be developed by different organisations, it is not practical to impose a single governance model on their development. The approach reported in this deliverable has been to propose a standardised framework for reporting transparency in the governance that has been applied by the developing organisation for each asset and the characteristics of trust that a potential adopter could look for. This deliverable presents a transparency framework that draws on and synthesises work from multiple previous projects.

Since multiple interoperability assets frequently need to be used together, especially technical ones, an additional aspect of adoption governance is for the decision maker to know which assets are collectively needed to achieve their desired end result on interoperability, and if there is any existing evidence or guidance on how these assets can be used in combination. This is the concept of the asset bundle, also introduced here.

The next step for WP6 will be to populate this asset and bundle transparency framework for the assets developed in XpanDH, to validate the framework and to assess its usefulness to some sample adoption stakeholders. This will be reported in D6.1.2 in December 2024.

It was envisaged in the project that this work package would also seek to establish a new entity or nominate an existing entity to hold and sustain those assets that are not being directly hosted by their developers, and to hold, maintain and promote asset bundle specifications. It is now becoming clear which existing entities and initiatives are the most likely to prove suitable for this. These options have been outlined in this deliverable, and the definitive plan for asset hosting, promotion and sustainability will be reported in D 6.1.2.