



# European Health Data Space

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# Problems

## Access to health data for healthcare in cross-border context

- Patients cannot access and share their health data cross-borders
- Limited digital interoperability of health care providers

## Access to health data for secondary purposes (research, policy making)

- Low re-use of health data for research and policy making
- Cross-border access to health data for secondary purposes is unclear and cumbersome
- Fragmented infrastructure for data use in research and policy making
- Limited output of eHealth Network of Member States on processing of health data for secondary purposes

## Limited free movement of digital health services (e.g. tele-health, m-health)

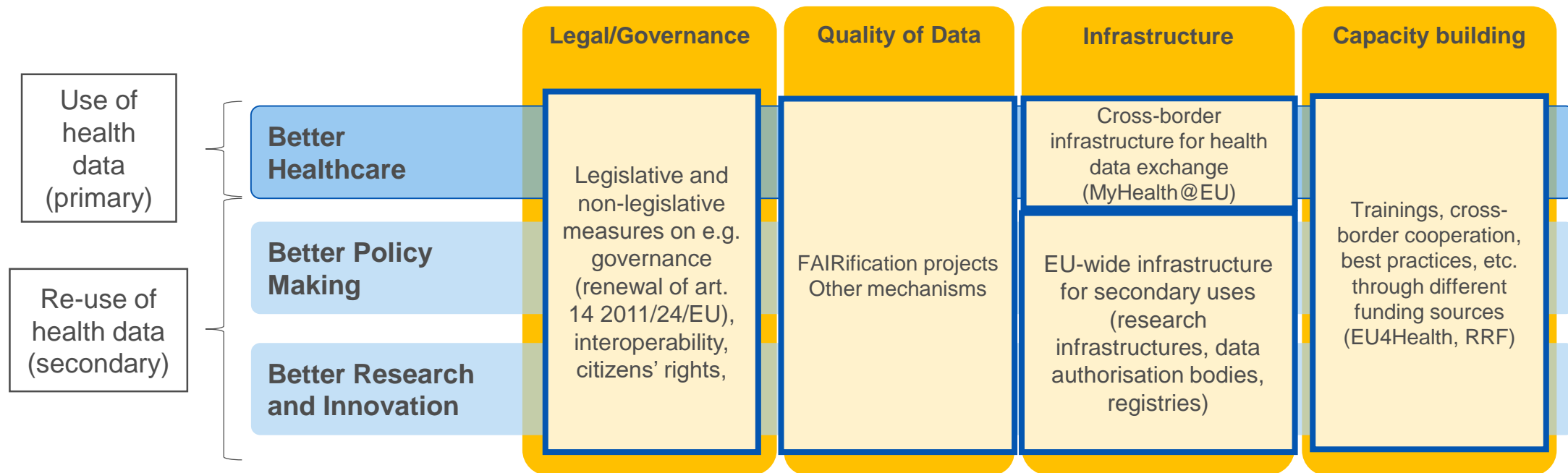
- Uneven legislative framework
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

## Slow roll-out of AI in health care

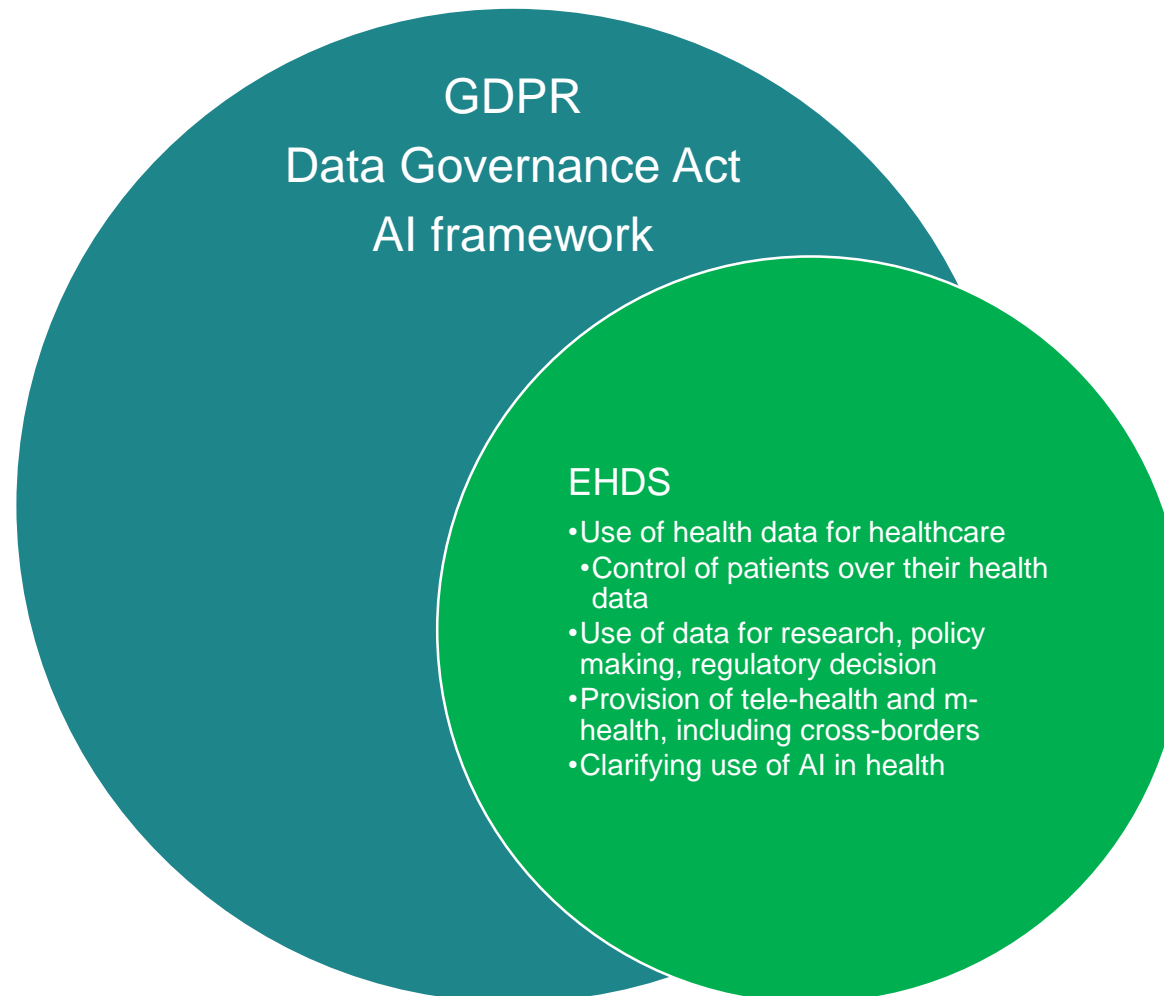
- Knowledge gaps and access to data to be used in AI applications
- Uncertainty on AI liability in health

# Primary and secondary uses of health data

- Timely and simplified *exchange of* and *access to* health data for different use cases, e.g. research on cancer, pharmacovigilance, etc., but also for healthcare provision.



# EHDS: articulation with EU regulatory framework



# A common European Health Data Space (EHDS)

## Health data exchange and access

- Healthcare, research and policy making
- Governance, privacy, quality, portability and access to data, infrastructures, interoperability

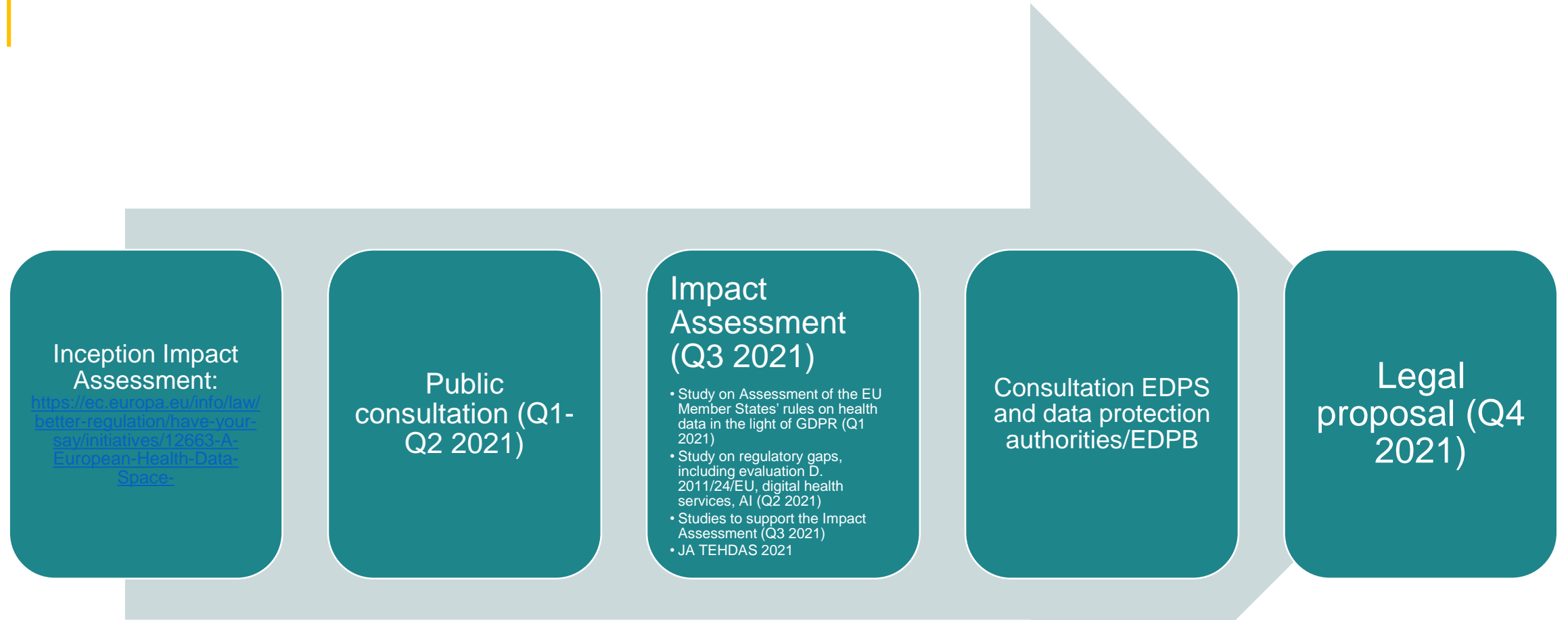
## Digital health services and products

- Eliminate barriers to free movement
  - Labeling
  - Interoperability
  - Reimbursement
  - Liability

## AI

- Liability
- Development of AI

# EHDS: next steps



# 1a. Use of data for healthcare

Primary use of health data (EHDS 1)

# EHDS1: **rules:** Commission Recommendation on a Electronic Health Record Exchange Format

Common technical specifications (baseline)



## Initial health information domains:

- patient summaries
- ePrescriptions
- laboratory reports
- medical images and reports
- hospital discharge reports



## Interoperability specifications

- HL7 CDA
- DICOM
- IHE profiles




## Incremental and selective approach

- adopting, refining, and maintaining the specifications of the European EHR exchange format

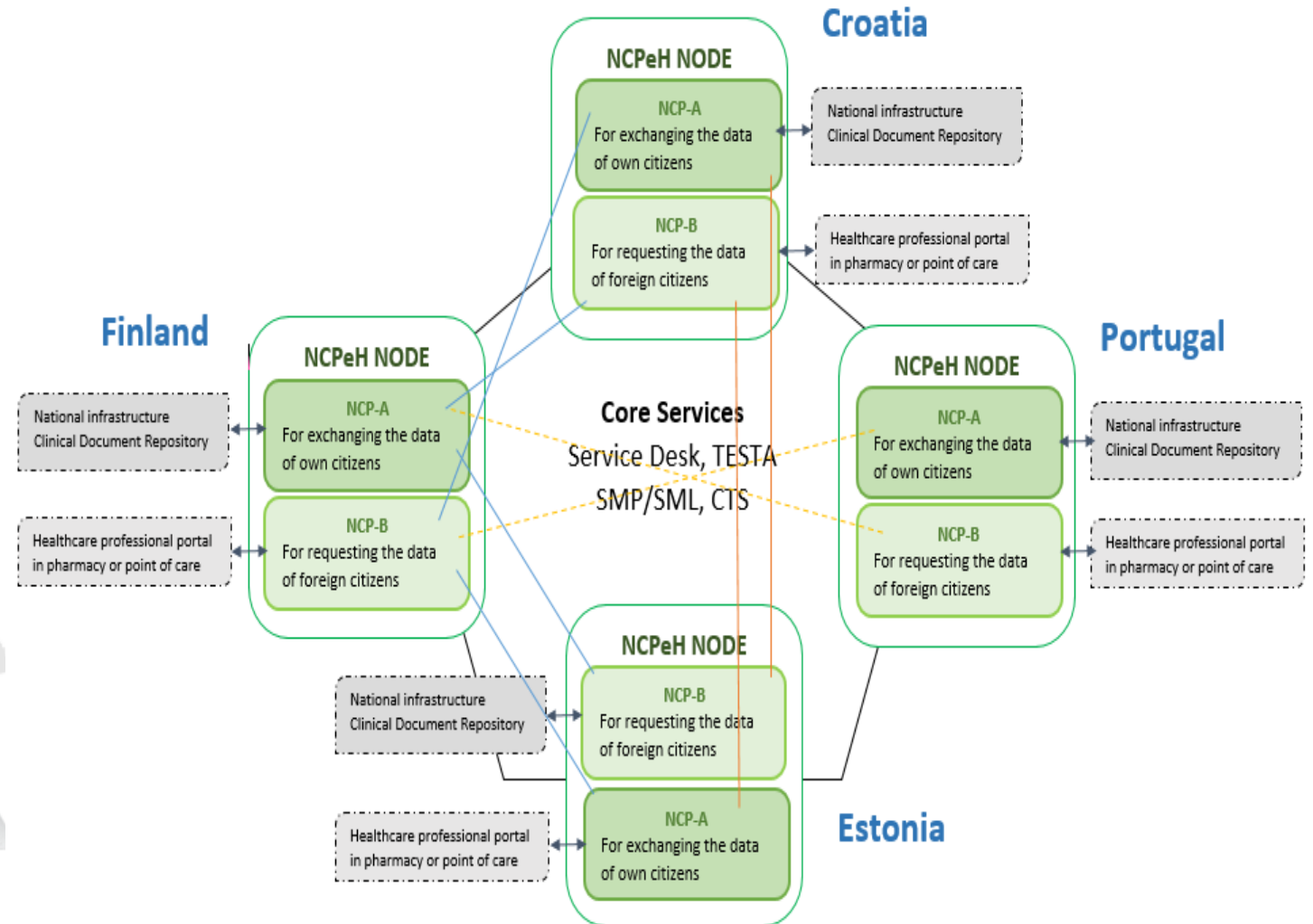
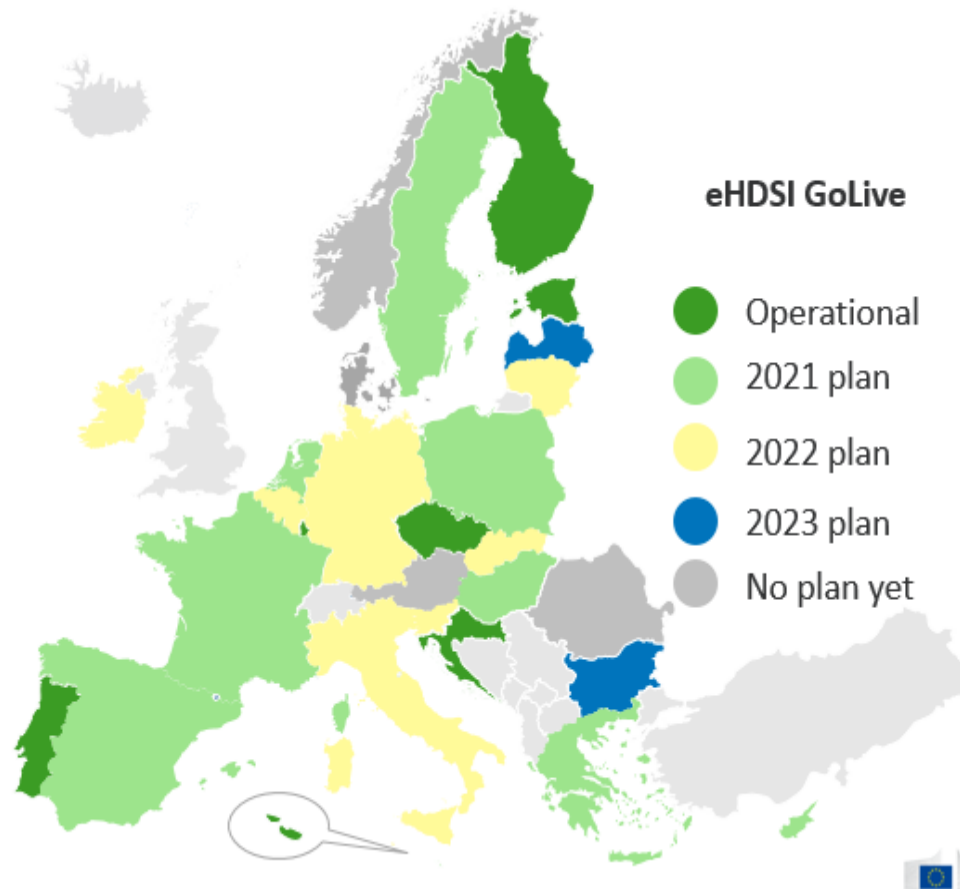


# Evolution of standards and specifications



European Health Data Space legislative proposal	<ul style="list-style-type: none"><li>• Interoperability: national and EU level</li><li>• Evolution of standards and specifications</li><li>• Legal act: by end 2021</li></ul>
Electronic health record exchange format	<ul style="list-style-type: none"><li>• Joint Coordination process</li></ul>
Standards and specifications:	<ul style="list-style-type: none"><li>• Patient Summaries; ePrescriptions<ul style="list-style-type: none"><li>• → eHealth Network guidelines</li><li>• → MyHealth@EU</li></ul></li><li>• xHealth: images, laboratory results, discharge letters</li></ul>

# EHDS1: MyHealth@EU: cross-border exchange of patients' data: 7 MS live, 15 in 2021





# Patients access to ePrescriptions abroad

Electronic prescription in Europe – a Finnish patient purchasing medication in a pharmacy abroad



## ePrescription

allows citizens in Europe to retrieve their medication in a pharmacy located in another European country without having to bring the printed prescription and without being concerned about the language barrier.

eHealth Network [ePrescriptions and eDispensation guidelines](#)



# Doctor access to foreign citizen Patient Summary

## Patient Summary

Used while traveling abroad and being in necessity of consulting a doctor in that country.

Provides information on important health related aspects such as your allergies, current medication, previous illness, surgeries.

Helps doctors to formulate an adequate treatment, avoid some possible risk (for instance in case of allergy) and overcome linguistic barriers.

[eHealth Network Patient Summary guidelines, including minimum dataset](#)



# 1b. Use of data for research and policy making

Secondary use of health data

# EHDS2: data for research and policy making (secondary use of health data)

Legislation: Data Governance Act-EHDS

## DGA

Minimum rules for access to data applicable to all sectors

A national single information point

National body(s) with support function

National authority(s) for providers of data sharing services

National data altruism organization(s)

European Data Innovation Board (cross-sector interoperability)

## EHDS (tbd)

Health specific

National data permit authorities/support function

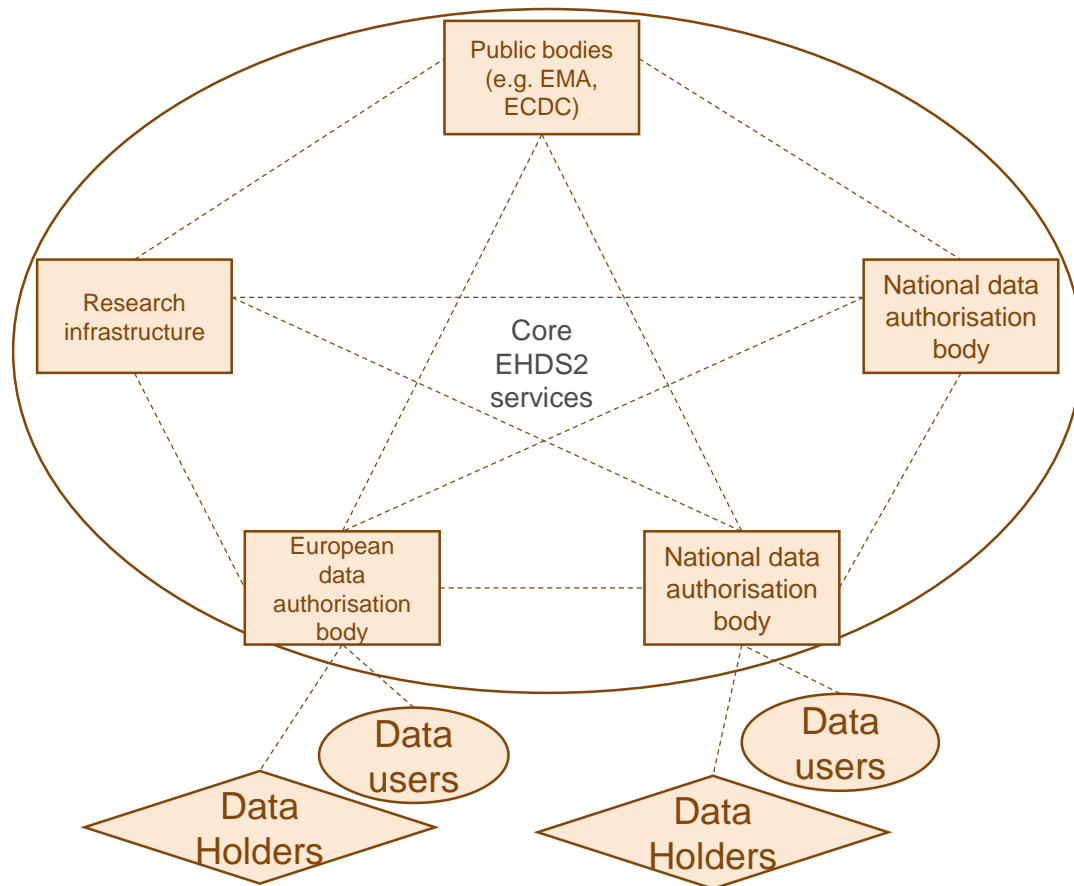
National sectoral bodies for interoperability

National sectoral bodies on data altruism/data permit authorities

EU level body on secondary use of health data, represented in EDIB

# EHDS2: access to data for research and policy making (secondary use of health data)

## Digital infrastructure – by 2025



EHDS2 NODEs are the entry point for stakeholders into the EHDS

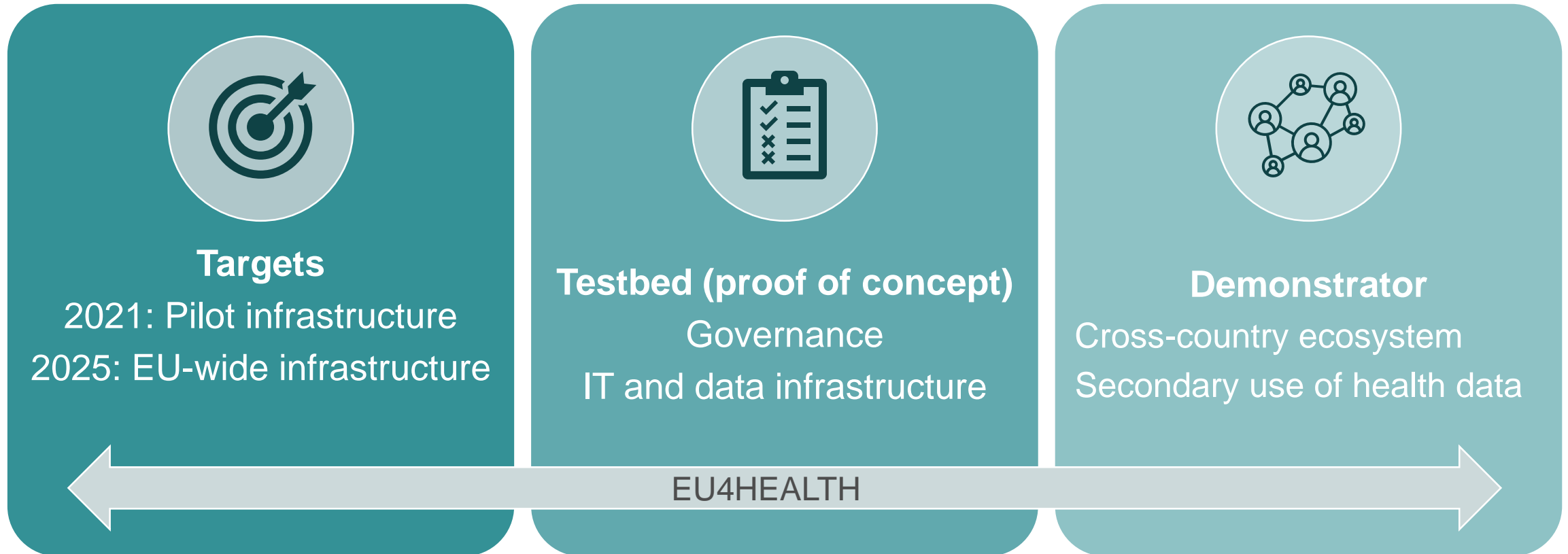
EHDS2 NODEs can be established by National or Trans-national stakeholders

EHDS2 NODEs follow common policies and interoperability specifications

DATA Holders make health data available for research and policy making

DATA Consumers use data for research or policy making

# Pilot project EHDS2: motivation







## 2. Digital health services

# Digital health (tele-health and m-health)

- Main challenges relate to adoption, deployment and integration of digital health (particularly true in cross border settings)

Reimbursement

Interoperability

Labelling/certification

Data privacy and  
liability

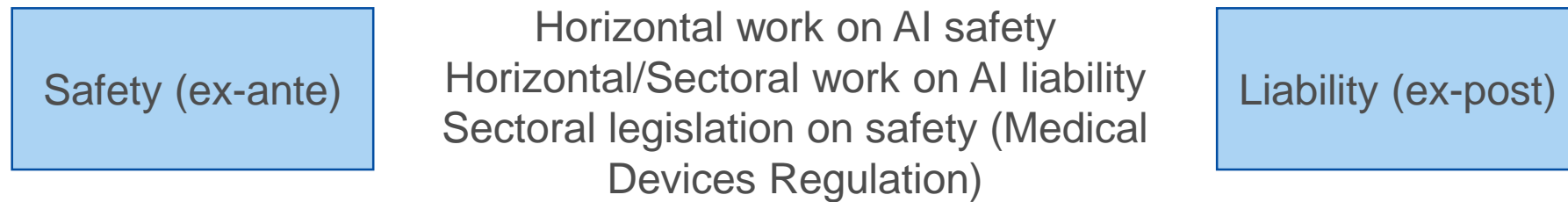
- Important elements
  - Extension of the existing cross-border infrastructure for health data exchanges (My@HealthEU)
  - Streamlining of assessments and guidance on assessment criteria (e.g. on clinical evidence, interoperability)
  - Enhancing control and access of citizens and patients over their own health data



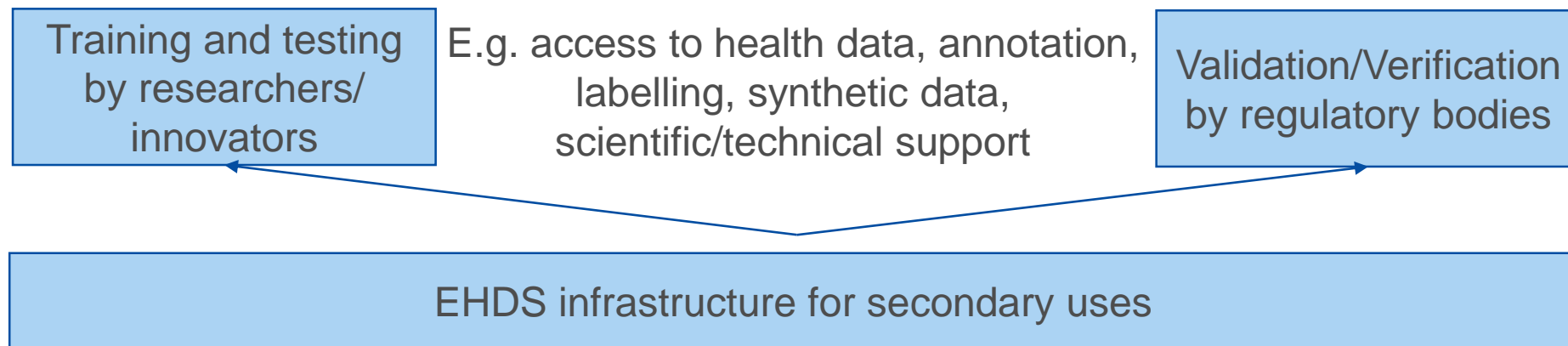
# 3. Artificial intelligence

# AI in health

- Ensuring an ecosystem of trust



- Ensuring an ecosystem of excellence



# Budget

## National level investments

- National funds
- RRF
- ERDF
- ESF+
- InvestEU

## EU level investments

- EU4Health
- DEP
- Horizon Europe

# Thank you



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