



- Please keep your microphone **muted**
- **Questions during the session?** Please use the chat box. We will address the questions in the second part of the webinar
- Note that this webinar will be **recorded** and made available on our IHE-Europe [YouTube channel](#)
- Slides will be **sent to you by email** early next week

Save the date for our next edition on
April 12th:



Check out the **agenda & register** here:
www.ihe-europe.net/IHE_Europe_Webinars

Save the date for the Plugathon
Town hall on March 15th:



Check out the **agenda & register** here:
<https://lnkd.in/dDHS7F2f>

INTERNATIONAL WOMEN'S DAY

The 2024 theme, “Invest in women: Accelerate Progress,” highlights the importance of gender equality, women’s and girls’ empowerment, and their rights to healthier lives.



Karlien Erauw



Sofia Franconi



Key insights and industry opportunities on the European projects related to EEHRxF

Henrique Martins, Alexander Berler and Robert Stegwee

8 March 2024 1PM CET
IHE-Europe Monthly Webinar



Henrique Martins



- Building of the **technical specifications for EEHRxF (FHIR)**
- **Creating a network to adopt the EEHRxF in EHDS**



Alexander Berler



Robert Stegwee



- **Share EEHRxF data in EHDS** via a click button
- Create the European EHRxF **Standards and Policy Hub**



XpanDH

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

XpanDH

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

IHE Webinar

*Henrique Martins
8 March 2024, Online*



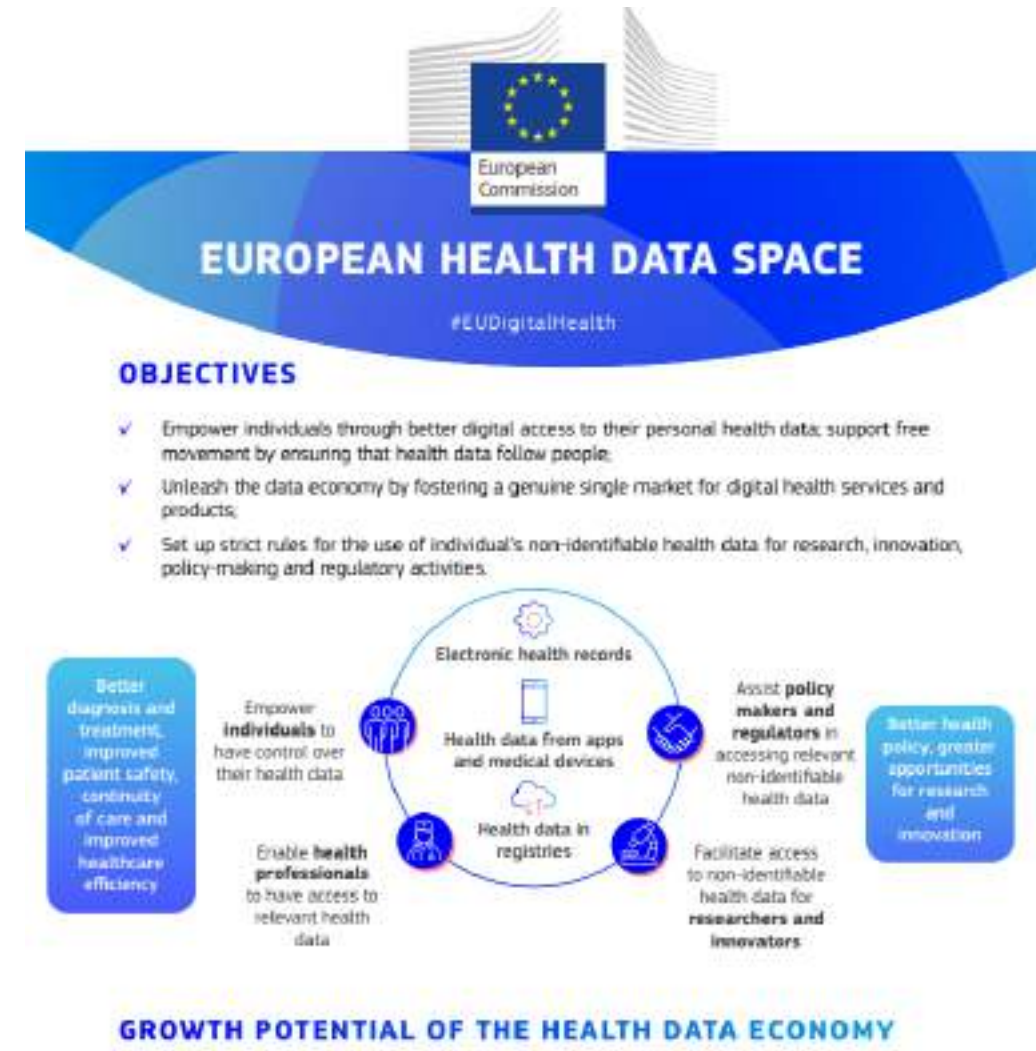
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European Context

The EHDS proposal also builds on the requirements that have been imposed on software through the Medical Devices Regulation and the proposed Artificial Intelligence Act. Medical device software already needs to be certified under the Medical Devices Regulation and AI-based medical devices and other AI systems would also need to comply with the requirements of the Artificial Intelligence Act once in force. However, a regulatory gap has been identified when it comes to information systems used in the health domain, also called electronic health record systems ('EHR systems'). The focus is therefore on these EHR systems that are intended to be used to store and share electronic health data of natural persons. Therefore, the EHDS sets essential requirements specifically for EHR systems in order to promote interoperability and data portability of such system, which would allow natural persons to control their electronic health data more effectively.



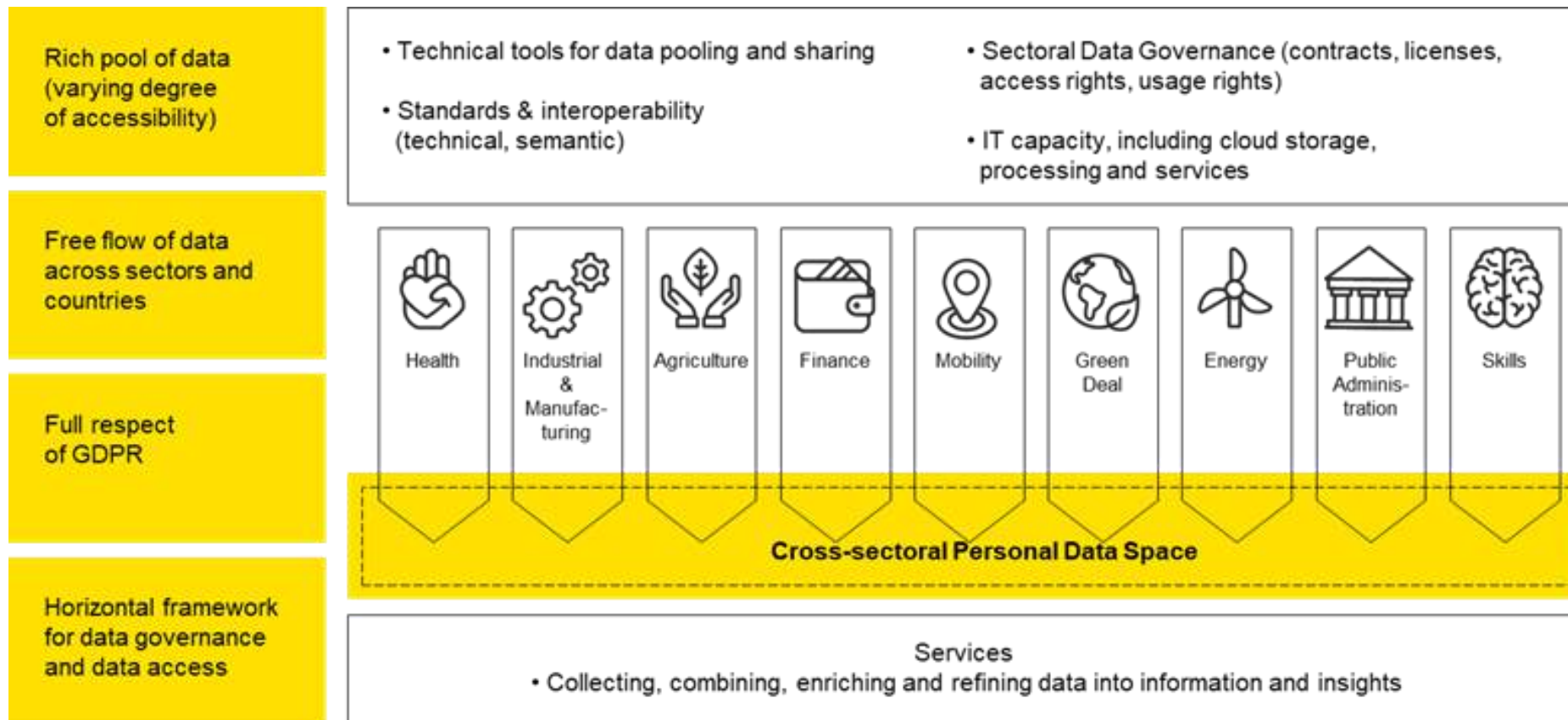


The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework

EHDS Proposal published 03/05/2022



EU data strategy and Data Spaces





XpanDH in the light of the EHDS proposal



OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.



GROWTH POTENTIAL OF THE HEALTH DATA ECONOMY

Main EHDS articles regarding the EEHRxF

- Article 5/6 – **European EHRxF**
 - Datasets
 - Coding systems and values
 - Technical specifications
- Article 12 – **MyHealth@EU**
 - Cross-border exchange of health data shall be under the EEHRxF
- Article 23 – **Common specifications**
 - Adopt common specifications
 - **Shall include:** scope; applicability to different categories of EHR systems or functions included in them; version; validity period; normative part; explanatory part, including any relevant implementation guidelines.
 - **May include:** datasets; coding systems and values; requirements related to data quality; technical specifications, standards and profiles; security, confidentiality, integrity, patient safety and protection of electronic health data; eID



European EHR Exchange Format is a PROCESS and PRODUCT and a REQUIREMENT (New “EHRxF Domains” --> Priority categories)

Article 6

European electronic health record exchange format

1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:

- (a) **datasets** containing electronic health data and **defining structures, such as data fields and data groups for the content representation** of clinical content and other parts of the electronic health data;
- (b) **coding systems and values** to be used in datasets containing electronic health data;
- (c) **technical specifications** for the exchange of electronic health data, including its content representation, standards and profiles.

- NEW IDEAS ??
- OLD IDEAS
 - ValueHealth project ??
 - Old “epSOS” (e.g Patient Access to Pat Summary OR HCR healthcare encounter report)
- Where to “pilot” new “domains/ priority categories
- **NEW CALLS – JOIN ME (and IHE)**

Article 5

Priority categories of personal electronic health data for primary use

1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories:

- (a) patient summaries;
- (b) electronic prescriptions;
- (c) electronic dispensations;
- (d) medical images and image reports;
- (e) laboratory results;
- (f) discharge reports.

The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I.

Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.

2. The Commission is **empowered to adopt delegated acts** in accordance with Article 67 to **amend the list of priority categories** of electronic health data in paragraph 1. Such delegated acts may also amend Annex I **by adding, modifying or removing the main characteristics of the priority categories** of electronic health data and indicating, where relevant, **deferred application date**.



Vision comes to live
through 4 main scopes



Establishing a scalable
public infrastructure for
digital health innovation



Demonstrating real-life
interoperable digital
solutions for
individuals,
researchers, health
services, and the
workforce across
borders



Establishing a Pan-
European ecosystem of
digital health



Creating and validating
a framework for further
exploitation of the
public infrastructure for
digital health
innovation.

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

XpanDH project supports an expanding ecosystem of individuals and organizations that are developing, experimenting and adopting the European Electronic Health Record Exchange Format (EEHRxF) providing a crucial contribution to the European Health Data Space. It is a 2-year Coordination and Support Action financed by the Horizon Europe Framework Programme.

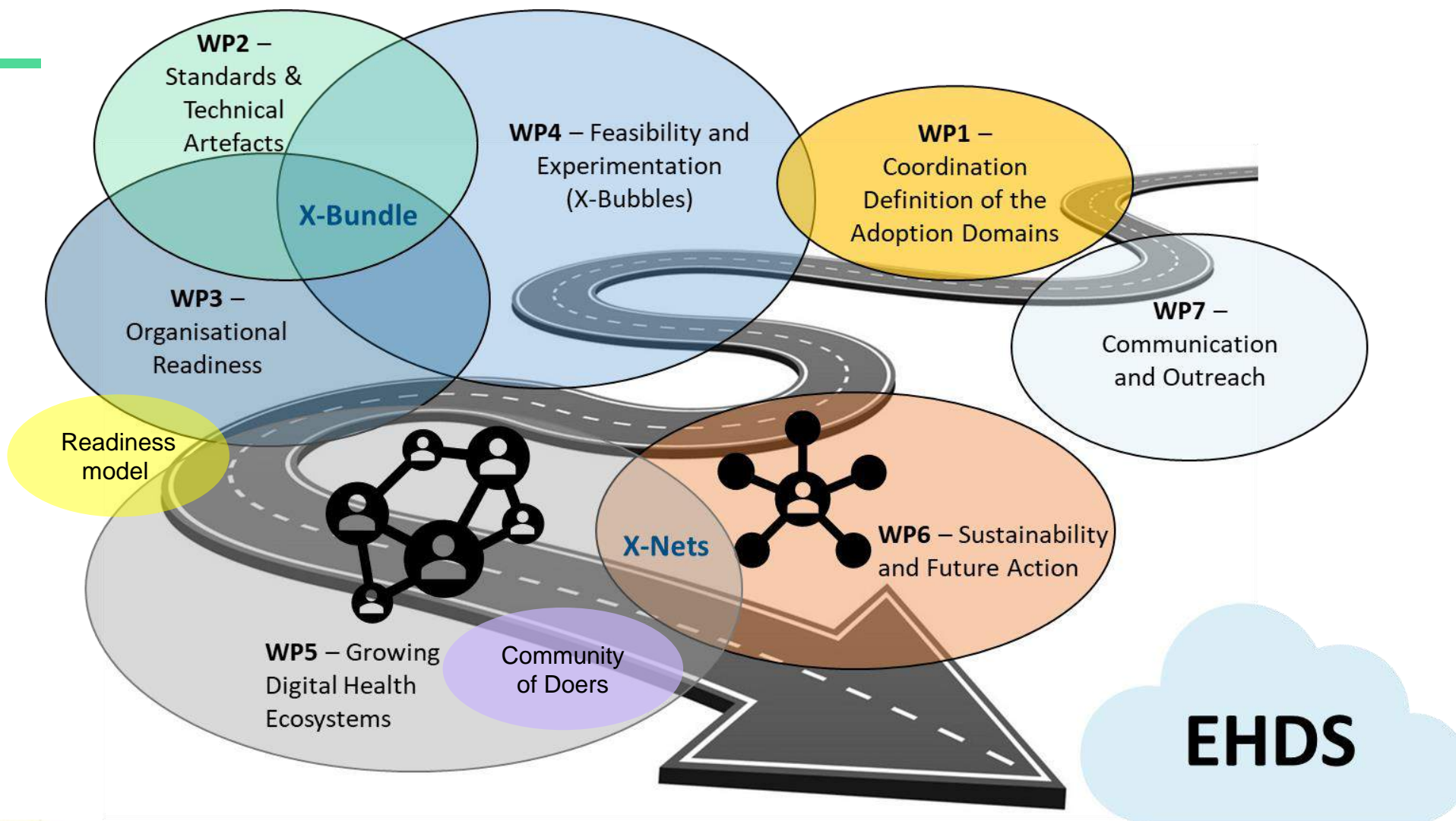


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<https://xpandh-project.iscte-iul.pt/>



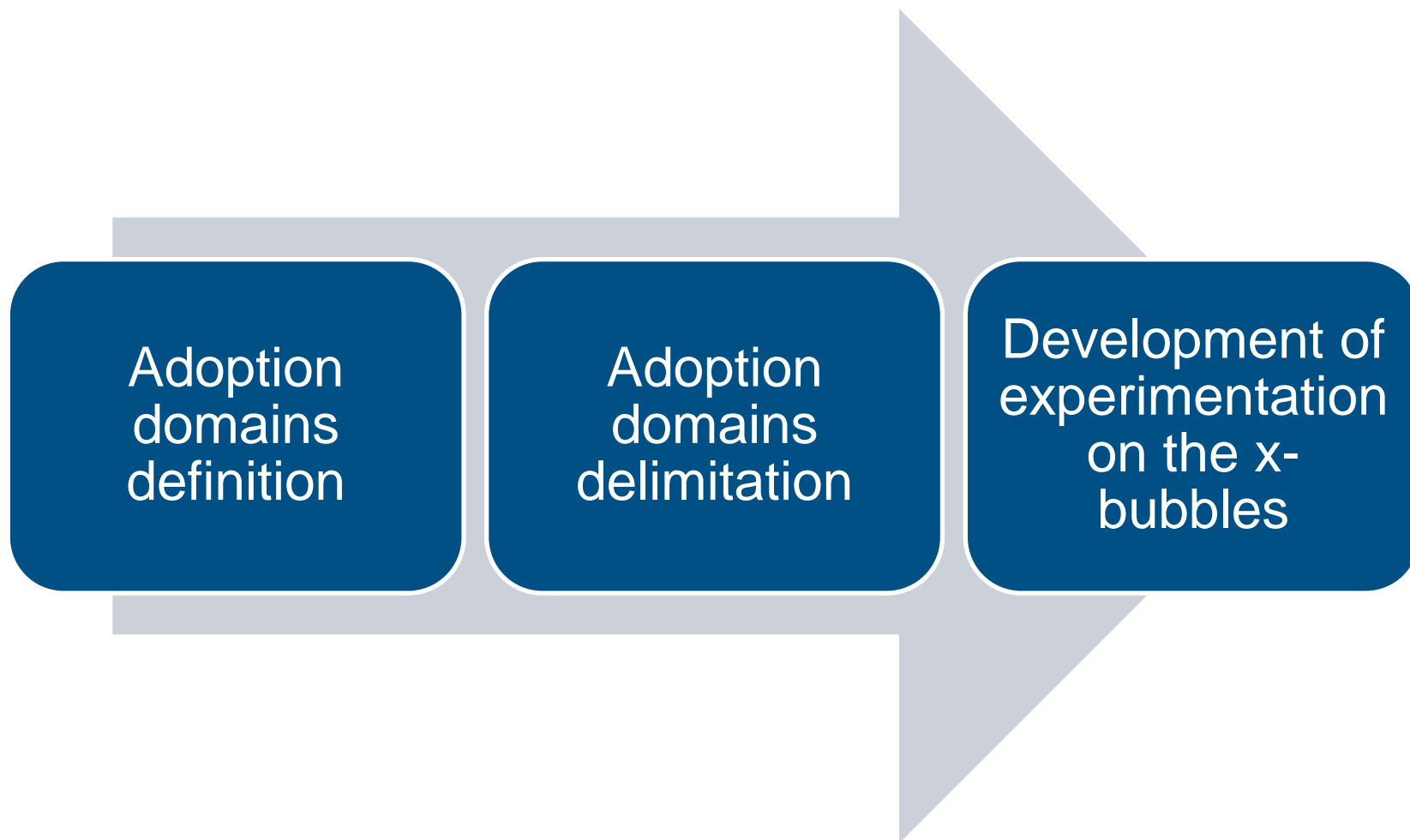
XpanDH workflow





From the Adoption Domains to x-bubbles

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



Selection of Specific Adoption Domains – EC priority categories

EEHRxF adoption domain could be considered as an instantiation of a use case, with a specific case application, that has meaning from a health system or clinical perspective, with defined implementable requirements, that satisfies all the conditions for users to be ready to implement data exchange in conformity to EEHRxF guidelines and specifications.



Laboratory report



Discharge report



Patient summary



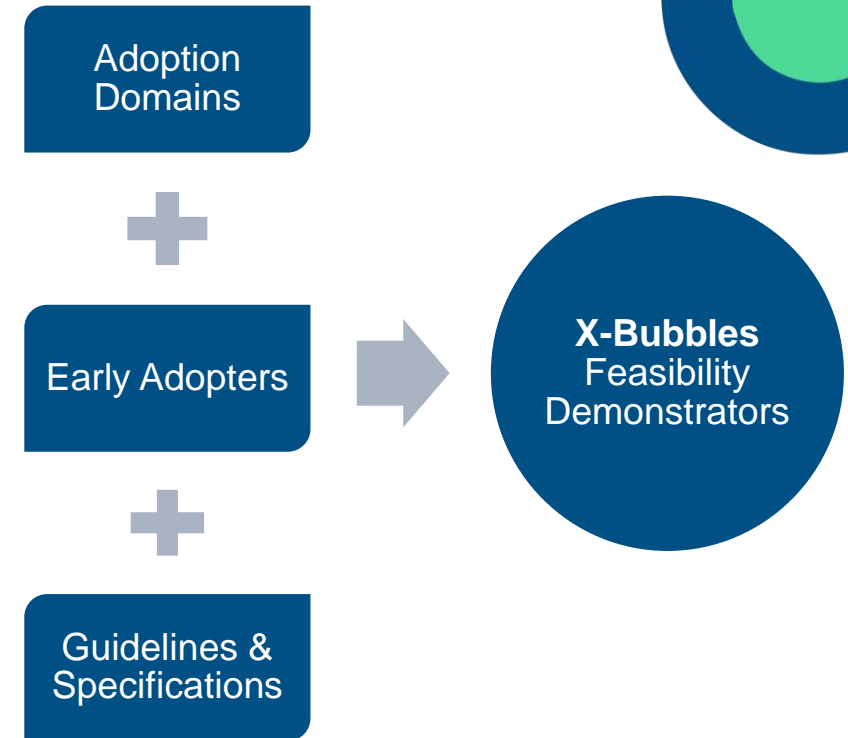
Medical images and
report



ePrescription/
eDispensation

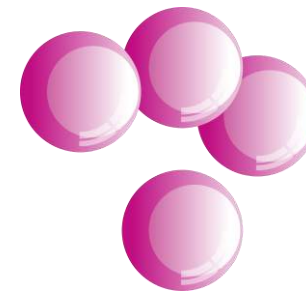
X-Bubbles aims

- Demonstrate feasibility in real-world experimentations with a set of EEHRxF early adopters' organisations grouped under selected adoption domains (X-Bubbles).
- Prove that guidelines and specifications produced are useful, creating conditions for purposeful-use of the EEHRxF in concrete health and care domains.
- Understanding the landscape of EEHRxF adoption as a whole.





XpanDH x-bubbles

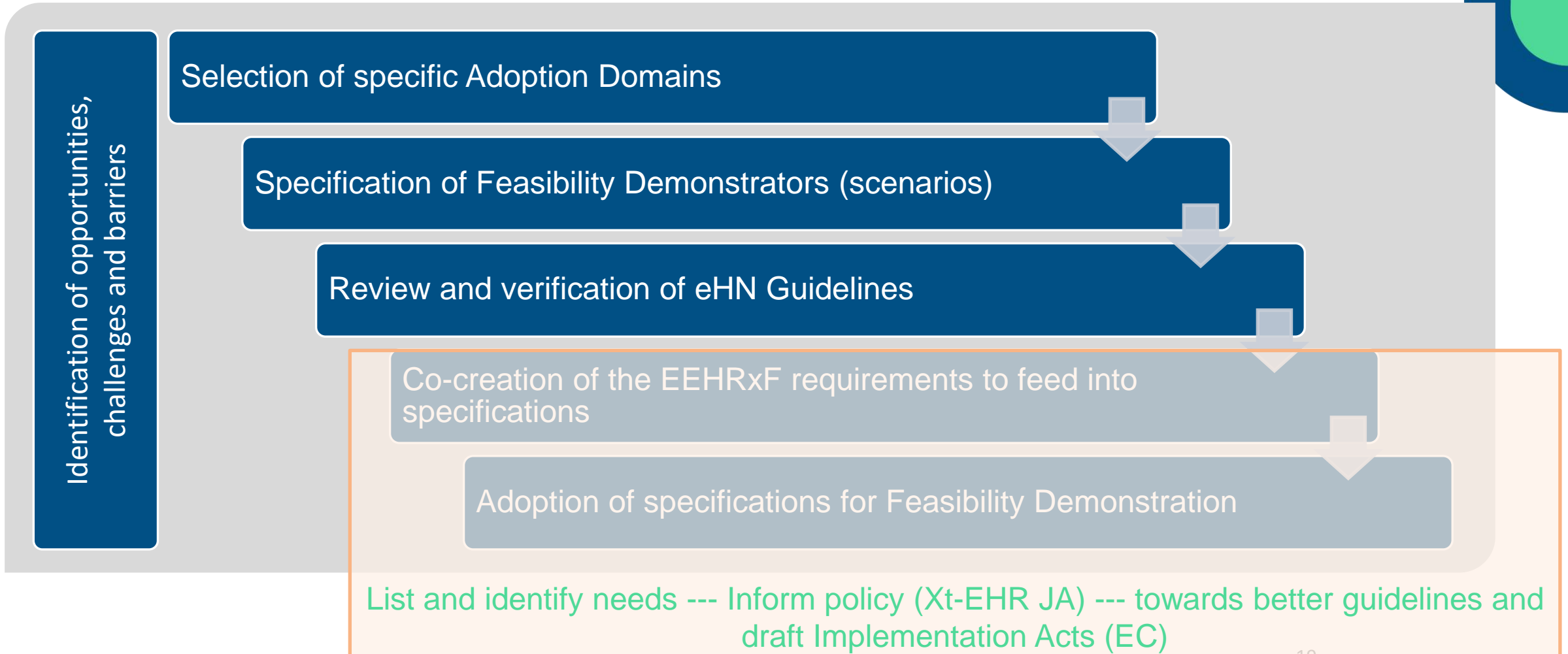


An **X-Bubble** is a list of organisations what will collaborate within the project to jointly adopt and demonstrate use of digital solutions (including interoperability) for an adoption domain.

- **Follow up**
 - The partners will analyse how to use the EEHRxF adoption domains experimentation to apply to a broad set of scenarios
- **Level 1 – Real testing (changing – Policy support to Xt-EHR)**
 - The selected adoption domains will be deeply analysed to determine their feasibility of experimentation;
- **Level 2 – Realignment**
 - The readiness model, will support the development of the strategy of implementation and feasibility.
- **Level 3a – Focused (Simulated Bubble)**
 - Using one domain and narrowing with EU-level partner (ESMO/ ERS
 - “Oncology hospital discharge letter? Other reports?) – Pathology
 - “Respiratory Medicine – particular condition”
 - (PEADIATRIC ASPECTS OF THE HOSPITAL DISCHARGE REPORT?)?
- **Level 3b – High level alignment**
 - The adoption domains in this level can be considered as an open-wider cross consortium, and should be directed to the recommendations – it is linked to the X-nets



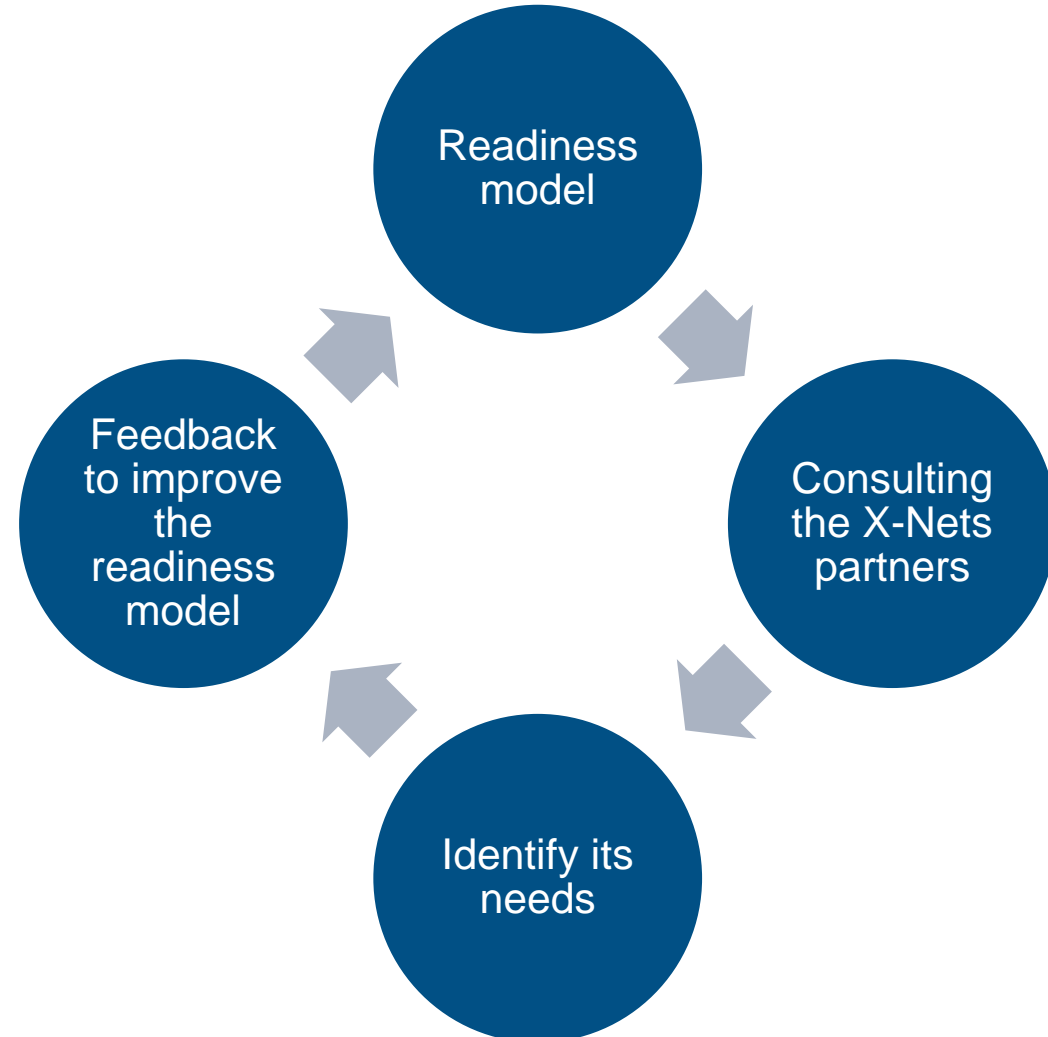
X-bubbles: Original strategy for real testing → Strategy focused on identifying NEEDS – informing policy (Xt-EHR Joint Action)





XpanDH bubbles Level 2 – Realignment

The readiness model, provided in WP3, is being prepared to support the development of the strategy of implementation and feasibility. The networks engaged on WP5 'X-Nets / telemedicine providers' will be activated to ensure their participation

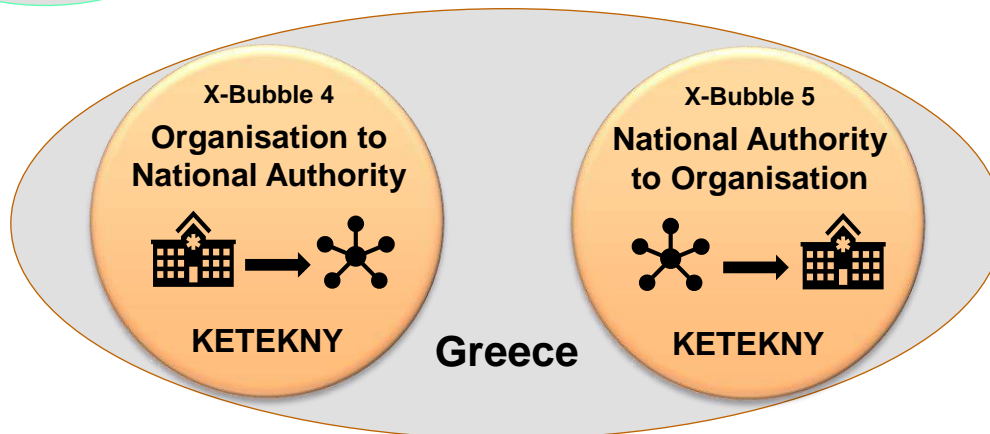
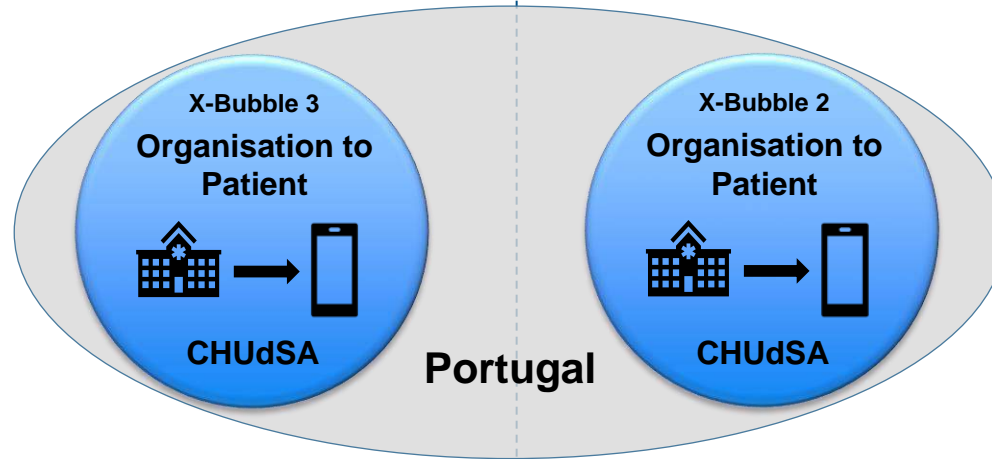




XpanDH bubbles Level 1 – Real testing

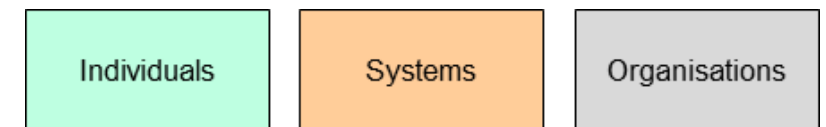
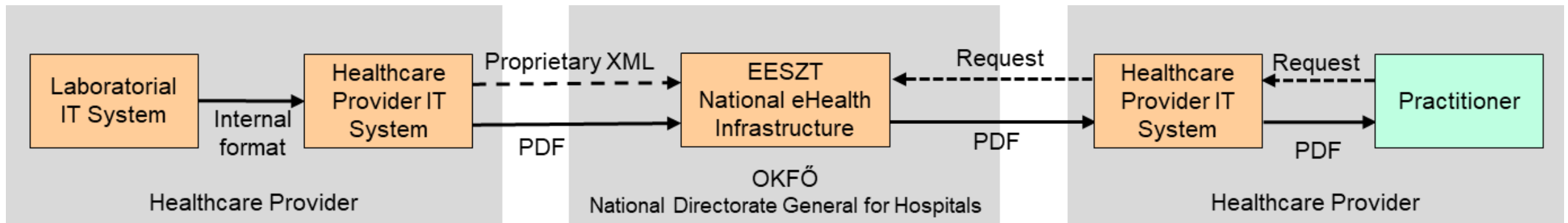
Discharge Reports

Laboratory Results (diabetes patients)



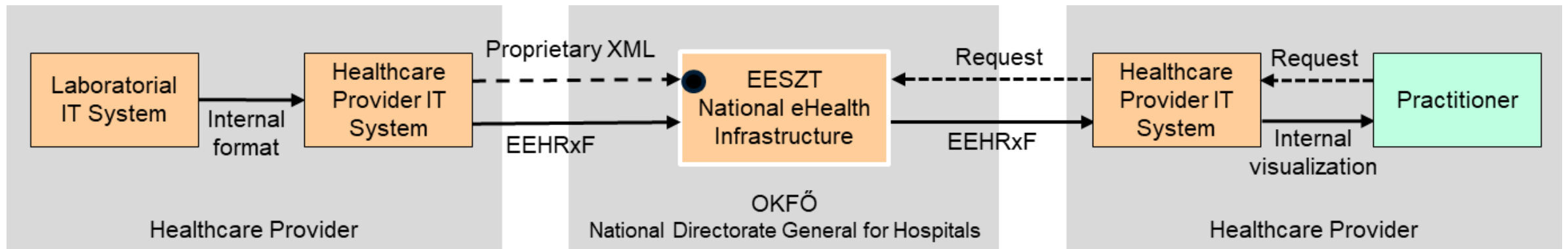
Specification of Feasibility Demonstrators

Bubble 1 – Laboratory Report – Organisation to Organisation – OKFO – AS-IS



Specification of Feasibility Demonstrators

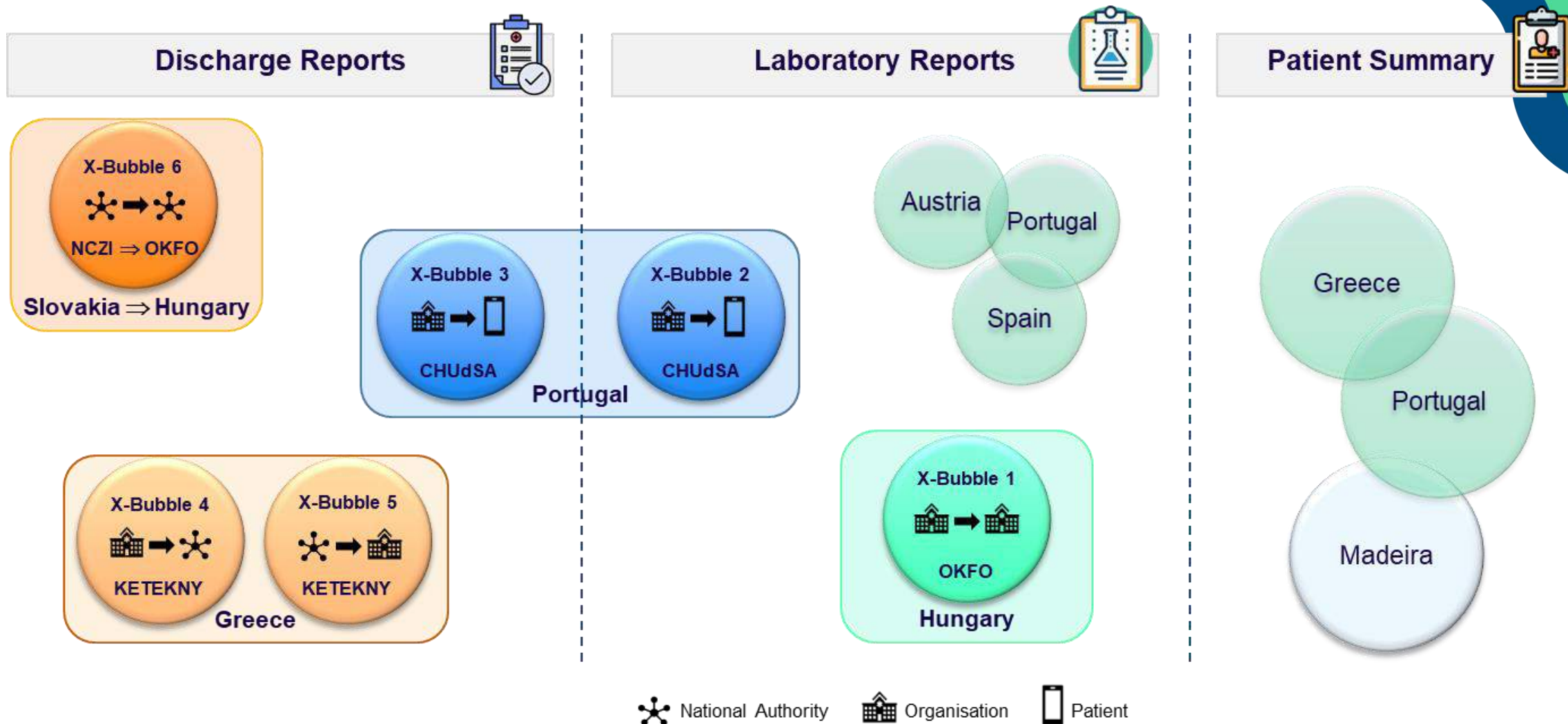
Bubble 1 – Laboratory Report – Organisation to Organisation – OKFO – TO-BE



Co-creation of the EEHRxF requirements to feed into specifications – Laboratory Report

Field	Bubble 1 Hungary	Bubble 2 Portugal	Field	Bubble 1 Hungary	Bubble 2 Portugal
A.1 Report header data elements			A.1.8 Laboratory report metadata (9)	6 mandatory 1 optional 2 not required	6 mandatory 2 optional 1 not required
A.1.1 Identification of the patient/subject (5)	4 mandatory 1 optional	5 mandatory	A.2 Order information (6)	6 optional	1 mandatory 5 not required
A.1.2 Patient/subject related contact information (2)	2 optional	1 optional 1 not required	A.3 Order reason (1)	1 optional	1 optional
A.1.3 Health insurance and payment information (4)	4 not required	2 optional 2 not required	A.4 Specimen information (9)	9 optional	9 optional
A.1.4 Information recipient (6)	6 not required	1 mandatory 3 optional	A.5 Results data elements		
A.1.5 Author (3)	3 mandatory	1 mandatory 2 optional	A.5.1 Laboratory report narrative (2)	1 mandatory 1 optional	1 mandatory 1 optional
A.1.6 Legal authenticator (4)	2 mandatory 2 optional	1 mandatory 3 optional	A.5.2 Observation details (14)	4 mandatory 8 optional 2 not required	6 mandatory 7 optional 1 not required
A.1.7 Result validator (4)	3 mandatory 1 optional	4 optional			

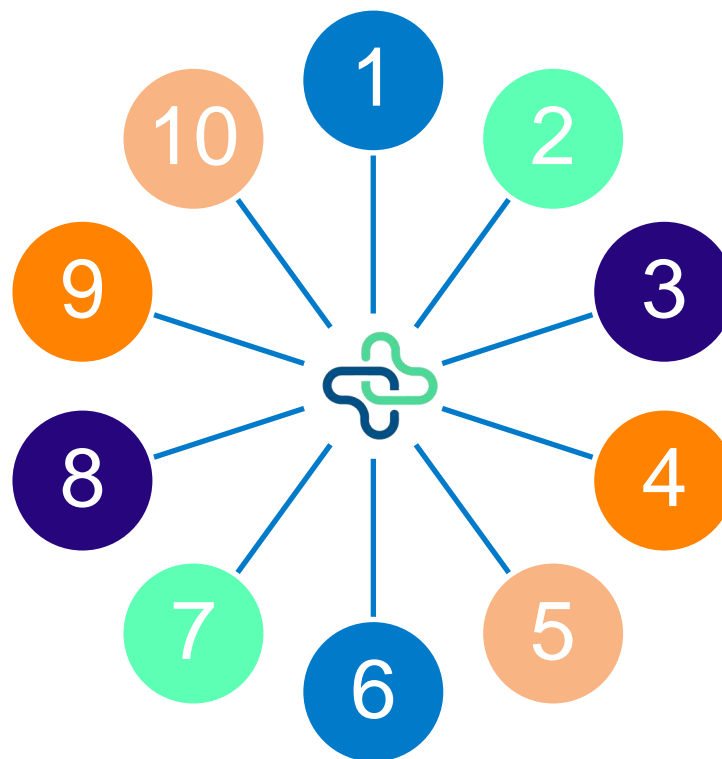
X-Bubbles: current and being prepared





Integration of the ecosystems through the X-nets

X-Nets are networks of organisations directly or indirectly related to health and digital health and that will be involved or need to be involved in an expanding European Digital Health Ecosystem as it matures its use of the European EHRxF (e.g., Networks of Patients and Patient Associations, HCP, ISP, Standards Development Organisations and Industry).

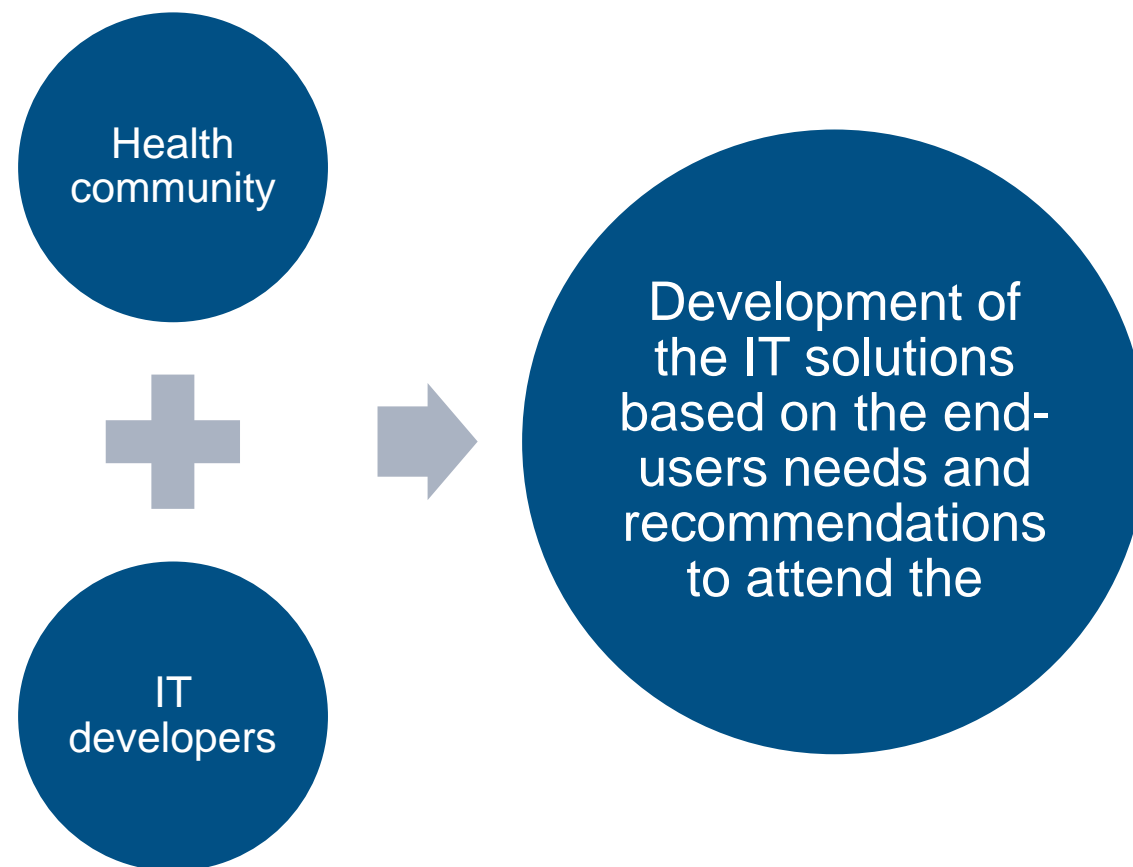


#	X-Net Name
1	Patient Association
2	SDO's & Industry Board
3	Hospitals-on-FHIR
4	Biomedical Research
5	Professionals Associations
6	Citizens and Society
7	Health Mgt & Regulators
8	Innovation Hubs
9	ERN and PerMed
10	Health Regional Authorities



Integration of the ecosystems through the X-nets

The **Community of doers** is bringing together implementers and end-users of new and existing solutions: IT developers and vendors/suppliers on one hand; patients and healthcare professionals on the other, under the concept of the 3C-3P community (Co-creation Community of Patients, Professionals and Programmers). The community is following an open-source community and collaborative approach inviting end-users to participate and support IT developers.



Thanks!



[XpanDH website & Social media](#)

Email to discuss new CALL for European EHR
Exchange format that NEEDS industry players
and healthcare providers –
Henrique@henriquemartins.eu



Alexander Berler
Healthcare Interoperability and Digital Health Expert
Gnomon Informatics
Strategic Business Development Director
IHE Catalyst

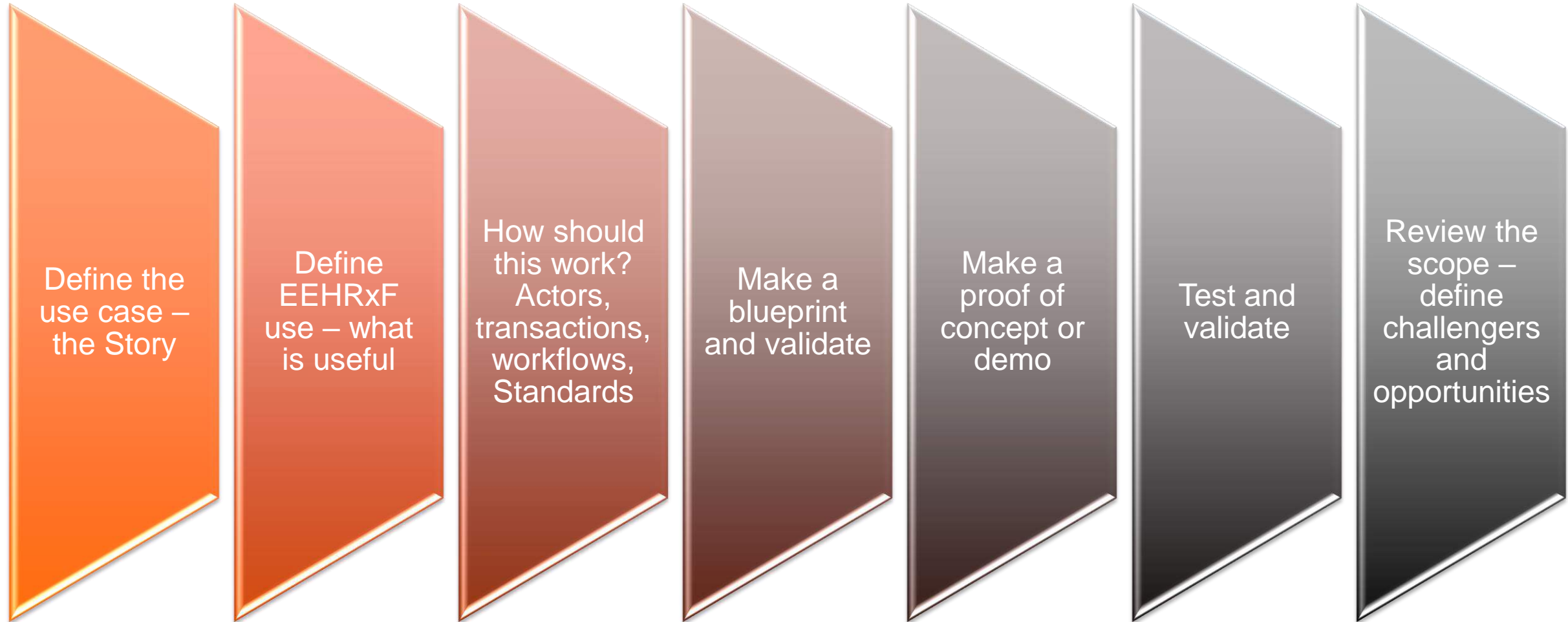
Community of Doers and Co-creators:

To bring together implementers and end-users of new and existing solutions:

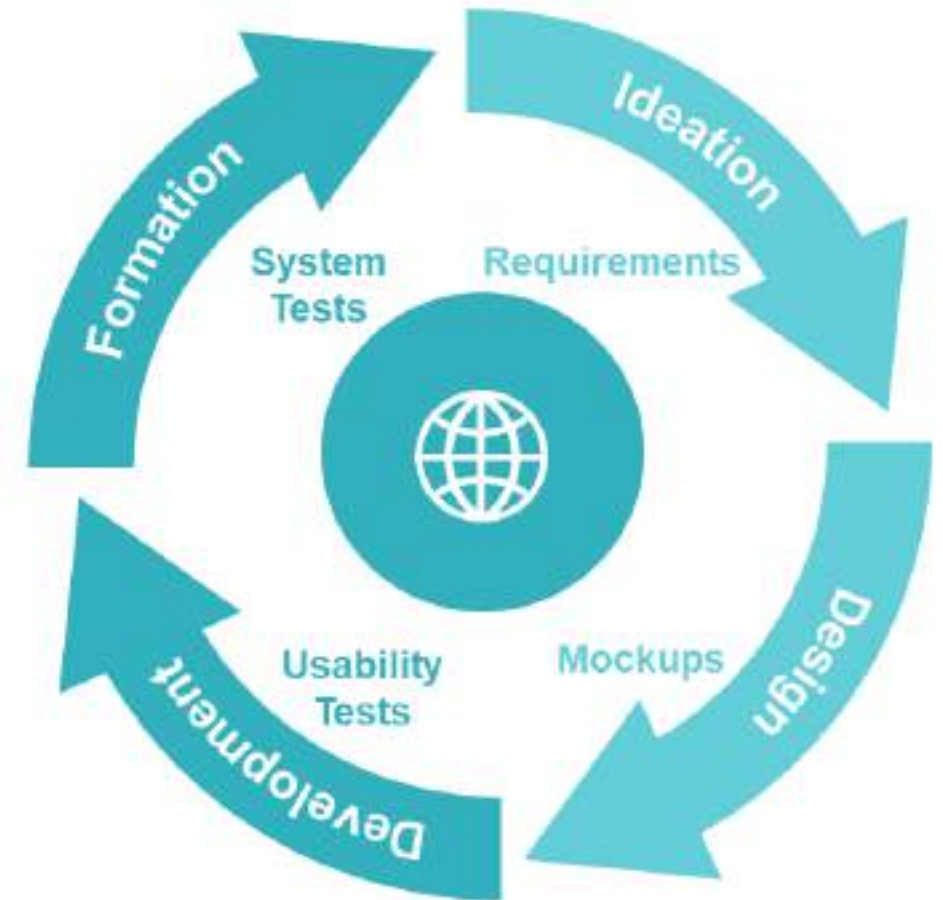
- IT developers and vendors/suppliers;
- patient and healthcare professionals,

in a 3C-3P community (co-creation Community of Patients, Professionals and Programmers)




- Co-creation **brings together** those that needs a service, solution or a process with those that can realise it.
- In our case we start by brining together patients' associations, healthcare providers and implementers (vendors, academia) to investigate future use of the EEHRx_F in business use cases that reflect real needs
- **Co-created solutions have a better chance of being adopted**
- Iterate with other XpanDH stakeholders to provide feedback on the X-Bundles, expand X-Bubbles, test EEHRx_F specifications, build proof of concepts, review the proposed readiness model
- Define risks, issues, problems but also opportunities, needs, open the future.
- **Mature new ideas** and investigating new domains



- X-bundles
- EEHRxF specifications as they are proposed as Standards and technical Artifacts
- Coverage of all EEHRxF documents
- Testing tools
- Software components
- The Readiness model of EEHRxF



How can I contribute?

Participation	Participation is open to individuals <u>from the communities of Patients, Professionals, and Programmers engaged in the healthcare sector.</u>	
Who	Whether representing patients or professionals, working as a programmer for an economic operator, or being involved in academia, start-ups, or innovation, <u>anyone can contribute.</u>	
People, organisations, entities	We seek people, organizations, and entities eager to delve into developing <u>innovative, person-centred concepts that demonstrate the value of EEHRxF in practice.</u>	

The Community is now officially launched!

- 1st experiment during the Athens Digital Health Week with 20-25 participants
 - <https://xpandh-project.iscte-iul.pt/xpandh-community-of-doers-workshop-explores-innovative-exchange-formats-for-enhanced-health-ecosystems/>

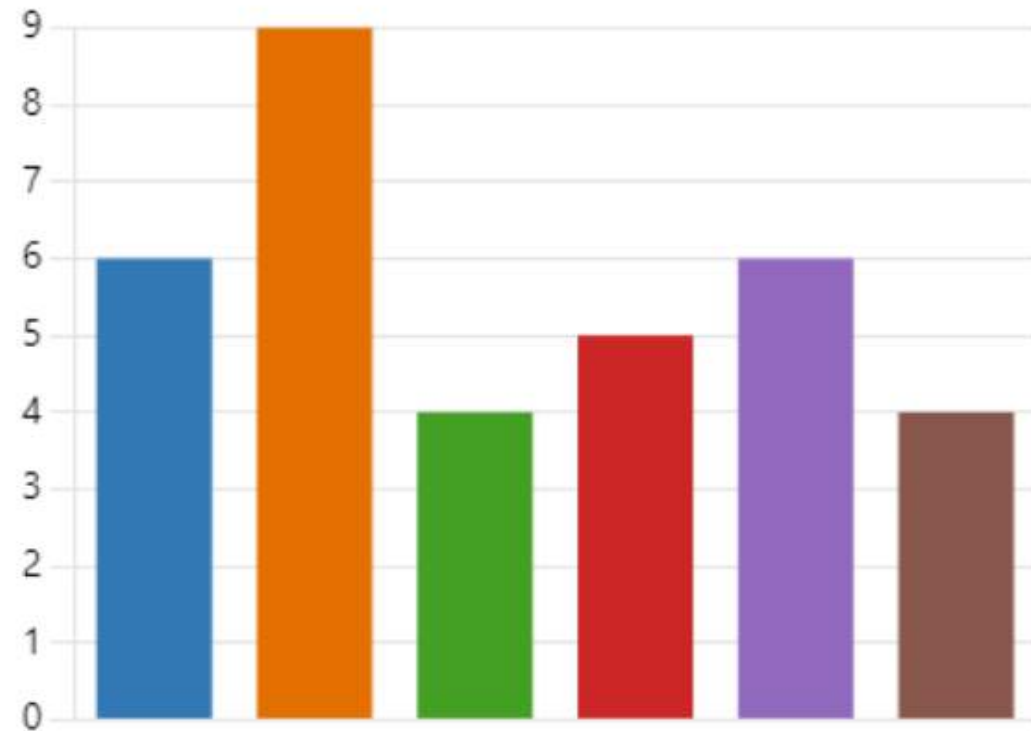


- Check XpanDH website, promote the community on social media and **register at the webinar on April 22nd, 2024**
 - <https://xpandh-project.iscte-iul.pt/shape-the-future-of-healthcare-join-xpandhs-community-of-doers-and-co-creators/>

- Register see QR Code
- Our Goal
 - 50 Participants
 - Multiple teams
 - Several countries
- Teams created will participate in XpanDH
Final event in December 2024
- Promote on Social media
 - #XpanDHHealthFuture #CommOfDoers #EEHRxF
#EHDS

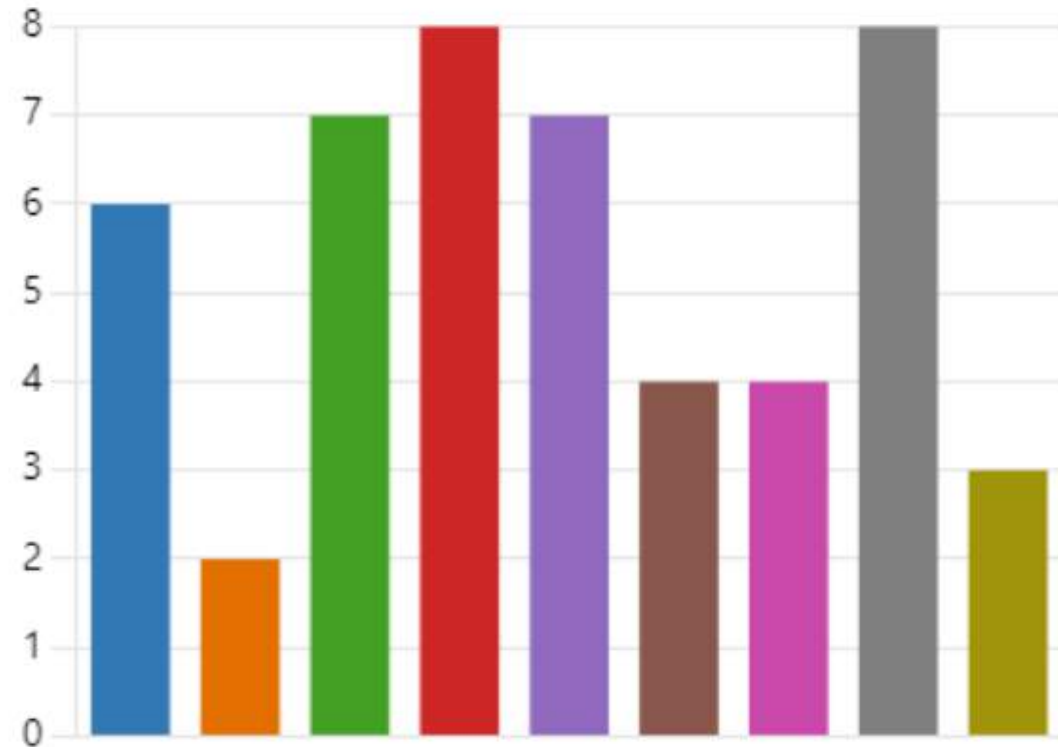


What is the current EEHRxF interest of participants?



Use case interest so far

● Cancer patient related use cases	6
● Rare disease related use cases	2
● Patient experience reporting	7
● Patient access reporting	8
● Deployment of national EHR Sol...	7
● Medical imaging and reports	4
● Active ageing use cases	4
● Patient mediated sharing of doc...	8
● Other	3



- XpanDH will promote testing EEHRxF (PS, Lab Reports)
- XpanDH will contribute to the IHE Plugathon parallel event in the EHDS track





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

IHE Webinar, 8 March 2024

Robert Stegwee, CEN/TC 251 Chair, Lead WP2: Creating the EEHRxF Standards and Policy Hub

Our launch event with Xt-EHR and XpanDH



17 January 2024, @ #AthensDigitalHealthWeek2024

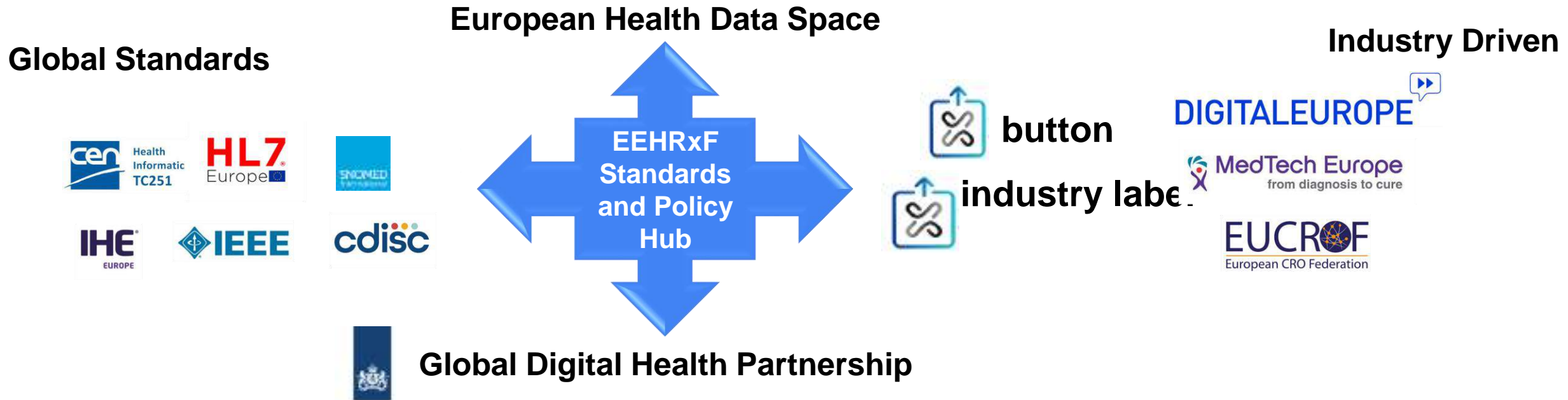
High expectations from the EHDS and EEHRxF



-  The objective of the proposed European Health Data Space (EHDS) regulation is to improve access to and control by natural persons over their personal electronic health data
-  The EHDS supports the implementation of the rights enshrined in the GDPR as applied to electronic health data, with assurances for quality, reliability, privacy and interoperability at the source
-  Natural persons will be empowered to exchange and to provide access to personal electronic health data to the health professionals of their choice, going beyond the right to data portability.
-  Healthcare professionals are expected to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European electronic health record exchange format (EEHRxF).

xShare vision:

Everyone can share their health data in EEHRxF with a click-of-a-button.

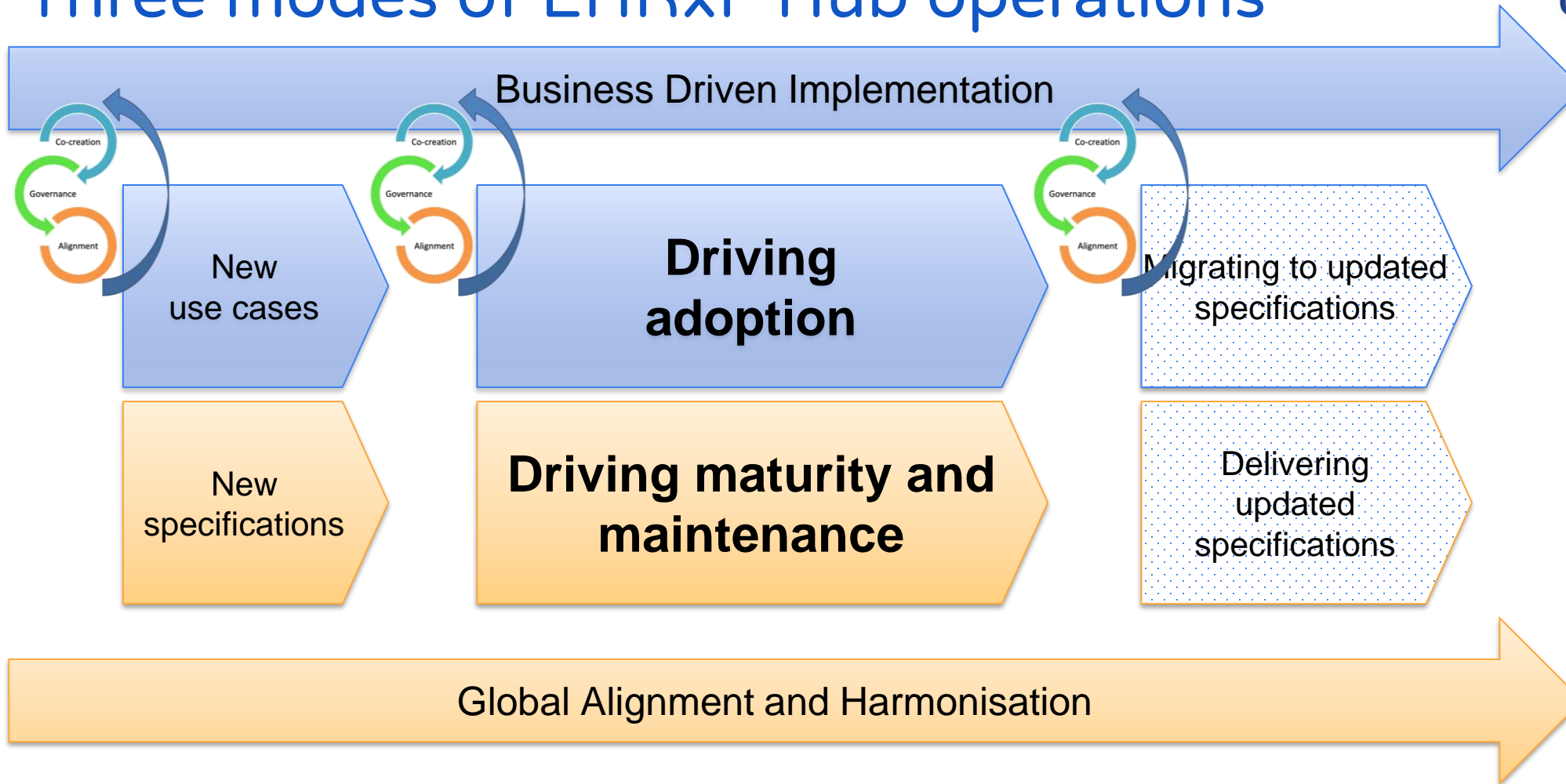


- Build the European EHRxF Standards and Policy Hub sustainable by design.
- Examine feasibility of the xShare industry label indicating EEHRxF capability




Why are we establishing a Hub?

-  The benefits foreseen by the European Health Data Space are dependent on the specifications of the European EHRxF
 - Standards-based innovation is a key policy objective across the European Union
-  Users wanting to realise interoperability for their specific use cases will never need the full breadth and complexity of the European EHRxF
 - The Hub will provide them with dedicated guidance, compliant with the EHRxF
-  Industry will realise systems conformant with the European EHRxF
 - The Hub will provide industry engagement from an early stage on
-  Regulators need to rely on mature specifications for legal reference
 - The Hub will provide regulatory responsiveness and alignment with (global) standards
-  The Hub enables a standards-based digital health ecosystem
 - Co-creating the health data economy in Europe

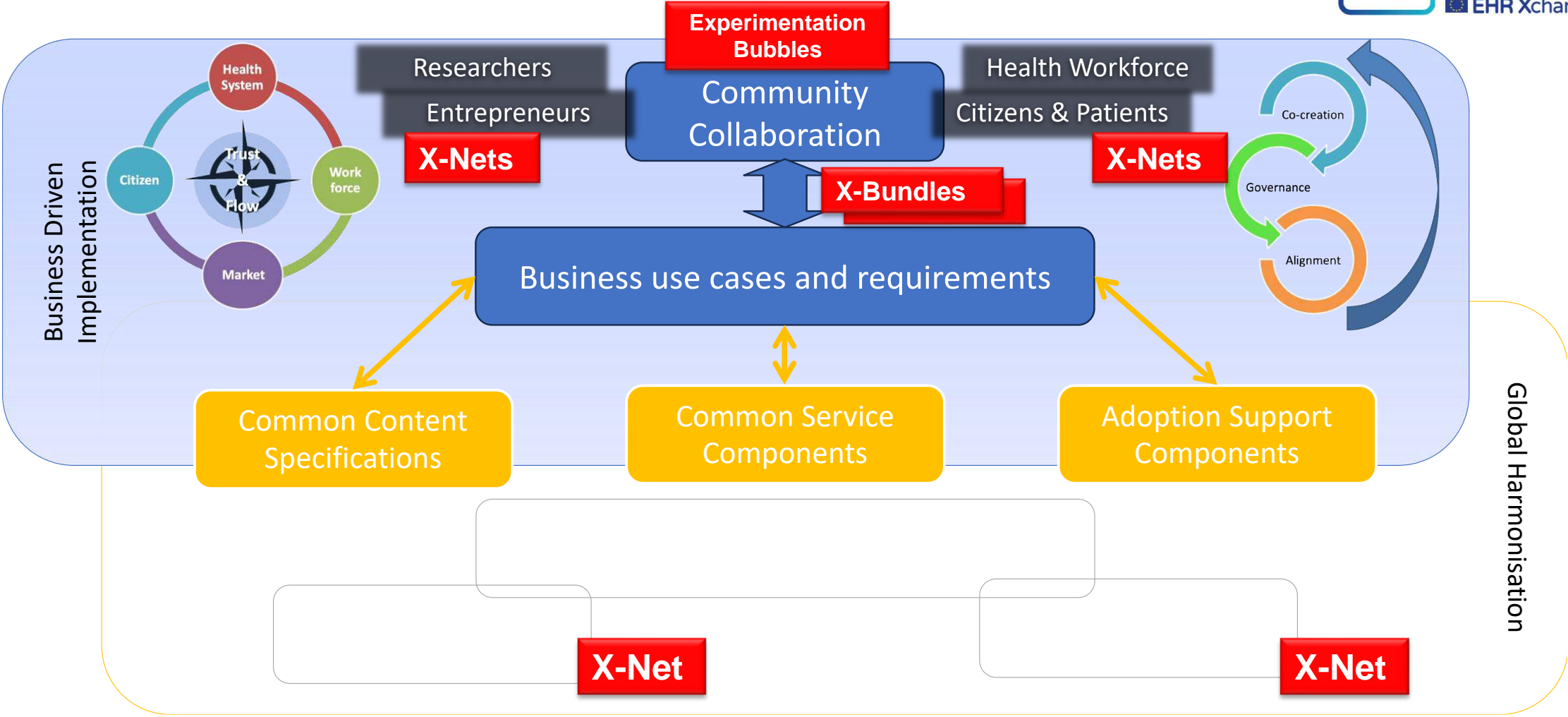
Three modes of EHRxF Hub operations








What does the Hub offer the industry?

-  Access to the latest knowledge and expertise around the European EHRxF specifications, including the tools and materials needed to implement, test and deploy conformant solutions
-  A neutral place, supported by global SDOs, to engage in alignment on development and maintenance of European EHRxF specifications
-  A way to engage in testing and assurance that is designed to support the regulatory requirements of EHDS, MDR and other (national) regulations.

The European EHRxF Standards and Policy Hub: Common standards as infrastructure for innovation



How can industry help establish the Hub?

-  Engage in the xShare Industry Forum
-  Share your experience and opinions on the European EHRxF
-  Co-create new (versions of) EHRxF compliant implementations with the community, ensuring business driven development
-  Provide tools and materials to drive adoption and maturity
-  Co-create novel ways of testing and assurance in conjunction with existing and future regulatory frameworks
-  Consider active participation in two new calls:
 - [DIGITAL-2024-CLOUD-AI-06-HEALTHACCESS](#) - Supporting patients' access to their health data in the context of healthcare services for citizens across the EU
 - [DIGITAL-2024-CLOUD-AI-06-HEALTHRECORD](#) - Demonstrating the in-service use of the European Electronic Health Record Exchange Format (EEHRxF) in healthcare settings

Help envision the xShare Industry Label!



semi structured interviews March/April 2024



questionnaires April 2024



industry workshops May 2024



vision for an xShare Industry Label June 2024

Liberating Health Data

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April 12th:



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