EHDS regulation: legal aspects

IHE Europe Webinar Series
21 February 2025

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EHDS regulation: legal aspects

Vanja Pajic

Eva Sabajova

IHE Europe Webinar Series - 21 February 2025

EHDS Regulation – Legal and Technical Aspects of the Framework

Towards the European Health Data Space

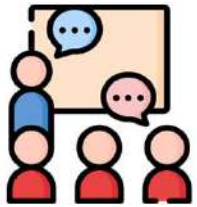
My health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

Vanja Pajić
Legal Working Group Chair,
eHMSEG/MyHealth@EU

Overview of the European Health Data Space (EHDS) Presentation

Overview of the European Health Data Space (EHDS) and its foreseen implementation in the EU Member States

- **Intro: EHDS as a Key Initiative for Digital Health Transformation in EU:**
  - Aims to enhance secure, cross-border sharing of health data across EU Member States.
  - Supports both healthcare delivery (Primary Use: MyHealth@EU) and research/policy innovation (Secondary Use: HealthData@EU).
- **Core Components & Infrastructures of the EHDS Legal Framework for Implementors:**
  - **Primary Use:** Seamless exchange of electronic health records for patient care continuity.
  - **Secondary Use:** Secure data sharing for research, public health, and AI-driven innovations.
- **Legal & Technical Frameworks:**
  - Built on existing EU legal instruments (GDPR, Data Governance Act, Data Act, AI Act, etc.).
  - Emphasizes interoperability standards and secure processing environments.
- **Governance & Stakeholder Engagement:**
  - Collaborative framework involving EU Institutions, Member States, legal working groups, and stakeholders.
  - Ongoing efforts to address legal uncertainties, interoperability challenges, and compliance requirements.
- **Roadmap & Future Challenges:**
  - Implementation milestones, national legal adjustments, and continuous support through legal and technical working groups.
  - Future considerations include adapting to emerging technologies and evolving global data exchange frameworks.



Introduction to EHDS

<u>European Health Data Space (EHDS):</u>

- Key EU initiative for **digital health transformation**.
- Aims to improve **health data sharing** across Member States while ensuring **privacy and security**.

<u>Provides requirements and rules for:</u>

- **Electronic Health Record (EHR) Systems**
  - Creating a single market for electronic health records systems.
- **other main pillars**:
  - **Primary Use (MyHealth@EU)**
  - **Secondary Use (HealthData@EU)**

<u>Primary use</u> = use of data for the delivery of healthcare

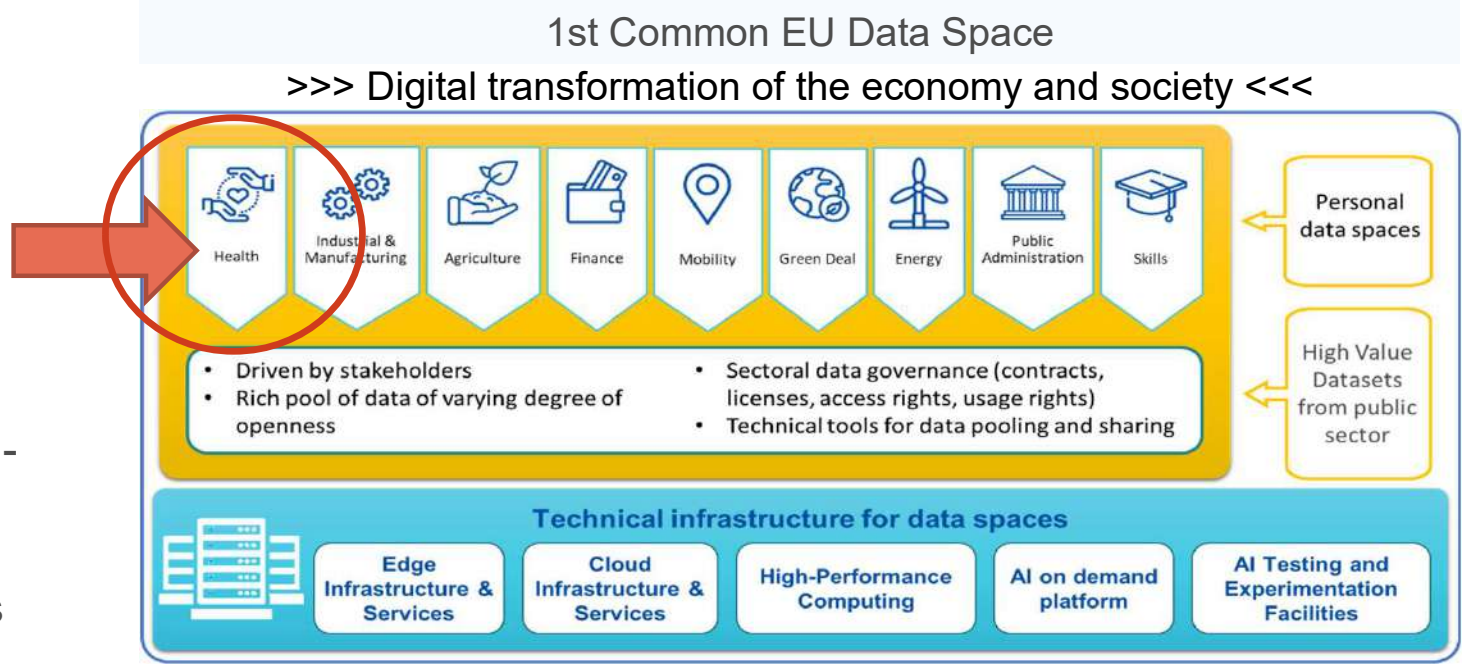
- Improving patients' access to their health data;
- Ensuring seamless exchanges for continuity of healthcare.

<u>Secondary use</u> = use of data for research and public interest purposes

Making data available for research, policy-making etc. in a safe and secure way.

Why is EHDS Important?

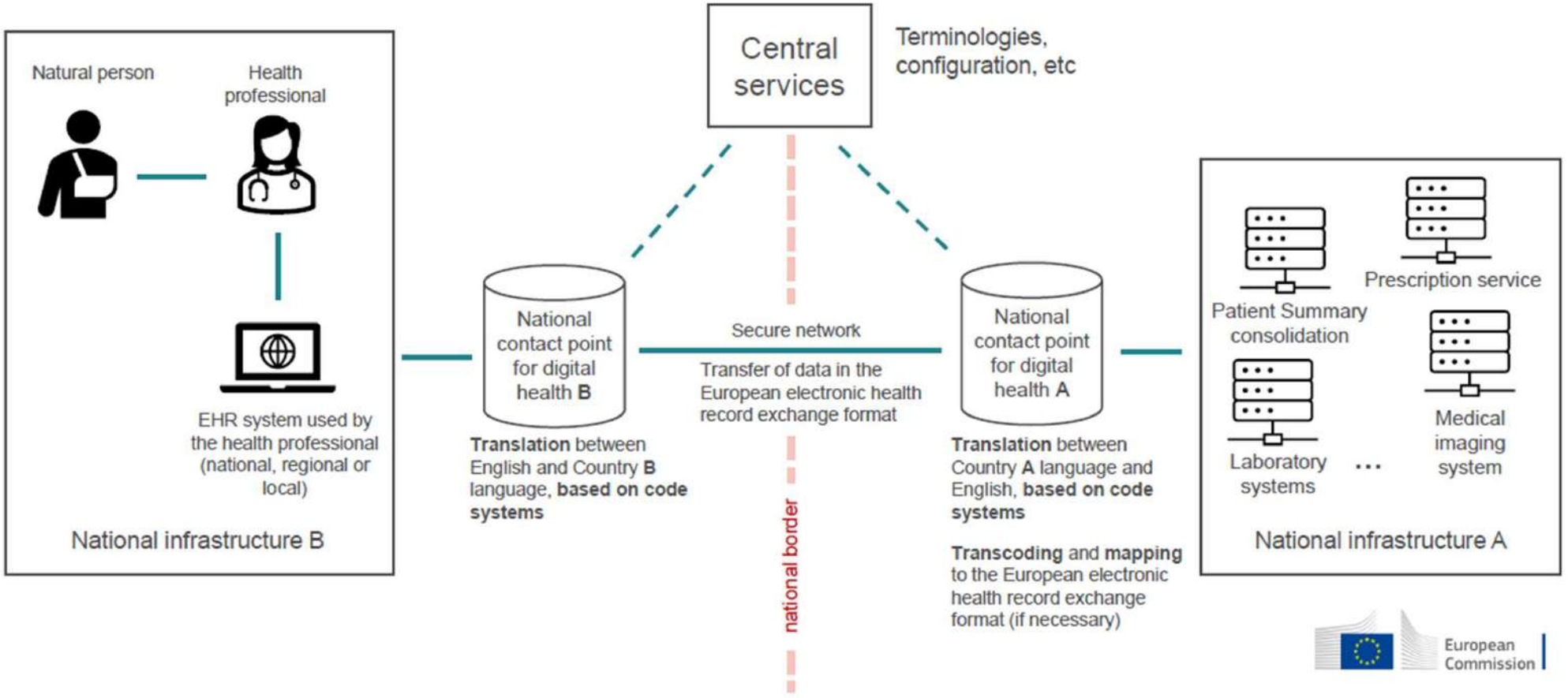
- **Empowers patients** with full control over their health data.
- **Improves continuity of care** in cross-border healthcare.
- **Facilitates secure data sharing** for research and AI-driven health innovations.
- **Supports digital transformation** of Europe's healthcare sector.



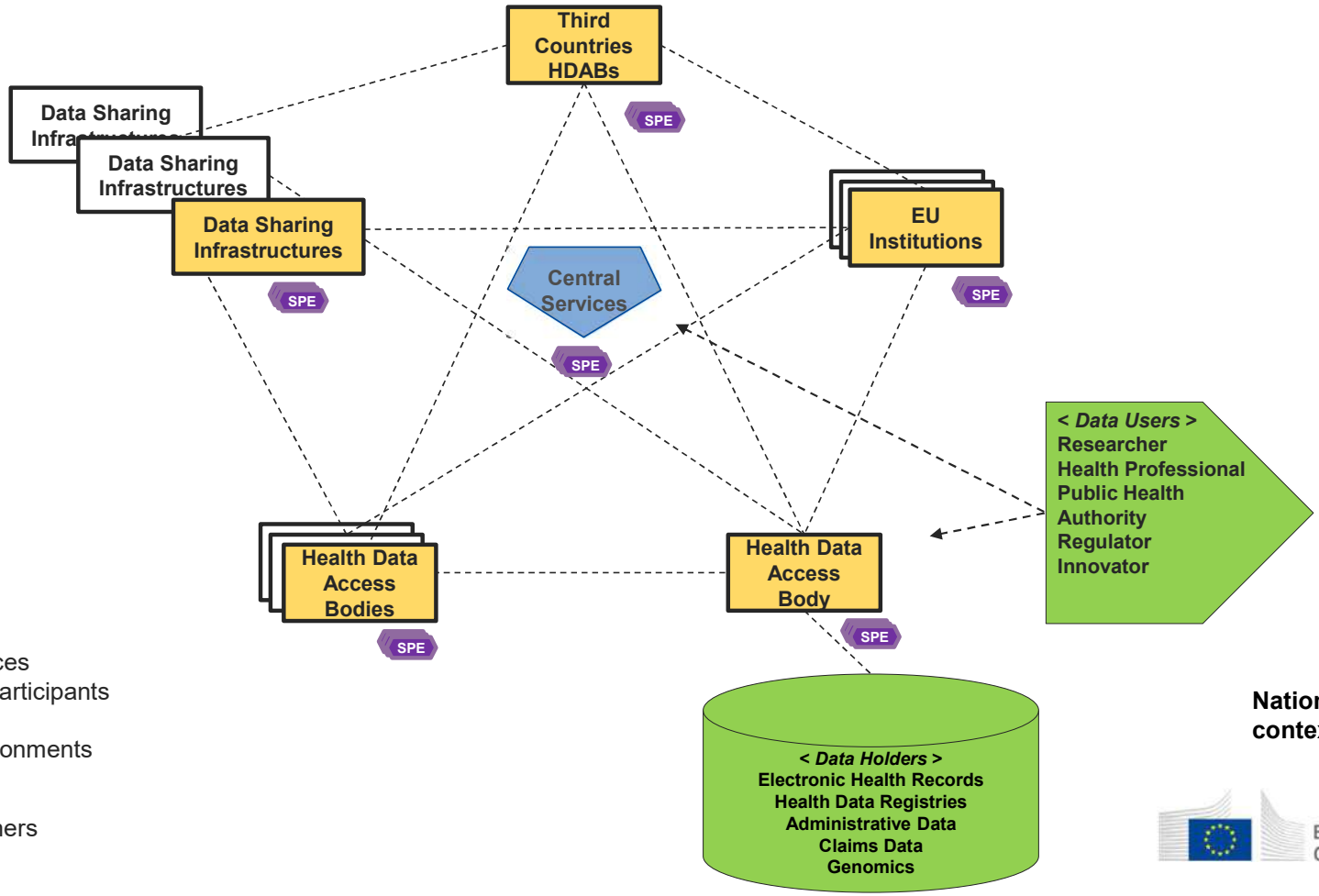
Data spaces are ecosystems that data providers, intermediaries, and users can access to share data.
>>> Secure exchange of data between EU Member States <<<

European Commission

MyHealth@EU - Data Infrastructure for Primary use



HealthData@EU - Cross-border secondary use infrastructure



Central support services provided by EC

Data management services provided by authorised participants

SPE Secure Processing Environments

Local services provided by/to local partners

European Commission

Interoperability for Primary Data and Data Categories under EHDS

PRIMARY DATA

- EHDS provides the **European Electronic Health Record Exchange Format (EEHRxF)**.
- **Standardized health data formats and specifications** will be provided in future Implementing Acts

Facilitate seamless exchange of various types of data

SECONDARY DATA CATEGORIES IN EHDS

Electronic health data from **EHRs**; healthcare-related **administrative data**, including dispensation, claims and **reimbursement** data	Human **genetic, epigenomic and genomic** data; other **human molecular** data such as proteomic transcriptomic, metabolomic, lipidomic and other genomic data;
Automatically generated personal electronic health data, through **medical devices**; data from **wellness applications**; other health data from medical devices.	Data on factors impacting health, including **socio-economic, environmental and behavioural determinants** of health; Aggregated data on **healthcare needs**, **resources** allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing; **Pathogen data**, impacting on human health
Population-based health data **registries** (public health registries); data from medical registries and **mortality registries**; data from registries for medicinal products and medical devices; health data from **biobanks** and associated databases.	Data from **clinical trials**, **clinical studies** and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively; data from **research cohorts, questionnaires** and surveys related to health, after the first publication of results

Legal Frameworks for EHDS

- EHDS is built on **existing EU legal instruments**:
  - **GDPR**
  - **Data Governance Act**
  - **Data Act**
  - **eIDAS**
  - **Artificial Intelligence Act (AI Act)**
  - **Directive 2011/24/EU** on the application of patients' rights in cross-border healthcare
  - **Medical Devices Regulation (MDR)**

EU Legal Frameworks

EHDS

Adjustments in Member States' legal frameworks are foreseen

Governance – MS and EU level

- MS to set up Digital Health Authorities (primary use) and Health Data Access Bodies (secondary use)
- Coordination on EU level in EHDS Board for exchanging best practices, coming up with guidelines.
- Steering groups for operational decisions regarding the infrastructures MyHealth@EU and HealthData@EU
- Stakeholders engagement at EU level in the Stakeholder Forum for information exchange and cooperation regarding EHDS implementation
- EHR certification enforcement

Member States

Stakeholder groups

Market Surveillance Authority

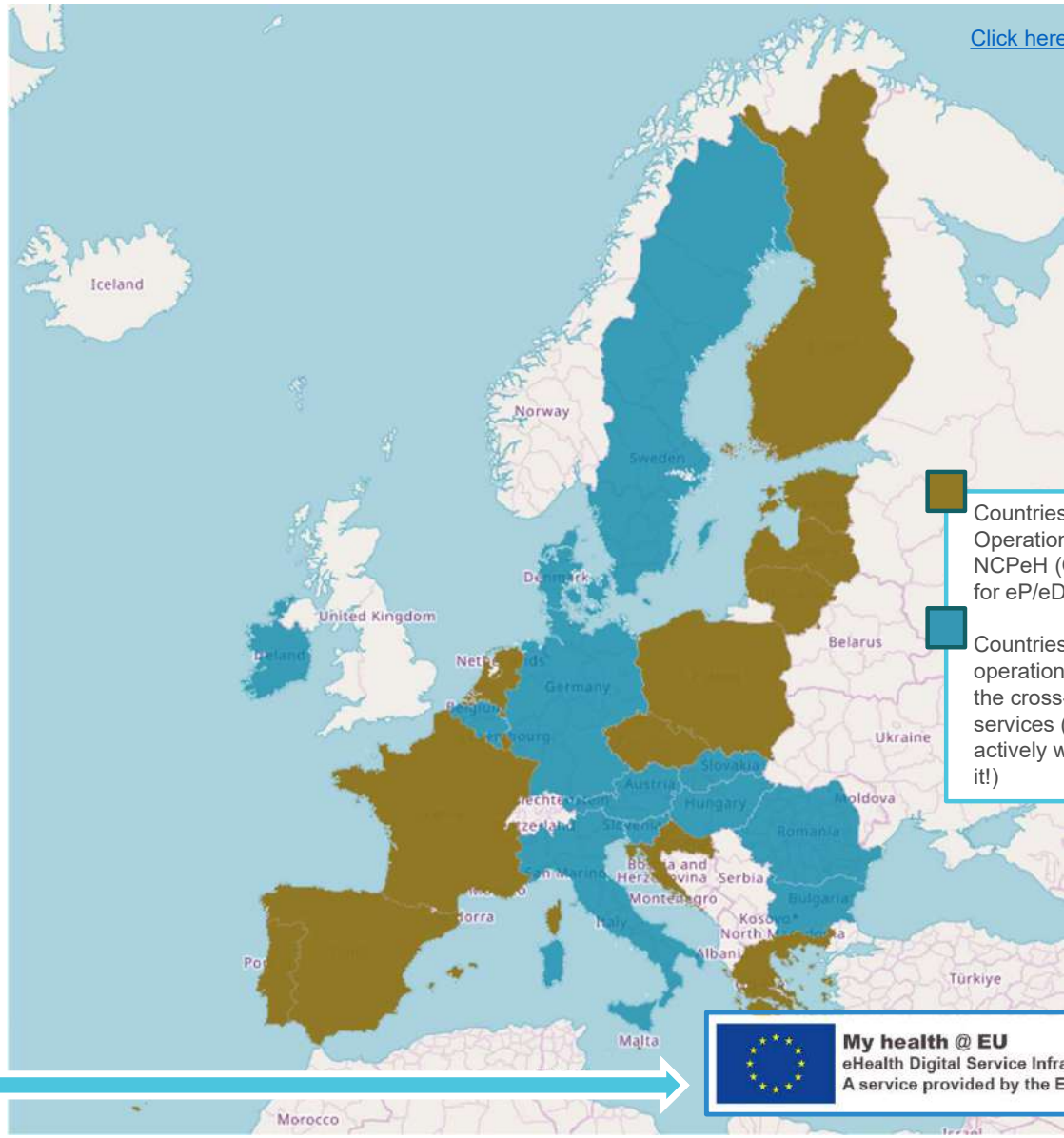
Cross-border services

Electronic cross-border health services are currently being introduced in all EU countries:

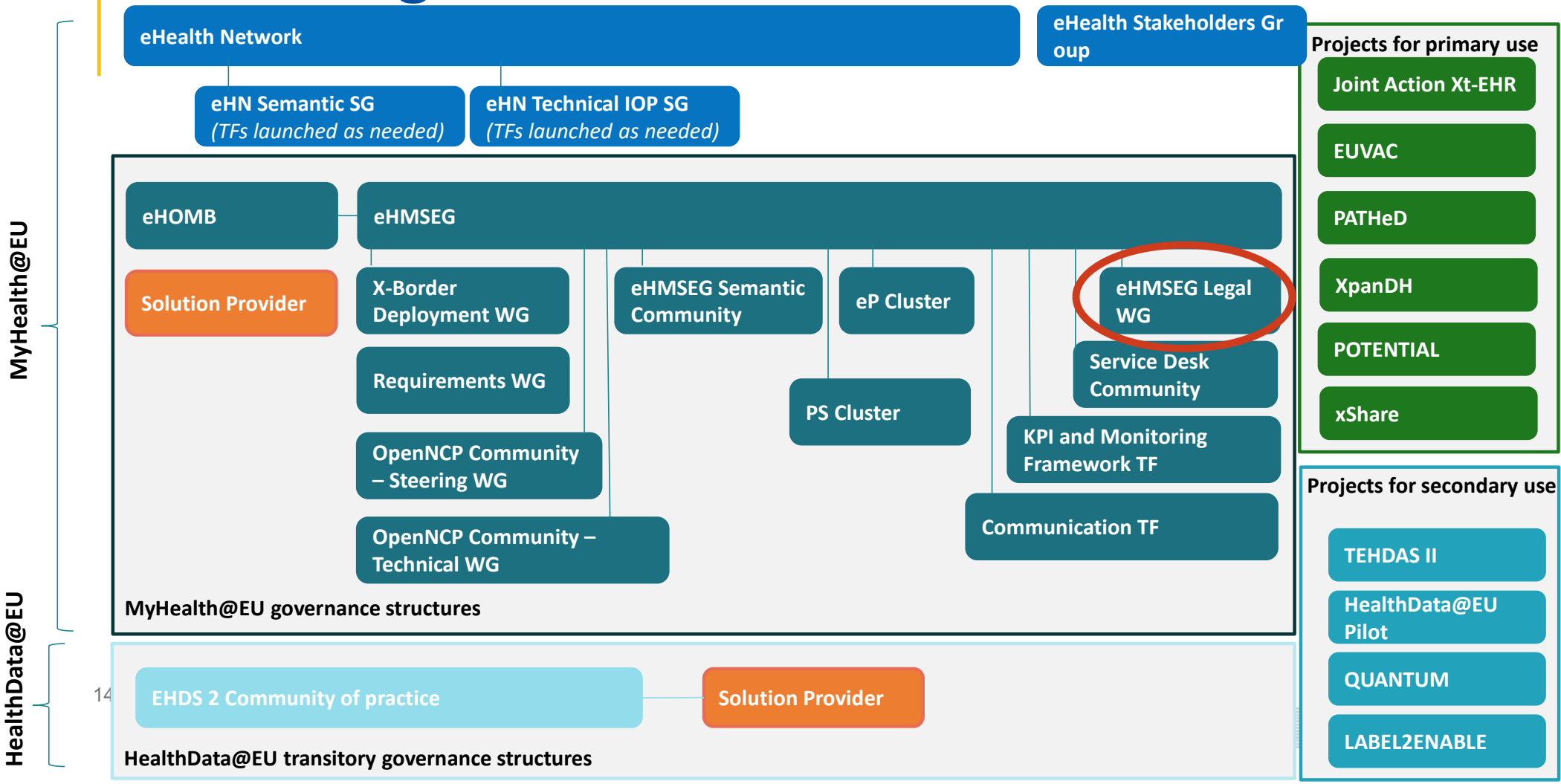
ePrescription / eDispensation allows EU citizens to obtain their medication in a pharmacy located in another EU country, thanks to the online transfer of their electronic prescription from their country of residence where they are affiliated, to their country of travel.

Patient Summaries provide information on important health related aspects such as allergies, current medication, previous illness, surgeries, etc. It is part of a larger collection of health data called an Electronic Health Record.

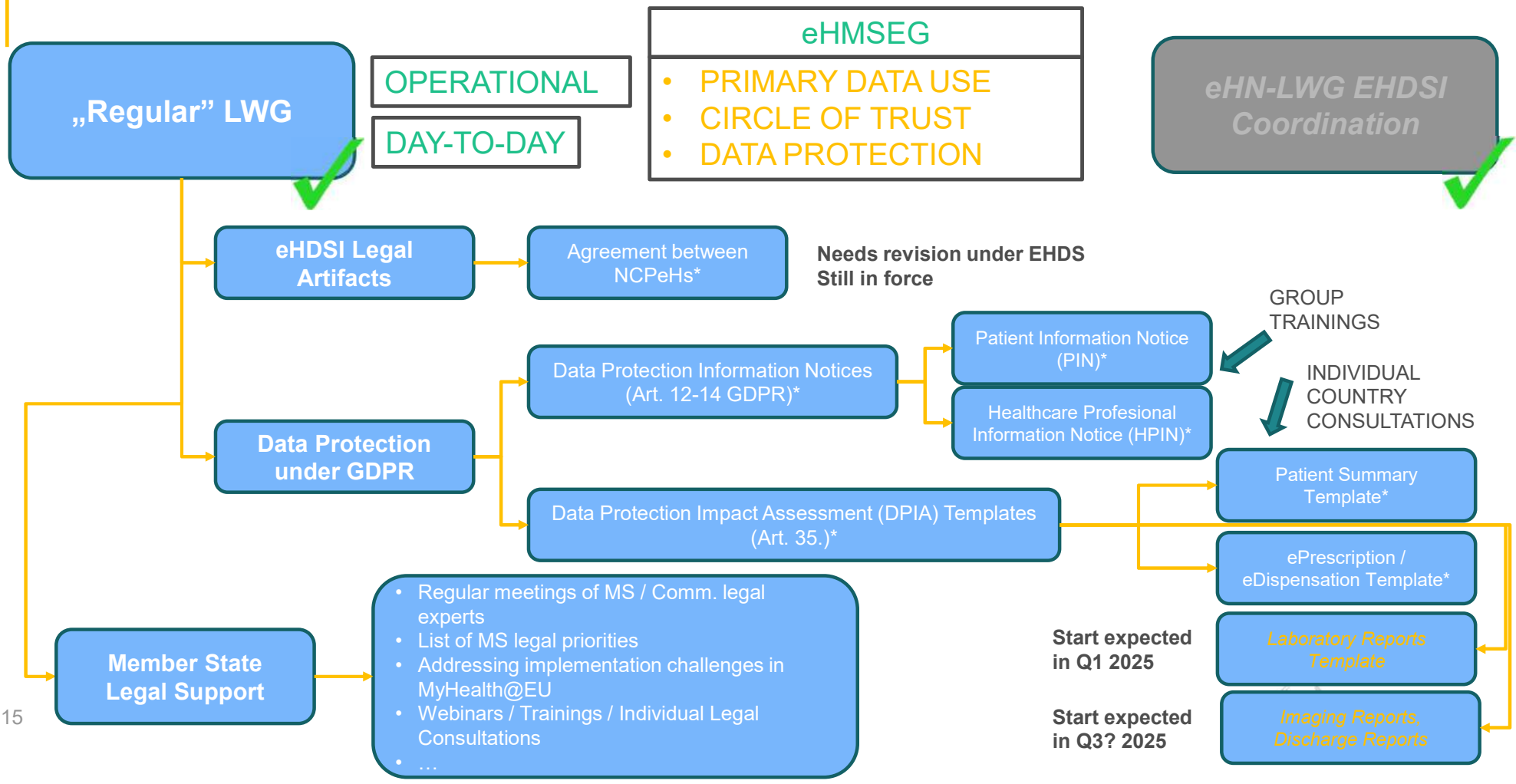
Additionally, **Medical Images, Laboratory Results and (hospital) Discharge Reports** will also be available across the EU, with the **full Electronic Health Record (EHR)** to follow later on.



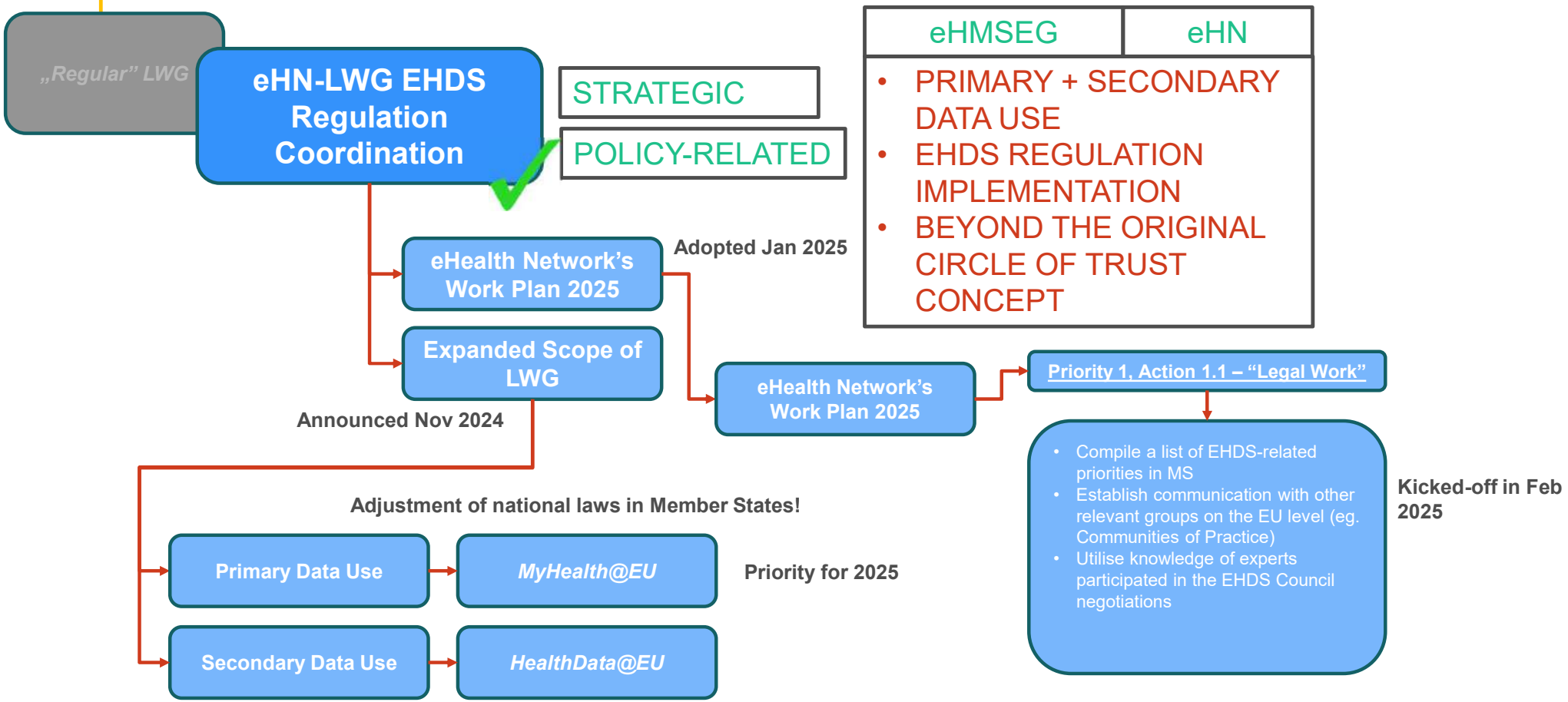
Current governance of the eHealth Network



eHMSEG Legal Working Group – Regular LWG



eHMSEG Legal Working Group – Coordination with eHN on EHDS Regulation Implementation



eHMSEG Legal Working Group and the eHN Work Plan 2025

eHealth Network's Work Plan 2025*

Priority 1, Action 1.1 – "Legal Work"

Primary Purpose:
Offer a forum for Member States (MS) to exchange information on national legal issues related to the EHDS Regulation.

Scope:
- **Legal Expertise:** Discuss expert legal interpretations of EHDS at the national level.
- **Sharing Experiences:** Provide a platform to exchange best legal practices among MS (e.g., data protection, privacy compliance).
- **Develop Tools & Materials:** Create or share resources (e.g., legal solutions, practical guidance) that support MS implementation of the EHDS.

Responsibility
- **Lead**: Jointly managed by the eHMSEG Legal Work Group chairs (**Vanja Pajić** & **Klára Jiráková**), and representatives from France (**Emilie Passemard**) and Finland (**Joni Komulainen**).

Proposed Next Steps (over the next two years):
- **National Legal Gap Analysis**: On a voluntary basis, MS share their assessments of discrepancies between the EHDS Regulation and their national laws, including solutions and best practices.
- **Develop Legal Tools & Guidelines**: Use existing eHN/eHMSEG materials to draft guidelines on data protection and cross-border data exchange for MS.
- **Support Member States**: Offer legal expertise, organise workshops, webinars, and training sessions to facilitate EHDS implementation.

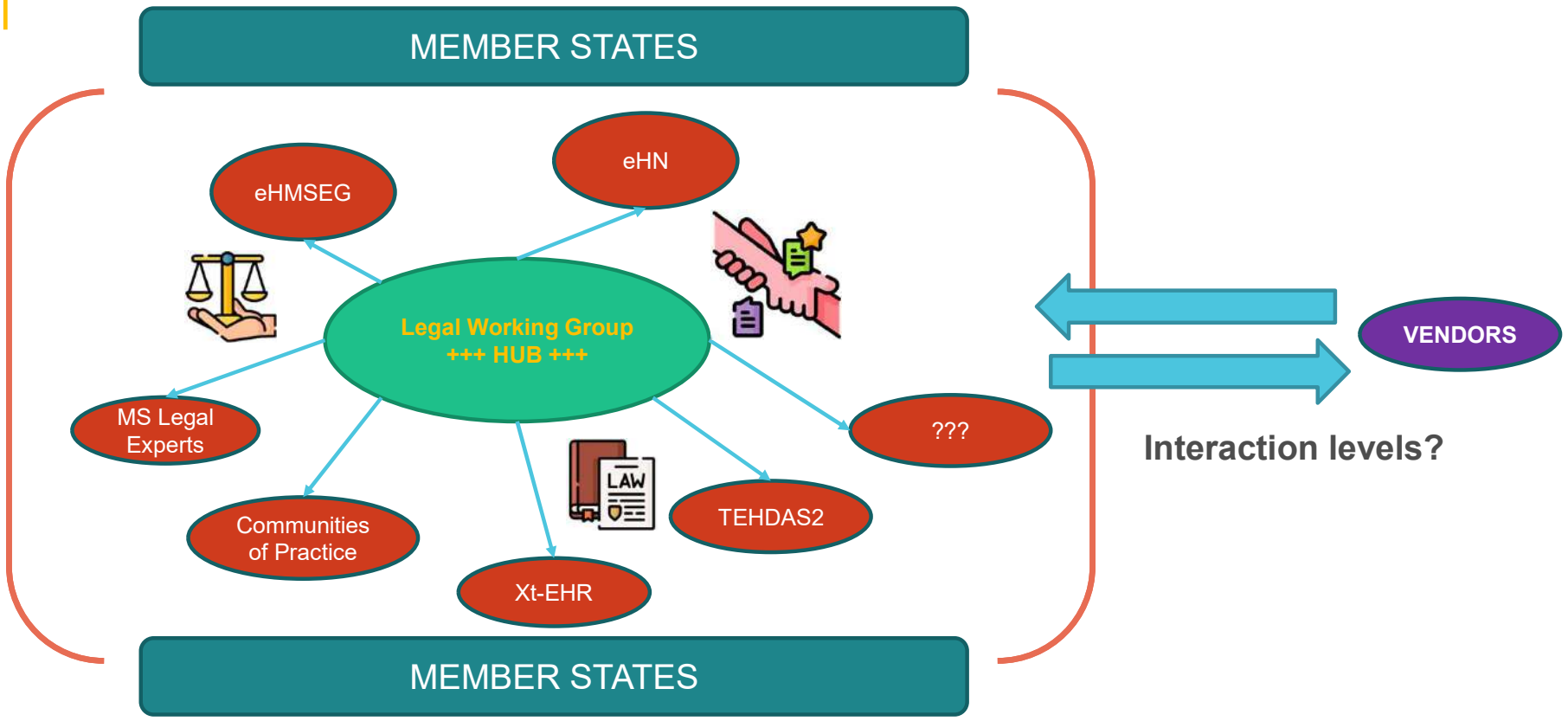
Expected Activities of the LWG:
- **Engage with Member States**: Work with national authorities and legal experts to align legal approaches for EHDS.
- **Consult Stakeholders**: In coordination with the eHN, involve patient groups, healthcare providers, industry, and data protection authorities where relevant.
- **Coordinate with Other EHDS-Related Groups**: Work in parallel with technical/operational groups, as well as Xt-EHR and TEHDAS2 joint actions, to ensure consistent legal considerations.

Our expectations:

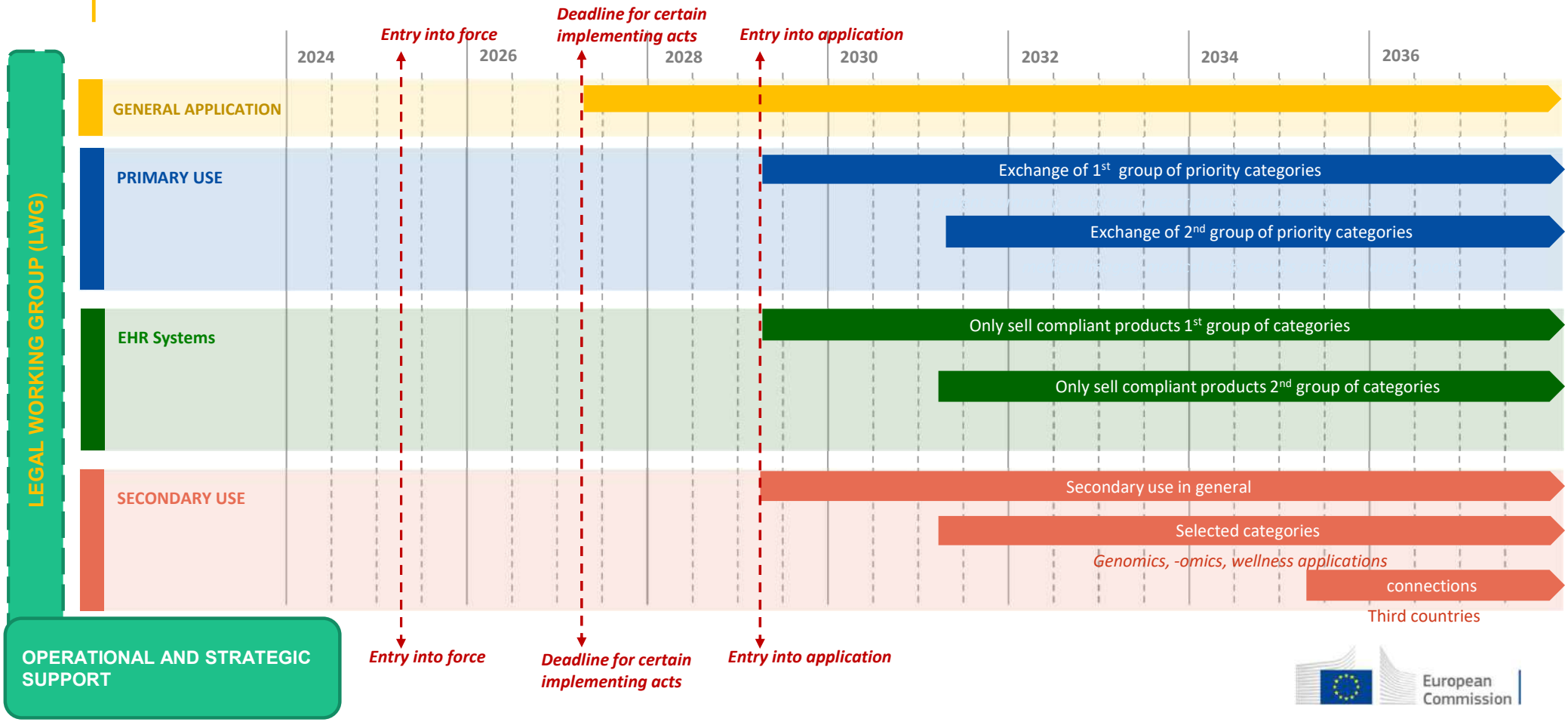
- Stronger commitment by the Member States
- Nomination of legal experts from all 27 Member States' + EEA/EFTA participation
- Roadmap for the group's governance under EHDS Regulation (including legal mandate and financing)
- Ongoing support from:
  - eHMSEG
  - eHN -> EHDS Board

Legal Working Group

Legal Working Group – Legal „HUB" under EHDS Regulation



Roadmap for EHDS Implementation & Support from Legal Working Group



European Commission

EHDS and open issues

Definition and Scope of "EHR Systems"	**Broad and unclear definitions** that could create unnecessary compliance burdens.
Interoperability and Testing Concerns	**Broad and unclear definitions** that could create unnecessary compliance burdens.
National Fragmentation and Legal Uncertainty	**Fragmentation across Member States**, leading to legal uncertainty.
Burden of Additional Compliance Requirements	**Additional compliance burdens** on top of existing regulations.
Burden of Additional Compliance Requirements	**Complex governance and data access rules** that could slow down innovation. **Market-readiness challenges**, particularly for SMEs and start-ups.
Data Sovereignty and Infrastructure Challenges	**Infrastructure and data sovereignty concerns**.

Examples of Implementation use-cases that need to be explored further in the LWG

- LWG is in the process of collecting inputs from Member States' organisations regarding implementation of specific „use cases" from EHDS articles

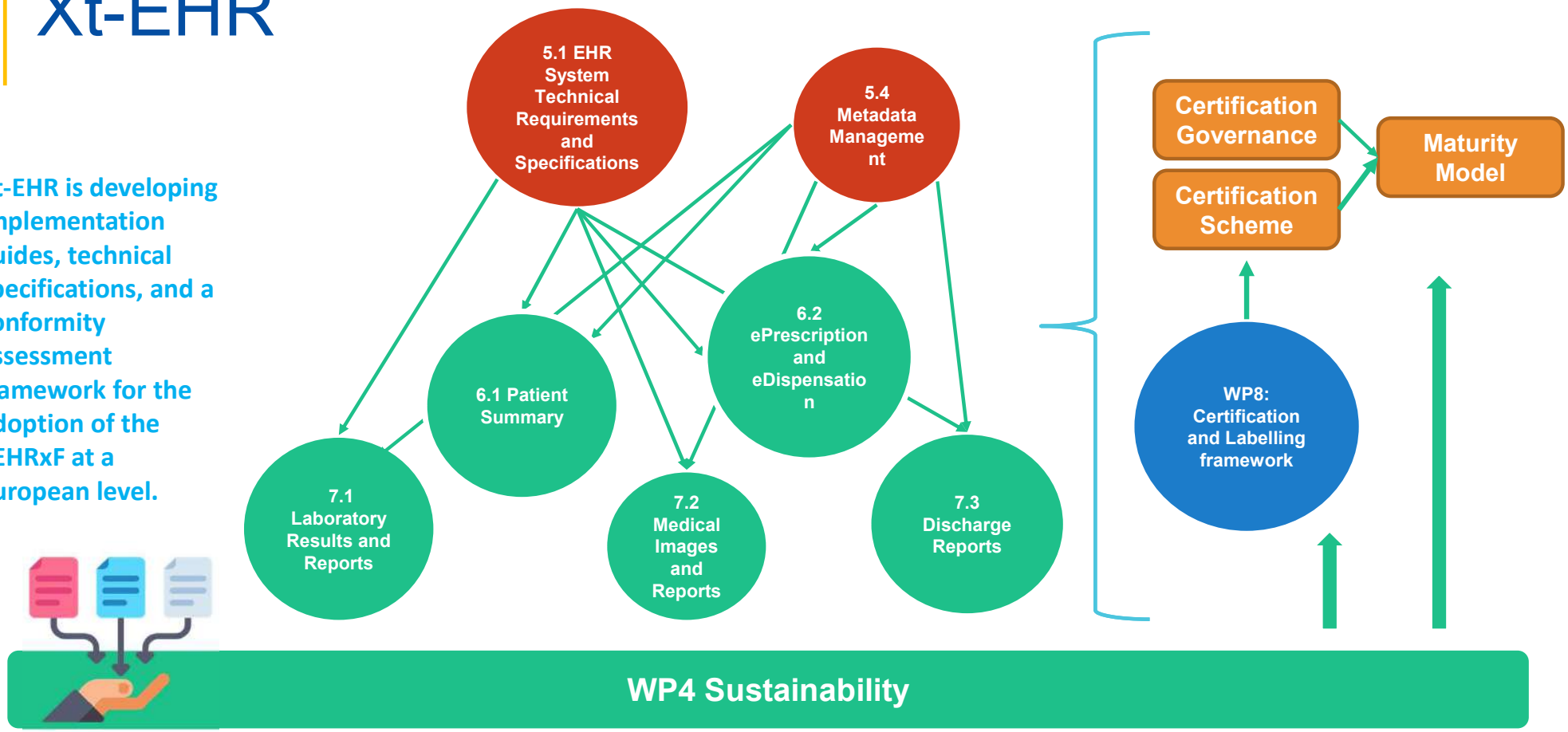
STRATEGY

OPERATIONS

	EXAMPLE
Article 39	
EU declaration of conformity	In hospitals in particular, many systems are integrated and interconnected, and it is cost-effective to fulfill many requirements on organisational level by one system or module only instead of redundant and costly implementation in all modules. The modules are often from different manufacturers and exchange data, only some of which belongs in priority categories. In situations where if is feasible to fulfil the goals of the regulation (rights of patients and professionals) on organisational level by some modules only, should the harmonised components of only these modules be within the scope of EHR requirements and declaration of conformity?
Article 30	
Obligations of manufacturers of EHR systems	EHR system manufacturer has the right to define the intended purpose of their system. Many EHR systems only deal with some parts or elements of priority categories or some essential requirements, and no EHR system handles all information in all categories. In one EHR system, should the conformity be ensured and declared only on those sections or documents of the format which match the intended purpose of each system? Should conformity be declared in relation to the requirements for the category of EHR systems (e.g. lab EHR system, GP EHR system) as defined in Article 36?
Article 26	
Placing on the market and putting into service	Will all currently used and already deployed EHR systems need to be modified, or do only new systems entering the European market need to demonstrate compliance? Existing systems are updated on regular basis for new features or security, is there a threshold of "how big an update" to an old system constitutes a deployment which must be assessed in terms of EHDS compliance?

Xt-EHR

Xt-EHR is developing implementation guides, technical specifications, and a conformity assessment framework for the adoption of the EEHRxF at a European level.

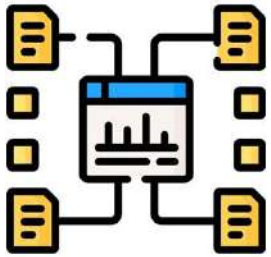


EHDS, ANNEX II – EHR Systems' Requirements

Requirement Category	Short Title	Requirement	Annex II Reference
General Requirements	Performance and Patient Safety	"The harmonised software components of an EHR system shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose and their use does not put at risk patient safety."	Annex II, Section 1.1
	Supply, Installation, and Operational Integrity	"The harmonised software components of the EHR system shall be designed and developed in such a way that the EHR system can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use."	Annex II, Section 1.2
	Interoperability, Safety, and Security Features Upholding Individual Rights	"An EHR system shall be designed and developed in such a way that its interoperability, safety, and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II."	Annex II, Section 1.3
	Interoperability and Compatibility with Other Products	"The harmonised software components of an EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system in relation to those harmonised software components of an EHR system."	Annex II, Section 1.4
Interoperability Requirements	Interface for Access in EEHRxF	"Where an EHR system is designed to store or intermediate personal electronic health data, it shall provide an interface enabling access to the personal electronic health data processed by it in the European health record exchange format, by means of the European interoperability software component for EHR systems."	Annex II, Section 2.1
	Capability to Receive Data in EEHRxF	"Where an EHR system is designed to store or intermediate personal electronic health data, it shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability software component for EHR systems."	Annex II, Section 2.2
	Provision of Access to Data in EEHRxF	"Where an EHR system is designed to provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability software component for EHR systems."	Annex II, Section 2.3
	Granularity and Structured Data Entry	"An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data with sufficient granularity to enable the provision of the entered personal electronic health data in the European health record exchange format."	Annex II, Section 2.4
	Prohibition of Access or Sharing Restrictions	"The harmonised software components of an EHR system shall not include features that prohibit, restrict, or place an undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes."	Annex II, Section 2.5
	Prohibition of Export Restrictions for System Replacement	"The harmonised software components of an EHR system shall not include features that prohibit, restrict, or place an undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product."	Annex II, Section 2.6
Security and Logging Requirements	Identification and Authentication of Health Professionals	"An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals."	Annex II, Section 3.1
	Comprehensive Logging of Access Events	"The European logging software component of an EHR system designed to enable access by healthcare providers or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record at least the following information on every access event or group of events: (a) identification of the healthcare provider or other individuals having accessed the personal electronic health data; (b) identification of the specific natural person or persons having accessed the personal electronic health data; (c) the categories of data accessed; (d) the time and date of access; (e) the origin or origins of data."	Annex II, Section 3.2
	Tools for Log Review and Analysis	"The harmonised software components of an EHR system shall include tools or mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes."	Annex II, Section 3.3
	Support for Retention Periods and Access Rights	"The harmonised software components of an EHR system that store personal electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data."	Annex II, Section 3.4

XT-EHR

- **EHDS Logical Information Models: https://xt-ehr.github.io/xt-ehr-common/**
- Xt-EHR Commons IG is a base for all the other implementation guides created in Xt-EHR project. FHIR Implementation Guides are created in cooperation with other EU projects working on EHDS implementation (please find the links under specific use cases).
  Information Models IG should be used as a basis for all the use cases to make sure common data objects (patient, medication, etc) are modelled in a consistent way. Use case specific FHIR implementation guides shall include mappings to information models.

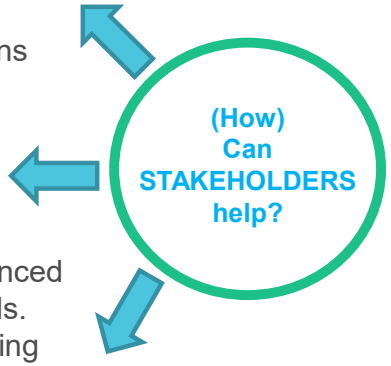


- **Common sources for all use cases include:**
  - eHealth Network guidelines (including the results from eHN Subgroup of Semantics guideline consistency task force);
  - MyHealth@EU requirements catalogue;
  - X-eHealth project;
  - XpanDH project.

Future Legal Landscape of EHDS

EHDS Implementation challenges

- **Interoperability of Systems**: Harmonizing diverse technical and data standards across Member States.
- **Data Protection & Privacy**: Ensuring secure handling and sharing of sensitive health data, in line with GDPR.
- **Public & Provider Trust**: Overcoming concerns about data misuse and administrative burden.
- **Digital Infrastructure Gaps**: Upgrading or establishing foundational eHealth systems, particularly in less digitized regions.
- **Lack of Specialized Expertise**: Shortage of professionals in areas like cybersecurity, advanced data governance, and interoperability standards.
- **Complex Governance Structures**: Coordinating multiple authorities at national and EU levels.
- **Financial & Administrative Costs**: Significant investments needed for complex systems' upgrades, training, and ongoing maintenance.
- **Balancing Innovation & Ethics**: Supporting research and development while safeguarding patient rights and data confidentiality.



Questions for the future?

- **Potential GDPR Revisions**: Will the EHDS prompt updates to existing data protection frameworks specifically for health data? Is the EHDS robust enough to ensure secure data processing in healthcare settings?
- **Impact of the AI Act**: How will AI-focused legislation interact with EHDS requirements, especially concerning automated data processing, accountability, and risk classification?
- **EU-Wide Harmonization**: To what extent can EU digital health laws be further standardized, and will new legislation or guidelines be needed for uniform implementation?
- **Global Data Exchange**: How might EU agreements expand beyond European borders (e.g., transatlantic deals) to facilitate secure and compliant exchange of health data?
- **Emerging Technologies**: Could the EHDS framework need to adapt for advancements like real-time patient monitoring, remote care devices, or genomics data?

How can stakeholders engage and help co-create EHDS implementing acts?

Submit your input for Xt-EHR and TEHDAS2 projects during the public consultations on the implementing acts

Join communities:

- *Hospitals on FHIR* Community
- *Industry X-NET*

Participate in key events:

- *IHE-Europe Connectathon* – Vienna, 23-27 June 2025
- *IHE-Europe Experience Days* – Vienna, 24-25 June 2025

How can IHE support the implementation of EHDS

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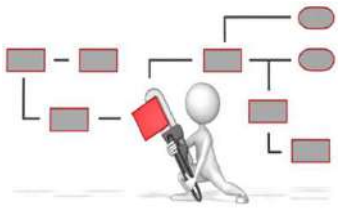
21/02/2025

Success of EHDS relies heavily on



How it implemented by all stakeholders

How fast it will achieve widespread adoption

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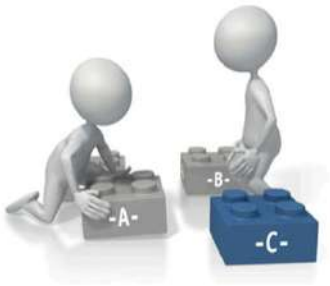
How can IHE contribute to making EHDS successful?



✅ **Proven IHE Methodology** (ISO TR 28380:2014) – Ensuring structured, scalable interoperability

✅ **IHE Profiles** – Implementable and conformance testable building blocks for real-world interoperability

✅ **Collaboration with SDOs** (e.g., HL7® FHIR®, SNOMED CT ®) – Building on existing base standards

✅ **Conformance testing & certification** – IHE Connectathon®, Integration Statements, Connectathon Seal

✅ **Deployment support** – Reducing risks and accelerating EHDS readiness

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Q&A

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