EHDS Regulation: Adoption and Implementing Acts

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DG SANTE C1

2nd EEHRRxF Expert Summit,
November 2024

Reminder on the timeline for the EHDS Regulation

Previous steps

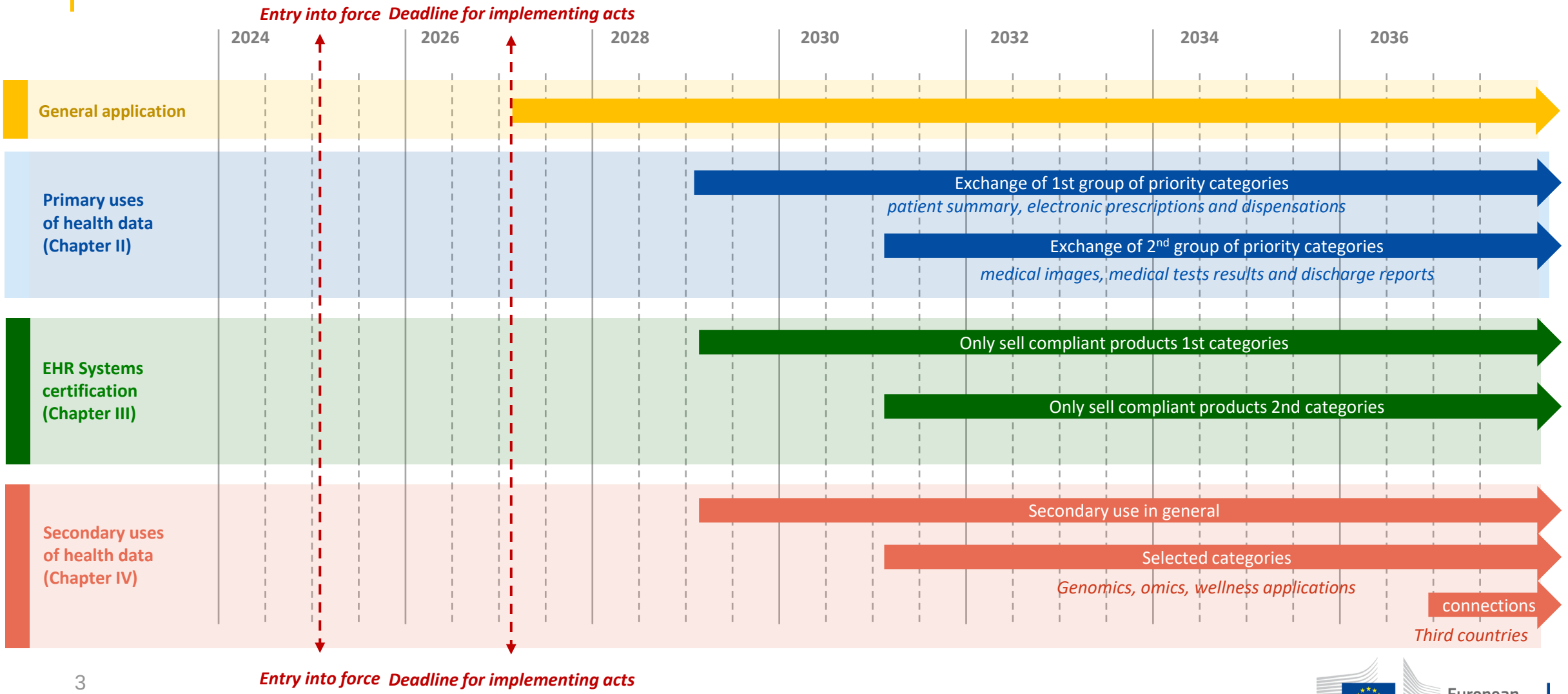
- **Provisional agreement** reached during the fifth trilogue 14/03/2024.
- Examination of the compromise by MS in COREPER on 22/03/2024
- Vote in EP ENVI-LIBE joint committee meeting 09/04/2024
- Vote in plenary session in EP **24/04/2024**

Is it done? Almost…

- Corrigendum procedure **ongoing**
- Expected final adoption in EP (expected year-end): Corrigendum procedure, as a package.
- Corrected text to be published in Official Journal of the EU (OJ), expected: **early 2025.**
- **Entry into force:** 20 days after the publication on the OJ

Implementation of the EHDS Regulation

Timelines are indicative.



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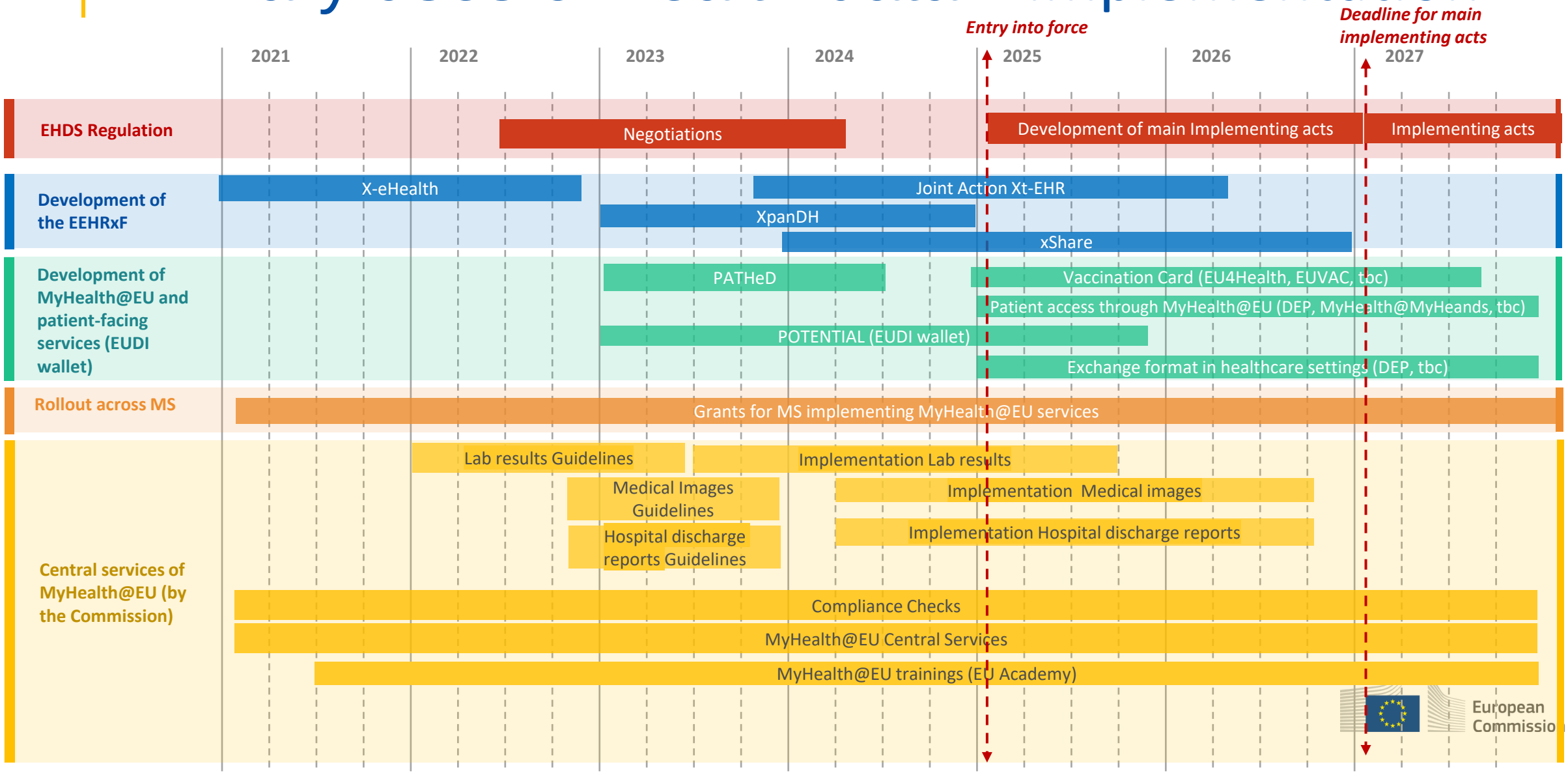
Timelines are indicative.

Primary uses of health data – Implementation



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Actions related to the European electronic health record exchange format (EEHRxF)

Innovation, experimentation

epSOS, EXPAND, JAseHN, eHAction

- Development of the MyHealth@EU infrastructure

X-eHealth

- Work on lab results, hospital discharge reports, medical imaging
- Defined use cases, data sets, data models
- Implementation guides for CDA and FHIR

XpanDH

- Further elaboration of the format
- Pilots, verification of implementability
- Set-up of the ecosystem

xShare

- Practical implementation of patient-mediated workflow for data portability
- Further development of the exchange format (e.g. care plans, telemonitoring)

Further actions

- In-service deployment of the EEHRxF
- Patient access to health data using MyHealth@EU
- EEHRxF support centre
- EUVAC

Formalisation

Work on the eHealth Network guidelines

- Use cases, data sets, principles
- Adopted by Member States in the eHN

Work by MyHealth@EU Solution Provider

- Implementable specifications, other artefacts
- Implementation in OpenNCP for MyHealth@EU
- Adopted by Member States in the eHMSEG

Joint action Xt-EHR

- Work on the formalisation of the format
- Requirements for the certification of EHR systems

(recommendations for possible future implementing acts under EHDS)

Implementing Decisions under the upcoming EHDS

- Legally binding requirements and specifications for the European health record exchange format
- Legally binding requirements for the certification of EHR systems

Infrastructure, deployment

MyHealth@EU current and future services

Patient Summary and ePrescriptions/ eDispensations

Original Clinical Documents

Lab results, hospital discharge reports, medical imaging

Further data categories

European Commission

Important differences

- Xt-EHR Joint Action **will not draft the implementing acts** but will provide the essential technical specifications that will be a major contribution into the most important implementing acts.

- Member States **should prioritise the participation in the Xt-EHR Joint Action** as this is the core of the groundwork for the European Health Data Space implementation for the next few years.

- Xt-EHR Joint Action will hold **stakeholder consultations** in 2025 for key deliverables!

EEHRxF Support Centre (EU4Health Work Programme 2024)

- **DI-p-24-72** *Support centre for the European Electronic Health Record exchange Format (EEHRxF) and for the interoperability and security of electronic health record systems*
  1. supporting the creation, stimulation and moderation of an EEHRxF community of practice
  2. consolidating requirements and specifications
  3. conducting analysis and monitoring work as well as support actions
  4. providing and maintaining tools and resources online
  5. support implementers and other relevant stakeholders on the adoption EEHRxF and best practices
- **Budget:** EUR 4.5 million
- Implemented by HaDEA
- **More information in the WP 2024:** 3_Annex I_Draft EU4Health WP 2024

The European Health Data Space is not just the Format

European Commission

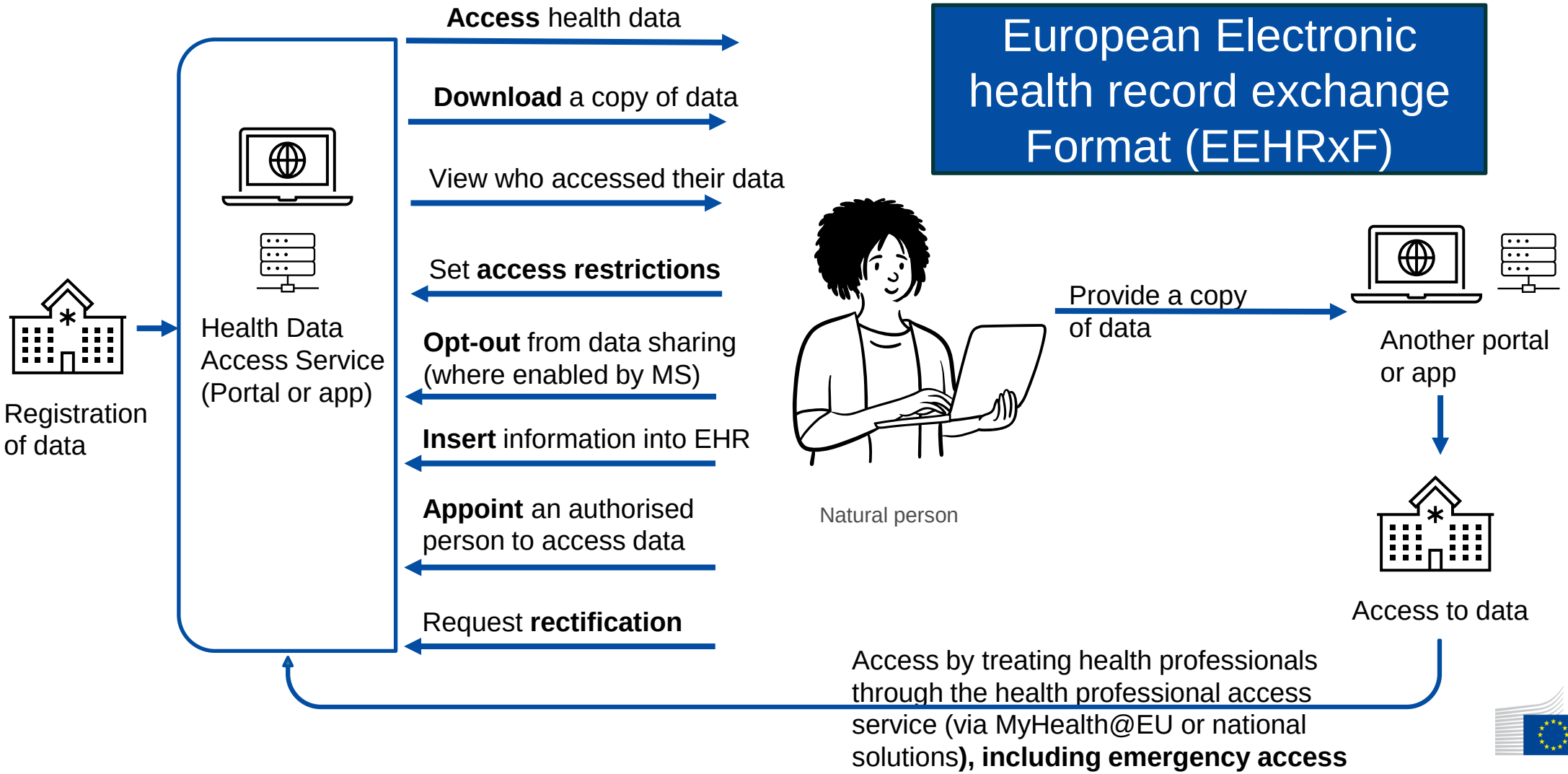
EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems

Rights of natural persons in primary use



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Scope of harmonisation

EHR systems must contain **two harmonised components**, starting 2028/2030 depending on which kind of data they process:

Interoperability component

- Provides capability to import/ export data in EEHRxF

Logging component

- Provides capability to generate the logs of access

Member States remain free to have requirements on other parts of EHR systems, provided they do not interfere with the harmonised components

Certification

- **Self-declaration of conformity**
- **Digital testing environments** across Member States for ex-ante assessment of compliance with the requirements
  - To assess compliance of harmonised components with essential requirements
- **Registration of certified EHR systems** in an EU database
  - For transparency and accountability on certified EHR systems

Thank you!

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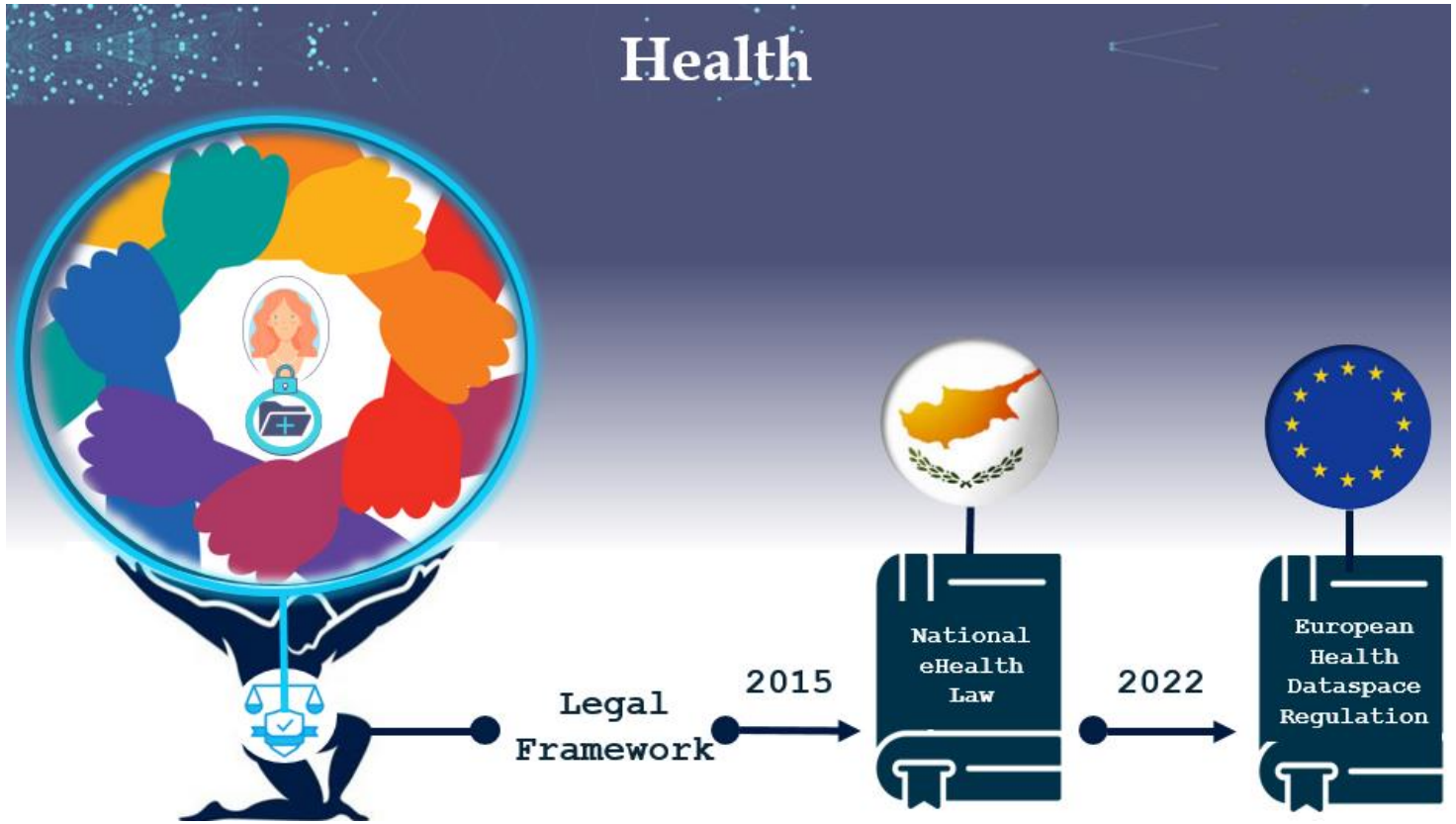
Xt-EHR Policy Overview:
Current Achievements and Future Requirements



Christos N. Schizas
Xt-EHR Coordinator

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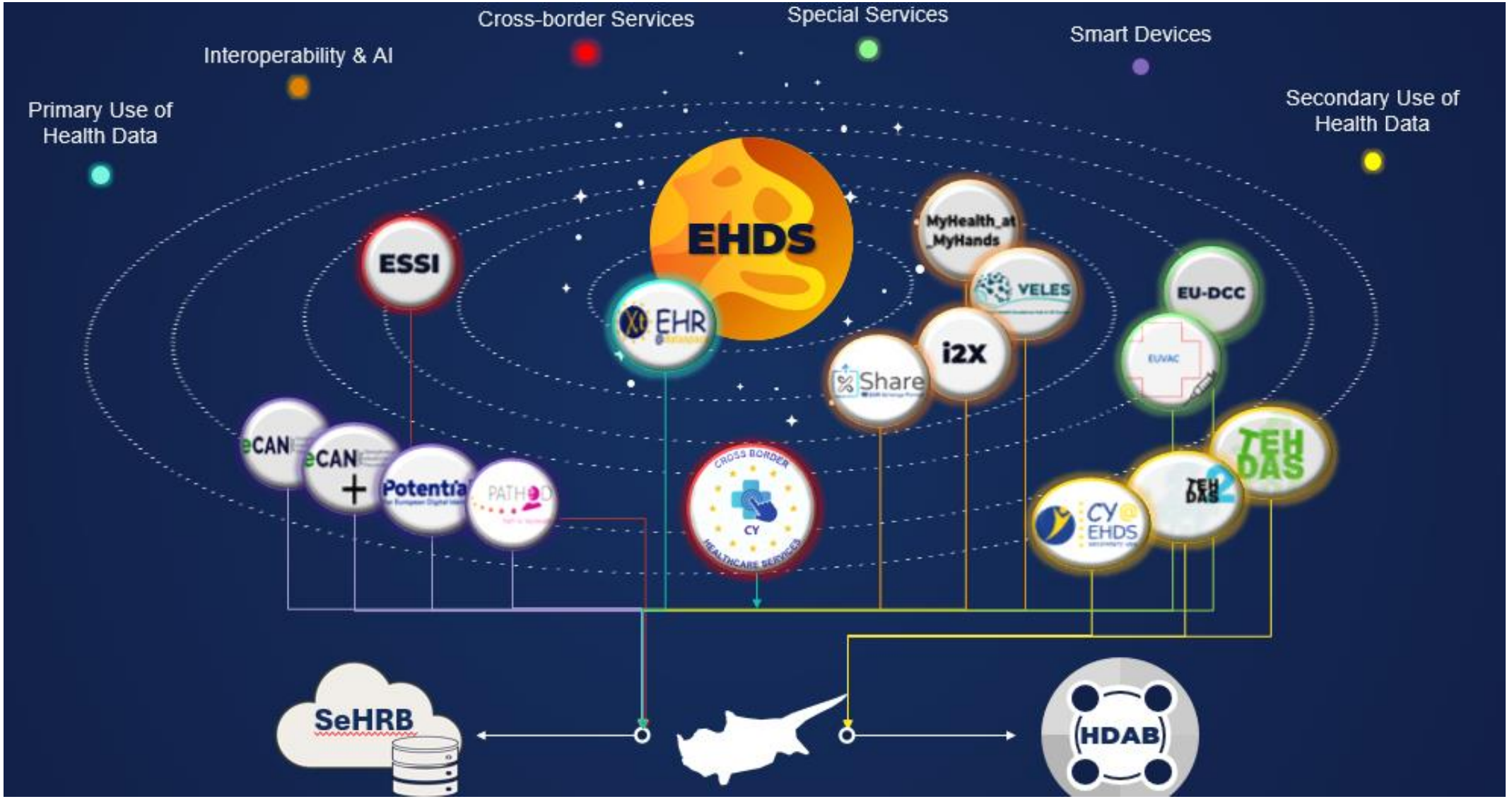

Cross-border Services
Special Services
Smart Devices
Interoperability & AI
Primary Use of Health Data
Secondary Use of Health Data
EHDS
ESSI
EHR
MyHealth_at_MyHands
YELES
EU-DCC
EUVAC
i2X
Share
eCAN
eCAN
Potentia
PATHOS
CROSS BORDER
CY
HEALTHCARE SERVICES
CY EHDS
TEHDAS
TEHDAS2
SeHRB
HDAB

- Patient Summary
- Electronic prescription and electronic dispensation
- Laboratory results and reports
- Medical images and reports
- Discharge reports

- Data Access Applications management solution
- National Dataset Catalogue for health data
- Secure Processing Environment for Health Data
- Cross-border gateway to connect with the HealthData@EU infrastructure
- Health data quality enhancement

Strengthening Cross-Border Cooperation

This project aims to enhance cooperation among EU Member States for better interoperability and exchange of healthcare data, supporting the foundations for primary use of electronic health data within the European Health Data Space (EHDS).

Evaluation of Digital Health Tools

The project will assess the requirements for telemedicine, mobile health applications, and electronic health records, focusing on interoperability, electronic identification, and the sustainability of cross-border telemedicine services.

Standardization and Guidelines

The Xt-EHR proposal will develop implementation guides, technical specifications, and a conformity assessment framework for the adoption of the European Electronic Health Record Exchange Format (EEHRxF), facilitating uniform standards across the EU.

Certification and Conformity

Xt-EHR will create conformity assessment schemes to certify EHRs under the EHDS regulation, helping establish a robust framework for interoperable health data exchange across the EU and complementing the MyHealth@EU initiative.

WP1: Project management and coordination

Tasks ongoing / completed

Collaborative Efforts: Close collaboration is maintained with other related projects (xShare, XpanDH, Label2Enable) and the subgroups of the eHealth Network (eHN) to leverage shared insights and foster a unified approach. Establishing a stakeholders engagement governance with key projects and relative SDOs.

Alignment with EHDS: Tasks under Xt-EHR are being mapped to the European Health Data Space (EHDS) framework, with adaptations planned to align with the new EHDS regulations. A completed mapping table will be disseminated for clarity and alignment.

Future work

Tender Process for Subcontracting: The coordination team plans to extend its technical team to provide technical support under WP1, Task 1.4, offering expert assistance from IHE, HL7 and CEN to Member States and WP leaders in creating interoperability specifications, supporting conformity assessments, and providing testing and training services.

Structured Deliverable Templates: Deliverable templates are organized to address technical aspects comprehensively, covering the logical models' structure, implementation guides, technical specifications, use cases, and annexes.

WP2: Dissemination

Tasks ongoing / completed

Bonn Workshop: An internal hybrid event featuring plenary sessions, breakout discussions and a parallel event on ‘eHealth in Medical Curricula’.

Project portal and social media: The project portal has been launched, providing information on events, news, and stakeholder engagement opportunities, including a subscription for the newsletter; additionally, a LinkedIn profile has been created to keep audiences informed and promote the project.

Stakeholder Engagement Strategy: A structured engagement plan for stakeholders has been developed, focusing on Member States (MSs) and the EU to ensure wide-ranging involvement and feedback integration. Activities for stakeholder engagement are taking place, e.g. Xt-EHR at stakeholder events.

Future work

Centralized Platform for Artefact Publication: We agreed to implement a centralized platform with clear links to external websites and other repositories to enhance the publication process, improve collaboration among stakeholders, and ensure easy access to resources. This streamlined approach will increase transparency, accountability, and foster the successful dissemination of knowledge within the eHealth community.

Stakeholder Briefing Workshops for deliverables: Dedicated virtual workshops will be organized for each deliverable of WP5 to WP9 to introduce stakeholders and experts to the Xt-EHR project, EHDS regulation, deliverable objectives, explain stakeholder consultation process and timelines, with Q&A sessions included.

Upcoming Events

WP3: Evaluation

Tasks ongoing / completed

Identification of KPIs: WP3 has successfully identified the Key Performance Indicators (KPIs) that will be used to assess progress and impact.

Consensus Panel Formation: A consensus panel, primarily composed of stakeholders, has been established to ensure broad input and agreement on project goals and strategies.

Creation of the Evaluation Plan: An evaluation plan has been developed to guide the assessment of the project's progress and effectiveness.

Future work

First KPI Assessment: The initial assessment of the KPIs is expected to be completed by the end of November.

Early Stakeholder Engagement: Moving forward, efforts will focus on organizing early stakeholder engagement activities, with the consensus panel playing a key role in this process. Opportunities such as the Athens eHealth Digital Week can be an option.

WP4: Sustainability and cross-border interoperability

Tasks ongoing / completed

D4.1: Current Status of EHR Adoption and Implementation in the EU: A report is available on the current state of EHR adoption in EU countries, focusing on the potential for a standardized cross-border EHR system within the scope of the European Health Data Space (EHDS).

Maturity model: Can have as a starting point the maturity model from XpanDH and use it to create the appropriate sustainability model. It is important to have the stakeholders involved in this.

Future work

Assessment of Interoperability Readiness and Development of EHDS Compliant Requirements: To evaluate current EHR inter-operability frameworks and develop EHDS regulation-compliant requirements for technical, semantic, organizational, legal, and policy interoperability levels, based on X-eHealth deliverables

EHDS Conformity Assessment Scheme Governance: Will describe the process for assessing EHR specifications, reusing artifacts from the XpanDH project, and other standards. It will develop guides for organizations to assess their readiness against the EHDS requirements

WP5: Sustainability and cross-border interoperability

Tasks ongoing / completed

D5.1: Metadata Standards for EEHRxF: Is focused on defining **metadata** types for classifying and identifying patient documents, following the patient journey or case management. Has developed metadata requirements to ensure that structured and unstructured health data is interoperable across systems and interoperability architectures.

Future work

General, Security, and Logging Requirements for EHR Systems: To define the essential requirements for the secure and efficient implementation of standardized EHR systems within the EU, focusing on security, **logging**, interoperability, and usability. Will include technical integration profiles, security protocols, and guidelines for data quality, confidentiality, and patient safety, ensuring EHDS Reg.

EHR Data Input and Output Requirements for Algorithm-Based Clinical Decision Support: To address the challenges related to data structures and communication interfaces between EHR systems and algorithm-based tools for primary use.

Identification and Authentication Requirements Across Europe: Will focus on the identification and authentication processes for both natural persons and healthcare professionals in traditional and online forms. Addressing challenges of identifying foreign patients, registering their health data under unique identifiers, and standardizing international search masks.

WP6: Electronic prescriptions and patient summary towards EHDS

Tasks ongoing / completed

T6.1: Patient Summary Specifications: Has defined the functional and technical requirements for interoperable electronic health data exchange, focusing on datasets, coding systems, and data quality to support the EHDS Regulation, including MyHealth@EU and the International Patient Summary.

T6.2: Electronic Prescriptions and Dispensations: Has developed machine-readable specifications for interoperable electronic health data exchange, focusing on electronic prescriptions and dispensations.

Future work

Implementation Guides: The next step involves developing comprehensive implementation guides that provide clear instructions on how to apply the EHDS regulations, ensuring seamless integration and interoperability of EHR systems across EU Member States.

Collaboration with stakeholders: Engaging EU member states and international organizations to ensure harmonization of standards, terminologies, and alignment with regulations for seamless cross-border health data exchange.

WP7: New services for EHR systems towards EHDS

Tasks ongoing / completed

Medical Test Results, including laboratory and other diagnostic related reports: Has defined machine-readable specifications and datasets for interoperable exchange of laboratory and diagnostic results across healthcare systems in compliance with EHDS regulation.

Medical Imaging Studies and related imaging Reports: Has established technical specifications for the cross-border exchange of medical imaging data (e.g., X-rays, MRIs) using international standards such as DICOM, IHE, and FHIR, ensuring interoperability in line with the EEHRxF.

Discharge Reports: Has created specifications for the interoperable exchange of discharge reports, ensuring data quality and compliance with EHDS regulations, using standards like HL7 CDA and FHIR.

Future work

Development of Implementation Guides (IGs): Creating clear and standardized IGs to facilitate the adoption of interoperable electronic health records (EHR) systems, ensuring cross-border data exchange, and meeting the requirements of the EHDS regulation.

Collaboration with stakeholders: Engaging EU member states and international organizations to ensure harmonization of standards, terminologies, and alignment with regulations for seamless cross-border health data exchange.

WP8: Certification and labelling framework

Tasks ongoing / completed

Classification and Functional Profiles of EHR Systems: Has reviewed existing functional models for EHR systems and examining to propose new profiles for certifying EHR systems and wellness applications. These profiles will align with the European Electronic Health Record Exchange Format (EEHRxF) and the specifications from WP4, WP5, WP6, and WP7 to ensure interoperability and compliance.

Maturity model: The functional profiles will take into account the maturity model that will be defined across Xt-EHR WPs.

Future work

Assertions for Conformity Assessment: Will develop testable assertions and verification methods, such as checklists, to support the certification of EHR systems based on harmonised components. This will ensure EHR systems conform to the EEHRxF and MyHealth@EU guidelines, particularly focusing on Article 23 requirements.

EHDS Guidelines for app developers of wellness applications in Europe: Will evaluate ongoing initiatives like Label2Enable and ISO/TS 82304-2 to propose a voluntary labelling scheme for wellness apps under the EHDS. It will create guidelines to help wellness app developers comply with interoperability and security requirements, as well as ethical and regulatory standards, while ensuring their alignment with EHDS

WP9 Telemedicine under MyHealth@EU in alignment with EHDS proposal

Tasks ongoing / completed

- **D9.1** - *Requirements and use cases on the availability of health data in cross-border telemedicine services under MyHealth@EU,* **was submitted on October 31st.**
- **D9.1 defined two** priority use cases and business requirements for **Cross-border telemedicine services:**
    - A teleconsultation between a patient in their country of affiliation (Country A) and a healthcare provider in a different country (Country B).
    - A teleconsultation between two Healthcare providers; one in Country A and the other in Country B, discussing the case of the patient from Country A.
- **Deliverable 9.2** - *Technical specifications on the availability of health data in cross-border telemedicine services under MyHealth@EU,* **will delve** into the **technical and legal aspects** of the **proposed solutions** and **mechanisms outlined** in **D9.1**.

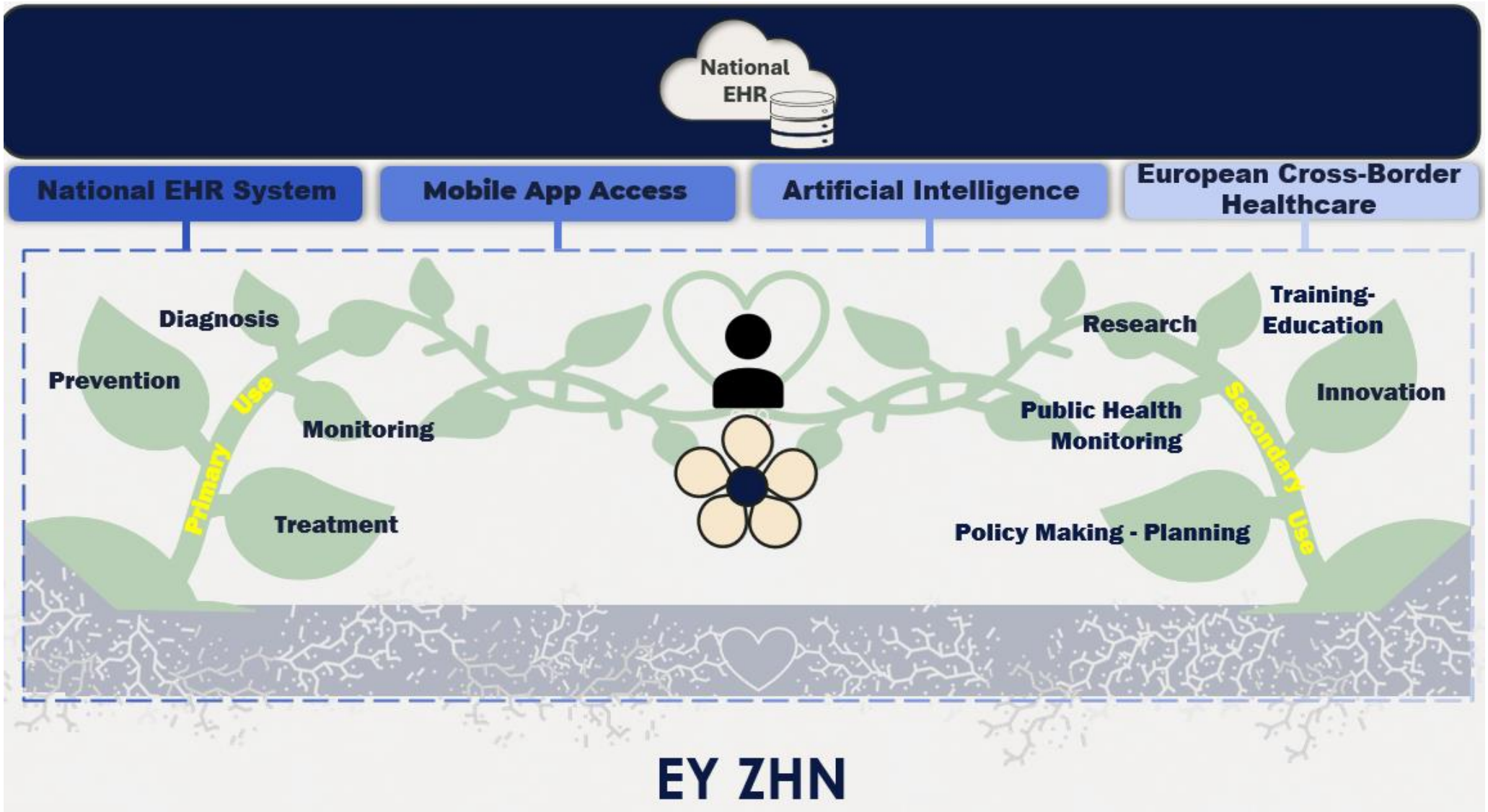
WP9 Telemedicine under MyHealth@EU in alignment with EHDS proposal

Ongoing / Future work

Kick-start D9.2: Development of a working plan, considering EC feedback for D9.2, and kick-start WP9 specific meetings to work on the deliverable.

Groundwork for the implementation of cross-border telemedicine services: Circulate questionnaire to gather information on existing pilots and Member States' experiences with telemedicine services.

Technical specifications in cross-border telemedicine services: Define mechanisms for patient authentication and identification, sharing information generated during teleconsultation, and patient validation for data sharing.


National EHR
National EHR System
Mobile App Access
Artificial Intelligence
European Cross-Border Healthcare
Diagnosis
Prevention
Monitoring
Treatment
Primary Use
Research
Training-Education
Innovation
Public Health Monitoring
Secondary Use
Policy Making - Planning
EY ZHN

Expand the outreach of EU EHDS

- Use the EEHRxF as the building block of a Global EHR Initiative
- International collaborations and prospects
  - Panamerican Highways for Health Initiative
  - WHO GDHCN
  - IPS and GDHP

EHR @dataspace @ ADHW

- Organise Stakeholder Engagement Workshops
- Organise Conformity Assessment Workshop
- Cooperate with other projects
- Promote MS collaboration on primary and secondary use of data
- Support Interoperability Labs for EEHRxF
- Host project meetings

ATHENS DIGITAL HEALTH WEEK

HOSTED BY

HAIKA

NATIONAL eHEALTH AUTHORITY

HL7 Hellas

European Commission

T H A N K

Y O U

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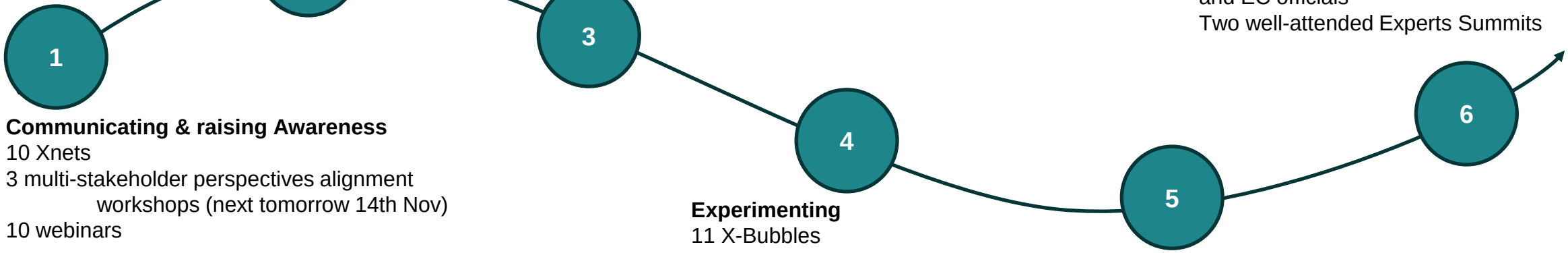
XpanDH Results: Our Journey Preparing the Digital Health Ecosystem for the Format



Communicating & raising Awareness
10 Xnets
3 multi-stakeholder perspectives alignment workshops (next tomorrow 14th Nov)
10 webinars

Co-creating
1 Community of Doers
4 working groups

Innovating
8 workshops with several EU-funded projects
Collaboration with xShare RIA (button, videos & the HUB)
Format and block chain (PPR Blockchain PT)

Experimenting
11 X-Bubbles
5 online surveys
2 workshops with national agencies

Supporting Implementation
FHIR IGs (Labs and HDReport (*ongoing*)
X-Bundles & online Repository
2 Readiness Models

Supporting formalisation
Recommendations to Xt-EHR
Policy dialogue with eHN subgroups and EC officials
Two well-attended Experts Summits

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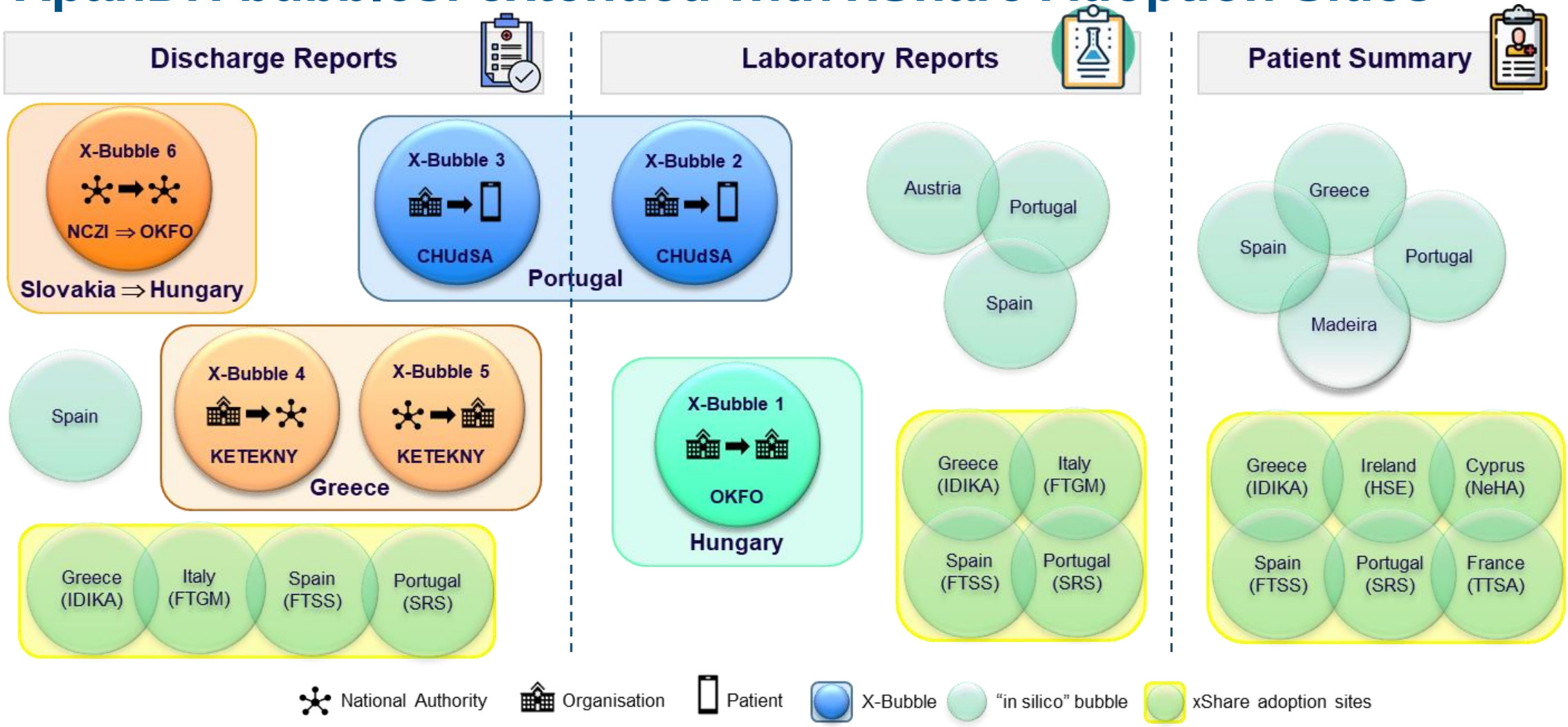
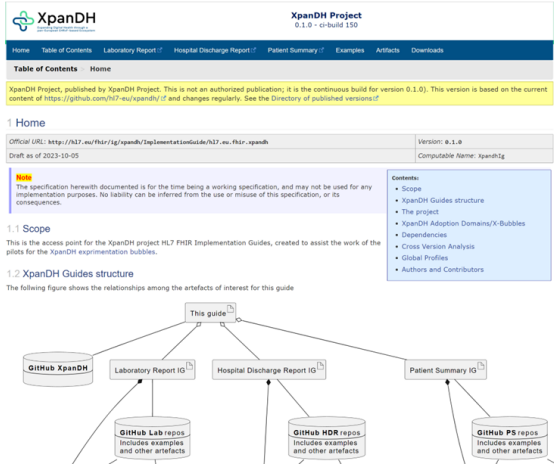
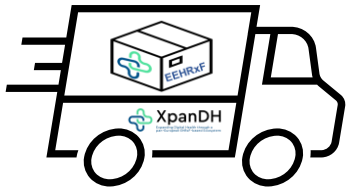
XpanDH bubbles: extended with xShare Adoption Sides



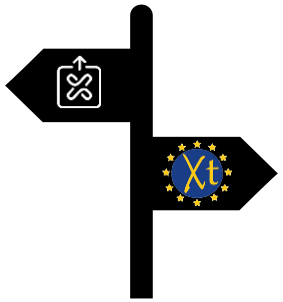
The X-Bundle consists of a **group of well-defined interoperability assets** aligned with the Refined eHealth European Interoperability Framework (ReEIF) across six dimensions: legal, organisational, semantic, technical, cybersecurity, and digital capabilities. It **enables** the implementation of simple or composite adoption domains **across multiple EEHRxF-compatible health data connections**. A centralised entry point provides access to a cohesive ecosystem of **technical specifications**, including **HL7 FHIR Implementation Guides** and **GitHub repositories** for priority domains such as Laboratory and Hospital Discharge Reports.



See also: D2.2



We are organising the existing X-Bundles within the EEHRxF project community based on their **intended use, production status,** and **adoption level**, focusing on mature assets ready for deployment. This effort assists **Member States** in **integrating** X-Bundle formats into national projects and supports **industry** in **embedding interoperability into their innovations**. To ensure the reuse and sustainability of XpanDH-produced X-Bundles, we are collaborating with **xShare** and **Xt-EHR** on joint activities, including refining concepts, developing and publishing X-Bundles for selected business use cases, and defining quality labelling metadata for the assets and bundles.



Proof of Concept repository

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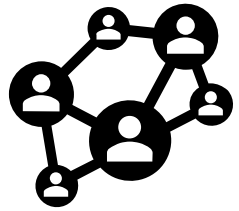
X-Nets – networks of networks



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

X-Net activation

Co-creation of X-Nets methodology for 10 X-Nets, defining their objectives, benefits, and engagement levels, and crafting an engagement plan. (with ISCTE)

Co-creation of X-Net engagement guide outlining engagement methodology, member characteristics, benefits, activities, engagement methods, and expected challenges.

See also: D5.1 (draft)

X-Net	N° meetings	Activated entities
Patient Associations	3	30+
Industry	9	25+
Hospitals-on-FHIR	3	70 hospitals
Clinical Research	1	70+
Health Professionals	2	30+
Citizens and Society	2	10+
Health Managers	3	20+
Innovation Hubs	2	10+
ERNs	1	30+
National and Regional Health Authorities	5	30+

3C-3P (community of doers)

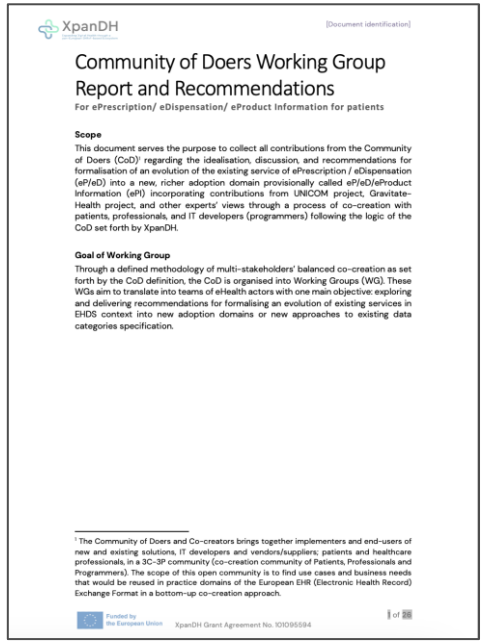
Co-Creation Community of Patients, Professionals and Programmers

To bring together implementers and end-users of new and existing solutions IT developers and vendors/suppliers; patients and healthcare professionals.

5+ meetings 42 participants	7 meetings 10 participants	Biweekly meetings 10 countries	4 workshops 28 participants
Multidisciplinary Tumour Boards for Cancer Patients	eP/eD and electronic Product Information	Patient mediated view of medical imaging reports (with IHE MCWG)	Telehealth — Teleconsultation encounter reports

Use case → EEHRxF → The How? → Blueprint validation → Proof of concept → Testing and validation → Review scope

Report & Recommendations template



XpanDH

[Document identification]

Community of Doers Working Group
Report and Recommendations

For ePrescription/ eDispensation/ eProduct Information for patients

Scope

This document serves the purpose to collect all contributions from the Community of Doers (CoD)[1] regarding the idealisation, discussion, and recommendations for formalisation of an evolution of the existing service of ePrescription / eDispensation (eP/eD) into a new, richer adoption domain provisionally called eP/eD/eProduct Information (ePI) incorporating contributions from UNICOM project, Gravitate-Health project, and other experts' views through a process of co-creation with patients, professionals, and IT developers (programmers) following the logic of the CoD set forth by XpanDH.

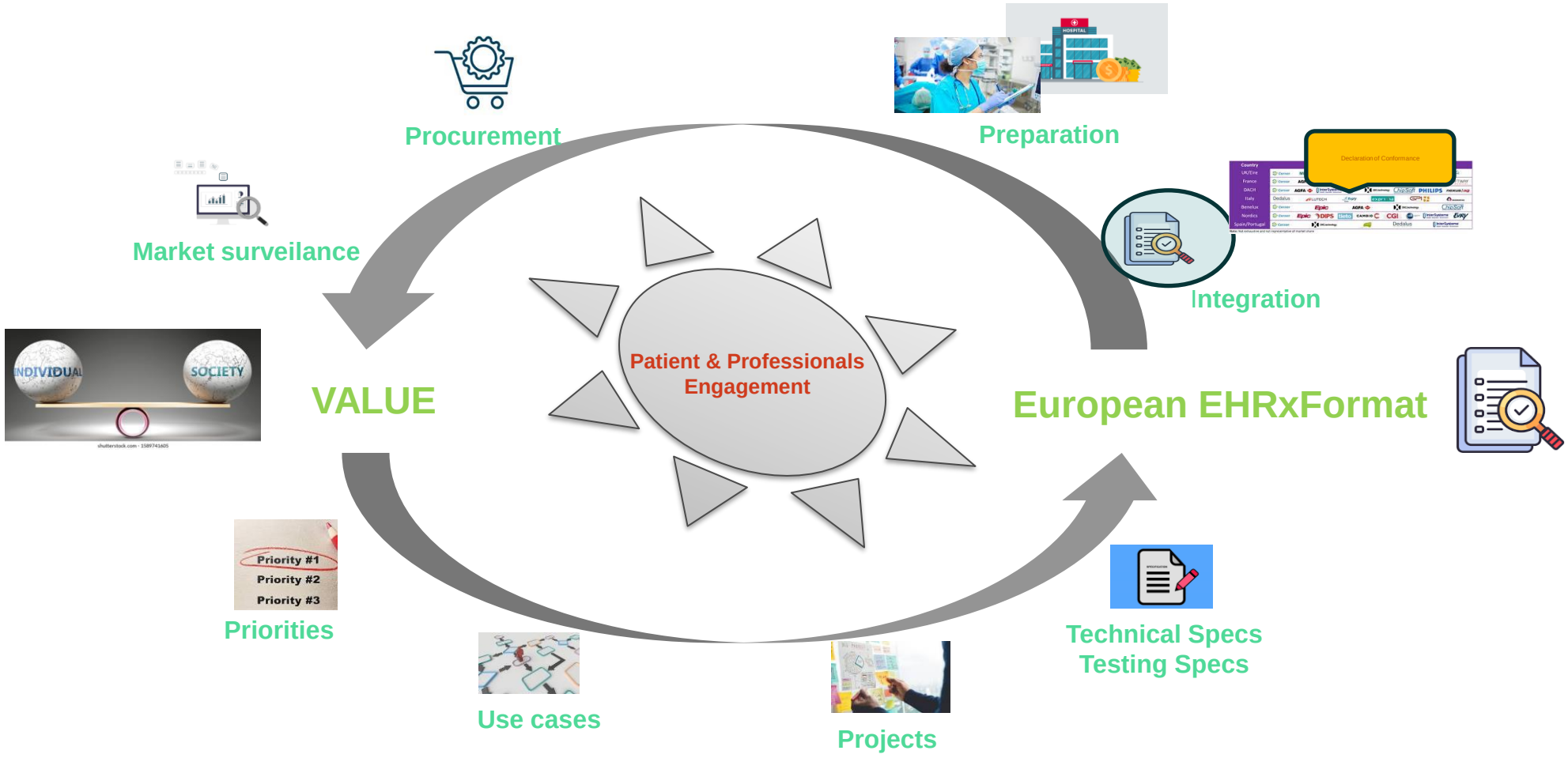
Goal of Working Group

Through a defined methodology of multi-stakeholders' balanced co-creation as set forth by the CoD definition, the CoD is organised into Working Groups (WG). These WGs aim to translate into teams of eHealth actors with one main objective: exploring and delivering recommendations for formalising an evolution of existing services in EHDS context into new adoption domains or new approaches to existing data categories specification.

[1] The Community of Doers and Co-creators brings together implementers and end-users of new and existing solutions, IT developers and vendors/suppliers; patients and healthcare professionals, in a 3C-3P community (co-creation community of Patients, Professionals and Programmers). The scope of this open community is to find use cases and business needs that would be reused in practice domains of the European EHR (Electronic Health Record) Exchange Format in a bottom-up co-creation approach.

Funded by the European Union — XpanDH Grant Agreement No. 101095594 — 1 of

See also: D5.3 (draft)



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Main Challenges

N°	Challenge
1	Regulatory Clarity and Consistency
2	Regulation as an enabler (innovation/data protection, privacy & security by design)
3	Data availability and dealing with unstructured data
4	Collaboration and engagement with stakeholders for Format dvpt (e.g. specification creation)
5	high complexity/lack of clarity (->Format Awareness/Education)
6	Inter-data priority category high complexity/lack of clarity (->integration, harmonisation)
7	Interoperable specifications btw EHDS and eGov (EU Wallet, eIDAS and national eGov)
8	Diverse Coding systems
9	Evolving needs (unmet needs)
10	Dynamic format (->preparedness, anticipation, modularity?)
11	Different maturities of the format for EU, cross-border and national-level usage (->delineation of 'responsibilities')
12	Patient Summary generation (updating, merging and multi-source conflicts)
13	Alignment of initiatives that use PSs with health cards
14	Interoperability (+ data quality) at the source Professionals'/orgs' capacity to produce and consume Format-based information adding value to health services (-> profs education)

N°	Challenge
15	Patient and stakeholders' ability to contribute to Format, to request Format-based service; (pro-actively)
16	Putting Format-based health data to valuable (primary/secondary) use
17	Value Measurement
18	EEHRxF branding and general communication
19	Easy, wide access to Format info; Availability of EEHRxF, adoption packages (different repositories: xShare/XpanDH, Xt-EHR, support center) (recommend the Hub); sub-section of lay language info about Format
20	Readiness and preparedness (Healthcare organisations', vendors' and national agencies, …); + implementation support and testing initiatives; AMO model; varying pace of national EHRs
21	Unfinished efforts (first step) of needed incremental efforts – RM, ecosystem activation,… (-> continuity of efforts)
22	Benefits realization through Format-based value-adding services Additional value-added services to bring the benefits such as standardised clinical dash boards, standardised interfaces; pre-populating apps with PS data for selfcare…
23	Adopt advanced innovative technologies into the Format

Main Challenges

N°	Challenge
1	Regulatory Clarity and Consistency
2	Regulation as an enabler (innovation/data protection, privacy & security by design)
3	Data availability and dealing with unstructured data
4	Collaboration and engagement with stakeholders for Format dvpt (e.g. specification creation)
5	high complexity/lack of clarity (->Format Awareness/Education)
6	Inter-data priority category high complexity/lack of clarity (->integration, harmonisation)
7	Interoperable specifications btw EHDS and eGov (EU Wallet, eIDAS and national eGov)
8	Diverse Coding systems
9	Evolving needs (unmet needs)
10	Dynamic format (->preparedness, anticipation, modularity?)
11	Different maturities of the format for EU, cross-border and national-level usage (->delineation of 'responsibilities')
12	Patient Summary generation (updating, merging and multi-source conflicts)
13	Alignment of initiatives that use PSs with health cards
14	Interoperability (+ data quality) at the source Professionals'/orgs' capacity to produce and consume Format-based information adding value to health services (-> profs education)

N°	Challenge
15	Patient and stakeholders' ability to contribute to Format, to request Format-based service; (pro-actively)
16	Putting Format-based health data to valuable (primary/secondary) use
17	Value Measurement
18	EEHRxF branding and general communication
19	Easy, wide access to Format info; Availability of EEHRxF, adoption packages (different repositories: xShare/XpanDH, Xt-EHR, support center) (recommend the Hub); sub-section of lay language info about Format
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23	Adopt advanced innovative technologies into the Format

Main Challenges

N°	Challenge	Phase
1	Regulation as an enabler (innovation/data protection, privacy & security by design)	G
2	Collaboration and engagement with stakeholders for Format dvpt (e.g. specification creation)	G
3	Inter-data priority category high complexity/lack of clarity (->integration, harmonisation); Interoperable specifications btw EHDS and eGov (EU Wallet, eIDAS and national eGov); Alignment of initiatives that use PSs with health cards	G
4	Diverse Coding systems	A
5	Evolving needs (unmet needs)	G
6	Dynamic format (->preparedness, anticipation, modularity?)	A
7	Different maturities of the format for EU, cross-border and national-level usage (->delineation of 'responsibilities')	A
8	Patient Summary generation (updating, merging and multi-source conflicts)	A
9	Interoperability at the source (+ data quality and quantity), dealing with unstructured data Professionals'/orgs' capacity to produce and consume Format-based information adding value to health services (-> profs education)	A

Legend: G-Generation; A-Adoption; H-Horizontal

N°	Challenge	Phase
10	Patient and stakeholders' ability to contribute to Format, to request Format-based service; (pro-actively)	A
11	Putting Format-based health data to valuable (primary/secondary) use	A
12	Value Measurement	H
13	EEHRxF branding and general communication, complexity, availability	H
14	Easy, wide access to Format info; Availability of EEHRxF, adoption packages (different repositories: xShare/XpanDH, Xt-EHR, support center) (recommend the Hub); sub-section of lay language info about Format	A
15	Readiness and preparedness (Healthcare organisations', vendors' and national agencies, …); + implementation support and testing initiatives; AMO model; varying pace of national EHRs	A
16	Unfinished efforts (first step) of needed incremental efforts – RM, ecosystem activation,… (-> continuity of efforts)	A
17	Benefits realization through Format-based value-adding services Additional value-added services to bring the benefits such as standardised clinical dash boards, standardised interfaces; pre-populating apps with PS data for selfcare…	G
18	Adopt advanced innovative technologies into the Format	G

SYNERGIES

Between primary and secondary use of health data

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Relevance

My work relevant to the topic

- Primary use of health data
  - eHDSI / myhealth@eu (2014-2016)
  - Study: Powering the social health and social care system with data (2023)
  - Study: Efficiency from data models to the social and healthcare system (2024)
- Secondary use of health data
  - National preparations for Findata, 2017 - 2019
  - Secondary use of health data in EU and Nordics (2020->)
    - TEHDAS (2021 - 2023), TEHDAS2 (2024– 2026)
    - Value from Nordic Health Data (VALO 2024-2026)
- EU data strategy
  - Study: 35 proposals to make data strategy work (2020)

Primary

”the purpose for which the data was originally stored”

- Data access is near real-time
- Interoperability is a must
- Data from one patient
- Large amount of data from one individual
- Often “fresh” data
- Often data origin can be contacted. For example treating physician.

Secondary

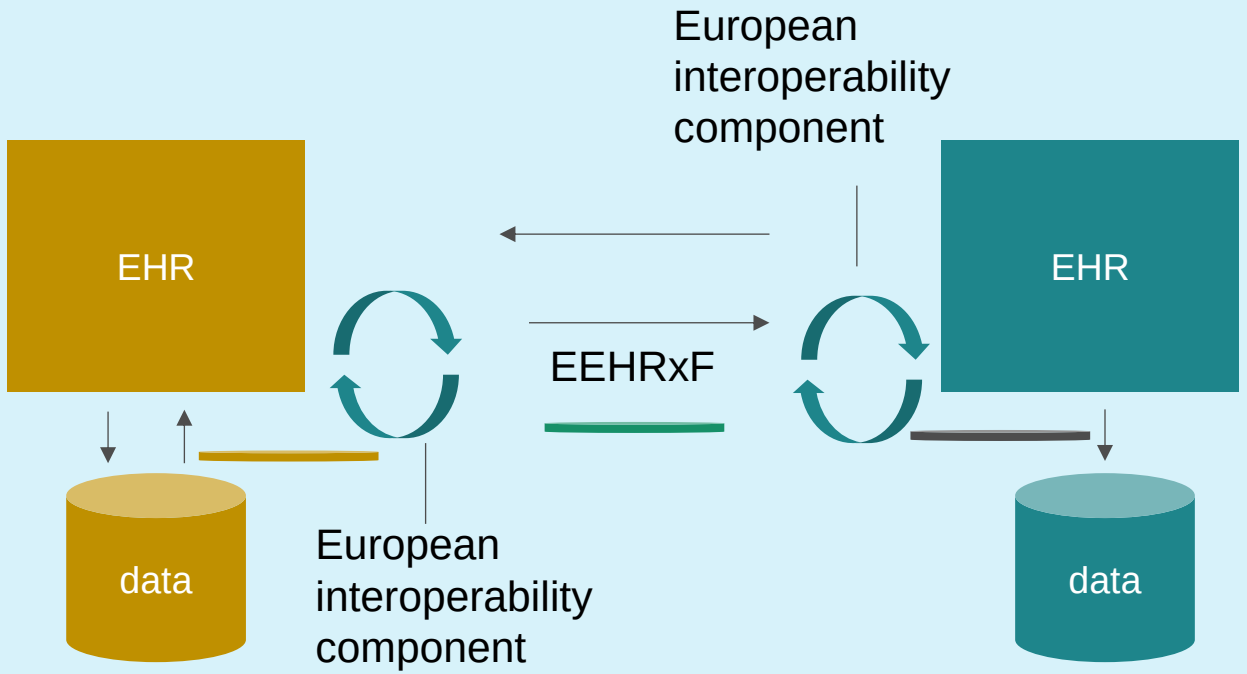
”the use of the same data for purposes other than the primary use”

- Data access can take a long time
- Interoperability not a necessity from the start. Can be built during the research.
- Data from multiple patients
- Limited amount of data from one individual (data minimisation principle)
- Data can be decades old
- Data origin hardly available

EEHRxF

Basic use case

- EEHRxF brings interoperability for specific data (minimum categories)
  - PS, EP, Lab results, Imaging, Discharge reports



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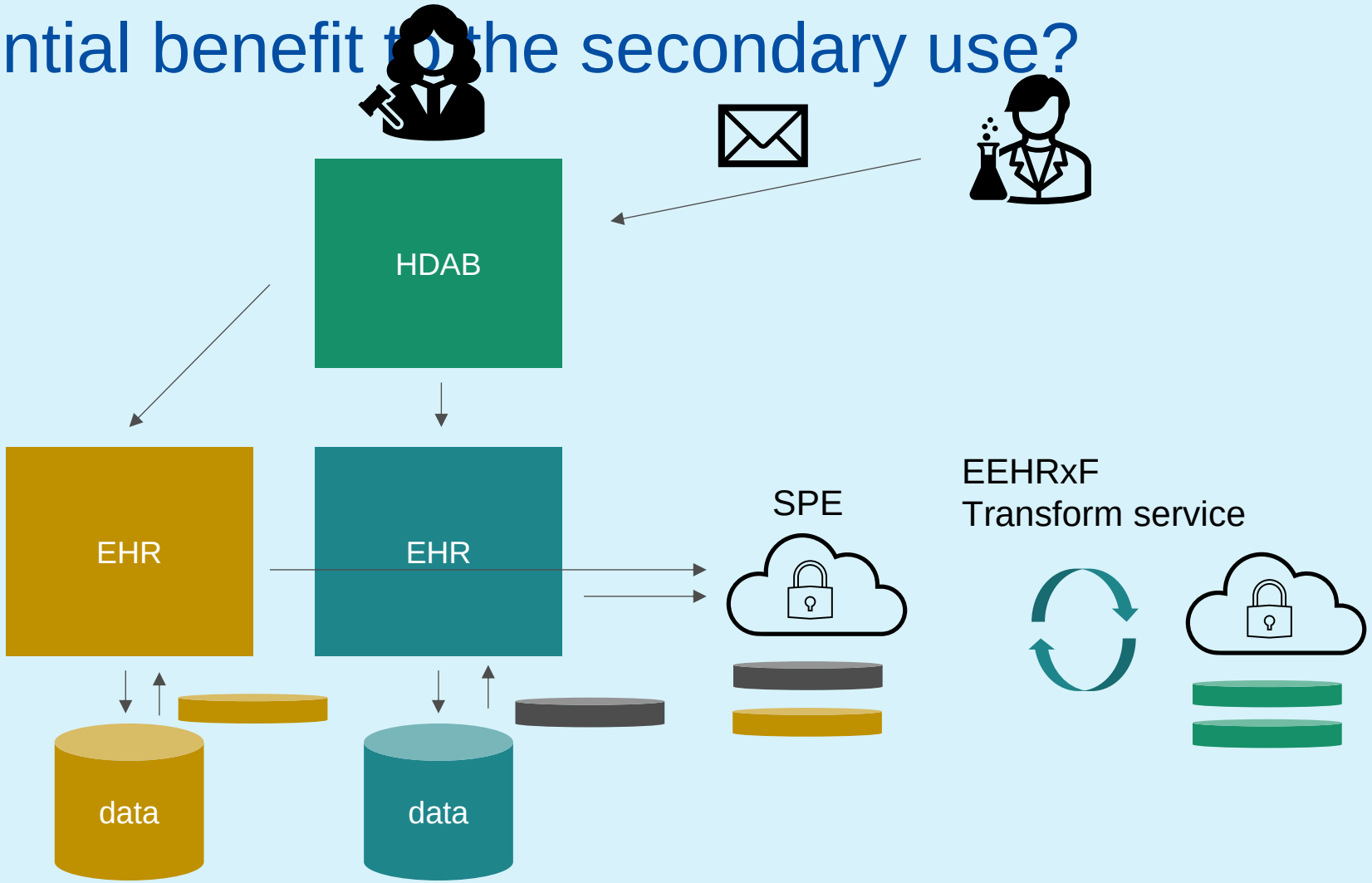
Potential benefit to the secondary use?

EHDS / EEHRxF does not accumulate interoperable data in persistence

EEHRxF

Potential benefit to the secondary use?



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Considerations and limitations

- This only works with the minimum category data -> not for example genetic data, survey data etc.
- Limiting the secondary use for only minimum category data is not in line with EHDS and not beneficial
- Could the minimum category data be requested from the data holder in EEHRxF in the data permit application -> maybe, but it is not in as EHDS requirement in Chapter 4.
- Can all data, even though it is minimum category data, be easily converted to EEHRxF data -> probably not. The raw data from EHR might need vendor specific converting.

Benefits

- Harmonising data in the beginning of a research is usually a huge burden
- If we can facilitate research with EEHRxF, we should try
- Especially when training AI, we need harmonised data. Product development life cycles as much faster than traditional research. We need ways to accelerate the harmonisation process

- There are potentially many other benefits beyond the described use case. Building interoperability and investing into standardisation and data quality always benefits the research in the long run!