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EHDS IMPLEMENTATION - MAIN CHALLENGES
AND THE ROLE OF HL7

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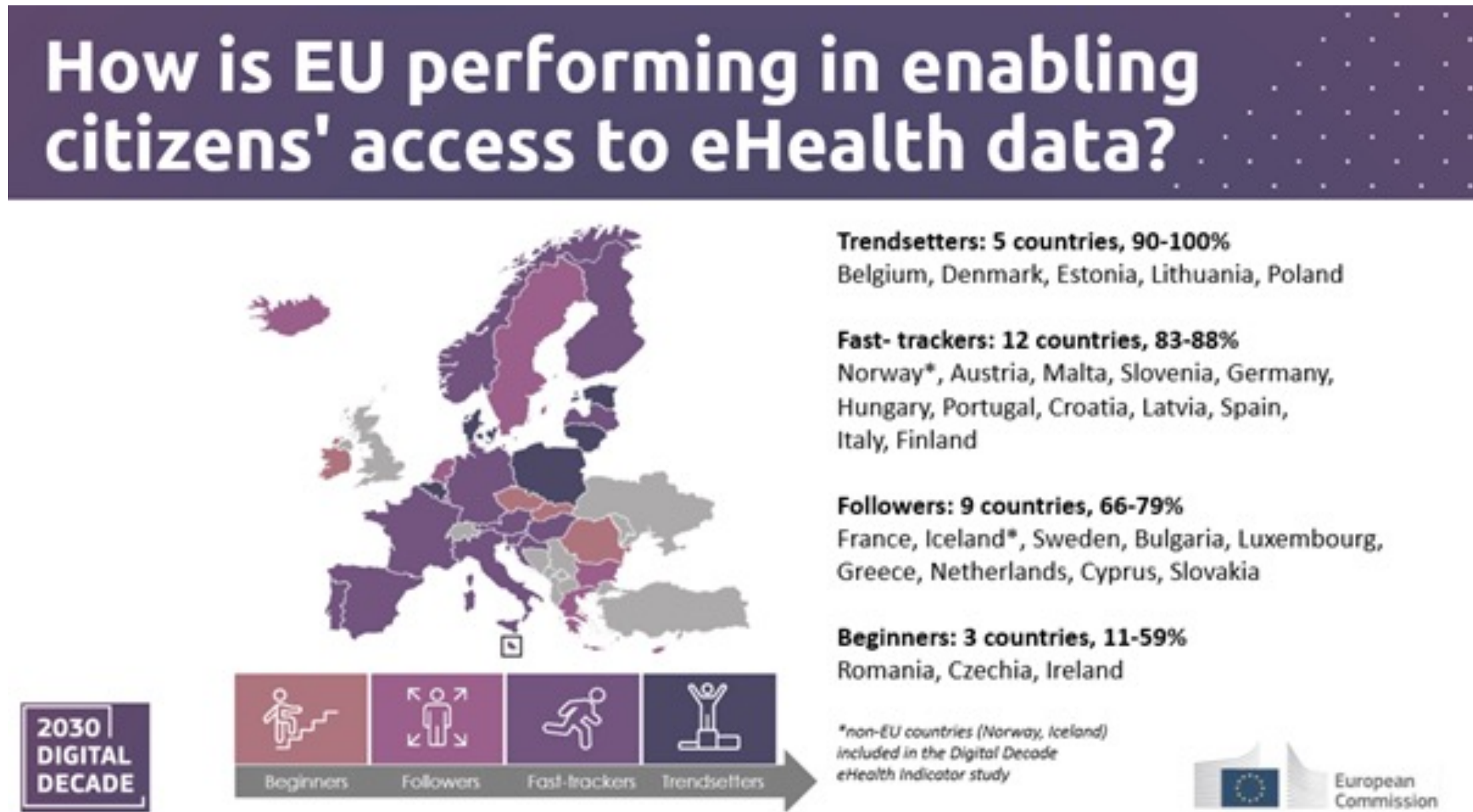
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EHDS - similar challenges, different levels of readiness

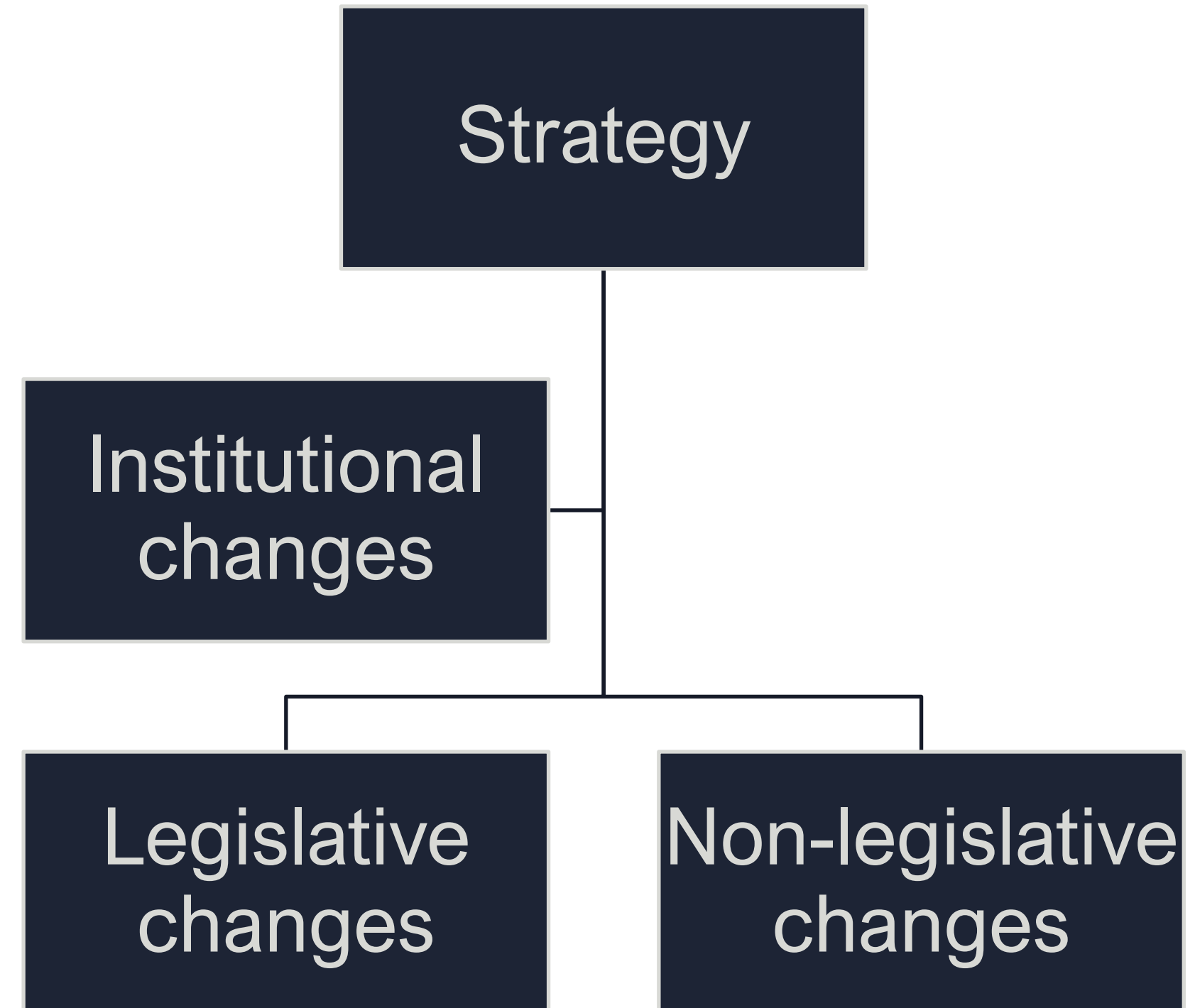
- Legal barriers
- Technical barriers
- Financial barriers
- Awareness barriers



Systemic approach

The first step will be to assign EHDS tasks to the relevant national entities

- 1) e-Health authority
- 2) health data access authority
- 3) market surveillance authority



What institutional changes await us?

Primary use of data

- **at least one e-health authority** should be designated to be responsible for the implementation and enforcement of Chapter II of the EHDS (primary use)
- **Main tasks:**
 - (a) creation of technical solutions, such as a national EMD,
 - (b) establishment of appropriate rules and mechanisms;
 - (c) ensuring the implementation at national level of the European format for the exchange of electronic health records;

Deadline: 2 years after entry into force of the EHDS

In addition: national contact points for eHealth

Secondary use of data

- **at least one authority for access to health data** should be designated
- **Main tasks:**
 - (a) issue decisions on requests for access to health data;
 - (b) process electronic health data to fulfil requests,
 - (c) may collect fees

Deadline: 2 years after entry into force of the EHDS

In addition: national contact points for secondary use of electronic health data

Market surveillance

- **a market surveillance authority or authorities should be appointed.** The market surveillance authorities may be the same as the eHealth authorities
- **Main tasks:**
 - (a) take measures to prohibit or restrict the availability on the market of the relevant EMD system.
 - (b) entitled to impose market surveillance measures in accordance with the standard arising from pursuant to Regulation (EU) 2019/1020
 - (c) verify the compliance of welfare applications with the essential requirements set out in Annex II of the EHDS.

Deadline: 6 years after entry into force of the EHDS

What could be the role of HL7 organizations?

The HL7 organization should play a crucial role in the implementation of the EHDS, particularly during the establishment of national authorities responsible for its rollout. HL7's involvement can cover several key areas:

1. Consultations on the division of responsibilities among national authorities

- **Providing expertise on interoperability** – HL7 can help define which institutions should oversee the adoption and enforcement of health data exchange standards (**FHIR, CDA, HL7 v2**, etc.).
- **Supporting the division of responsibilities** – HL7 can offer recommendations on which aspects (e.g., compliance, security, certification) should fall under national regulators and which should be delegated to technical institutions or private entities.
- **Ensuring EHDS compliance with international standards** – HL7 can collaborate with national authorities to align local regulations with EU and global requirements.

2. Subcontracting Opportunities for National Authorities

- **Act as a subcontractor for interoperability services** – as a leading expert in health data standards, HL7 could support national authorities in designing and developing digital infrastructure.
- **Collaborate with national infrastructure operators** – working with entities responsible for national e-health platforms to align their architecture with EHDS requirements.
- **Provide training and certification services** – HL7 could establish accreditation programs for IT system providers in healthcare, ensuring compliance with EHDS standards.

3. Developing Guidelines for EHDS Implementation at the National Level

- **Technical baseline requirements** for systems processing data within EHDS.
- **Recommendations on security and GDPR compliance** regarding data exchange and processing.
- **Standardized data exchange protocols** for various healthcare providers and IT systems (e.g., public and private facilities, telemedicine, integration with national registries).

Strategic actions needed

Actions for the effective implementation of the EHDS should be started today, including in particular:

- **establishing a team**, operating under the Minister of Health, for increasing the interoperability and openness of data in the health sector and implementing the;
- **developing a strategy** for the implementation of the EHDS, which will include a plan and schedule of activities;
- **developing assumptions for draft legislation** that will reform the system of information circulation in health care;

What should we aim for?

- **Institutional changes**
- **Digitalization** - Ensuring the completeness of health data processed in the e-health system.
- Increasing the **interoperability of medical records**.
- Standardising **the rules of access to health data** in accordance with the EHDS.
- Developing rules for handling **data generated outside of a doctor's control**, such as by remote medical devices or lifestyle apps.
- **Providing solutions to improve work with health data**, including regulations on the rules for storing medical records in the cloud, and addressing basic questions and concerns related to the use of AI in health care.
- It is necessary for health care providers to meet the requirements necessary to ensure **a high level of protection of health data**.
- **Secondary use** - developing standards for the anonymisation and pseudonymisation of health data by adopting dedicated regulations or a clear standard.



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Thank you

