



European Health Data Space

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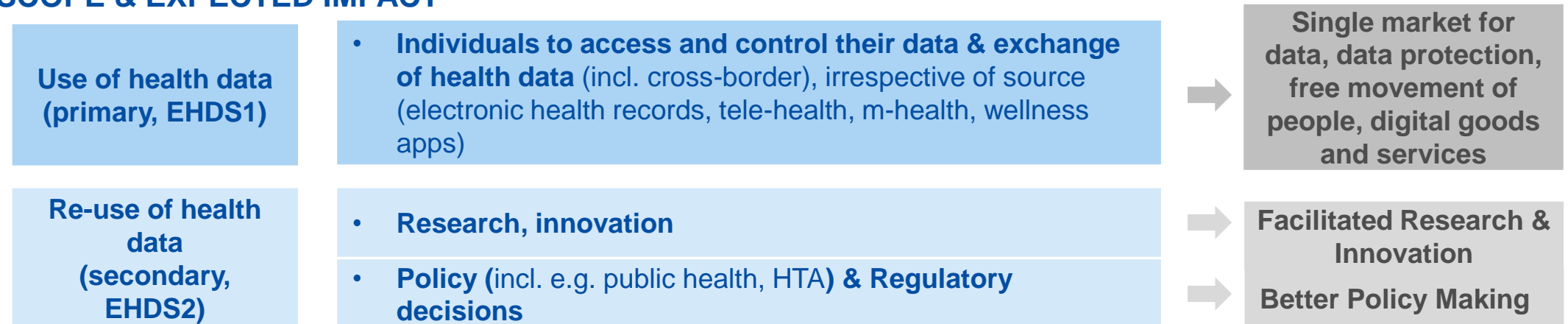
*European Reference Networks
and Digital Health, DG SANTE*

Towards a European Health Data Space (EHDS)

► OBJECTIVES

Timely and simplified *exchange of and access to* health data

► SCOPE & EXPECTED IMPACT



► MEANS



EHDS: What are the problems?

Use of health data for healthcare (primary)

Sharing of health data for healthcare

- Limited control to and access to patients
- Repeated tests and high costs
- **Insufficient exchange** of health data
- **Limited interoperability** between health care providers

Single market for digital health products and services

- Uneven national **legislative frameworks**
- Uneven **quality / interoperability** frameworks
- Uneven **procedures** for prescriptions, reimbursement, liability

Re-use of health data (secondary)

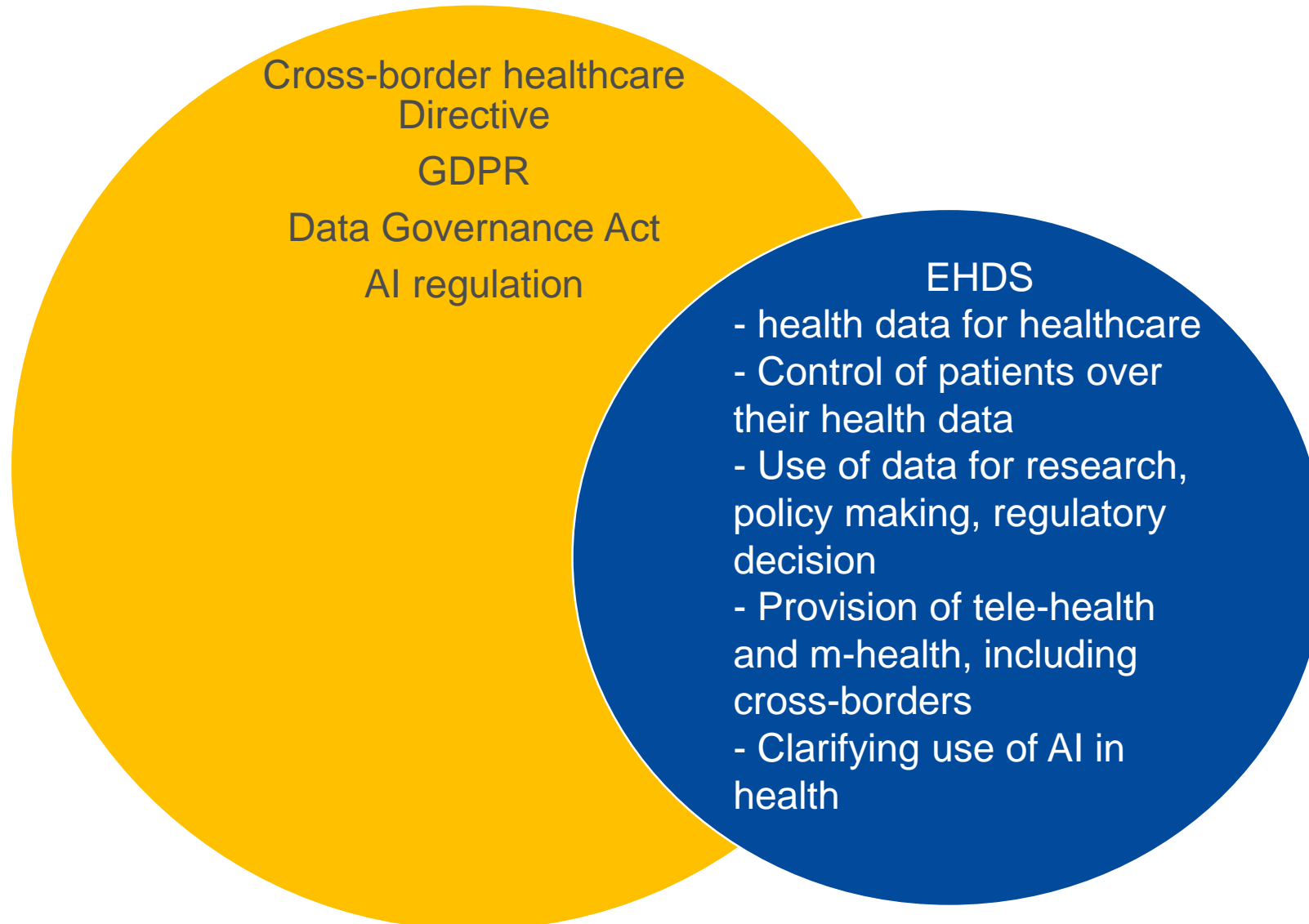
Access to health data for research, innovation, public health policy making

- **Low re-use** of health data
- **Cumbersome cross-border access** to health data
- Fragmented digital **infrastructures**

Artificial Intelligence

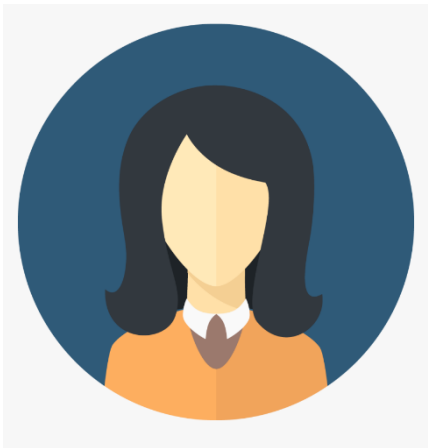
- Limited **provision** of data for training of AI
- Difficulties for regulators to evaluate
- **AI algorithms**
- Uncertainty on AI **liability** in health

EHDS: Articulation with EU regulatory framework



1a. Use of data for healthcare

Primary use of health data (EHDS 1/MyHealth@EU)



Access to health data in digital format

Today, a large number of EU citizens and healthcare professionals cannot access health data in a **digital format**. Data are often available in paper, or only a limited set of data categories are available in digital format.

Interoperable health data

Health data is collected in such a way, that **the format is different** everywhere. This makes it impossible to understand the meaning of health data in different contexts. Therefore, interoperability standards are required to **promote wider use and understanding**.



Tools and infrastructure

Member States organise health data access through different means. Some member states have patient or professional **portals** at the level of healthcare provider, region or nation, while others have apps or **personal data space** solutions. Also, registries of who should have **access** are also local, regional or national solutions.

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



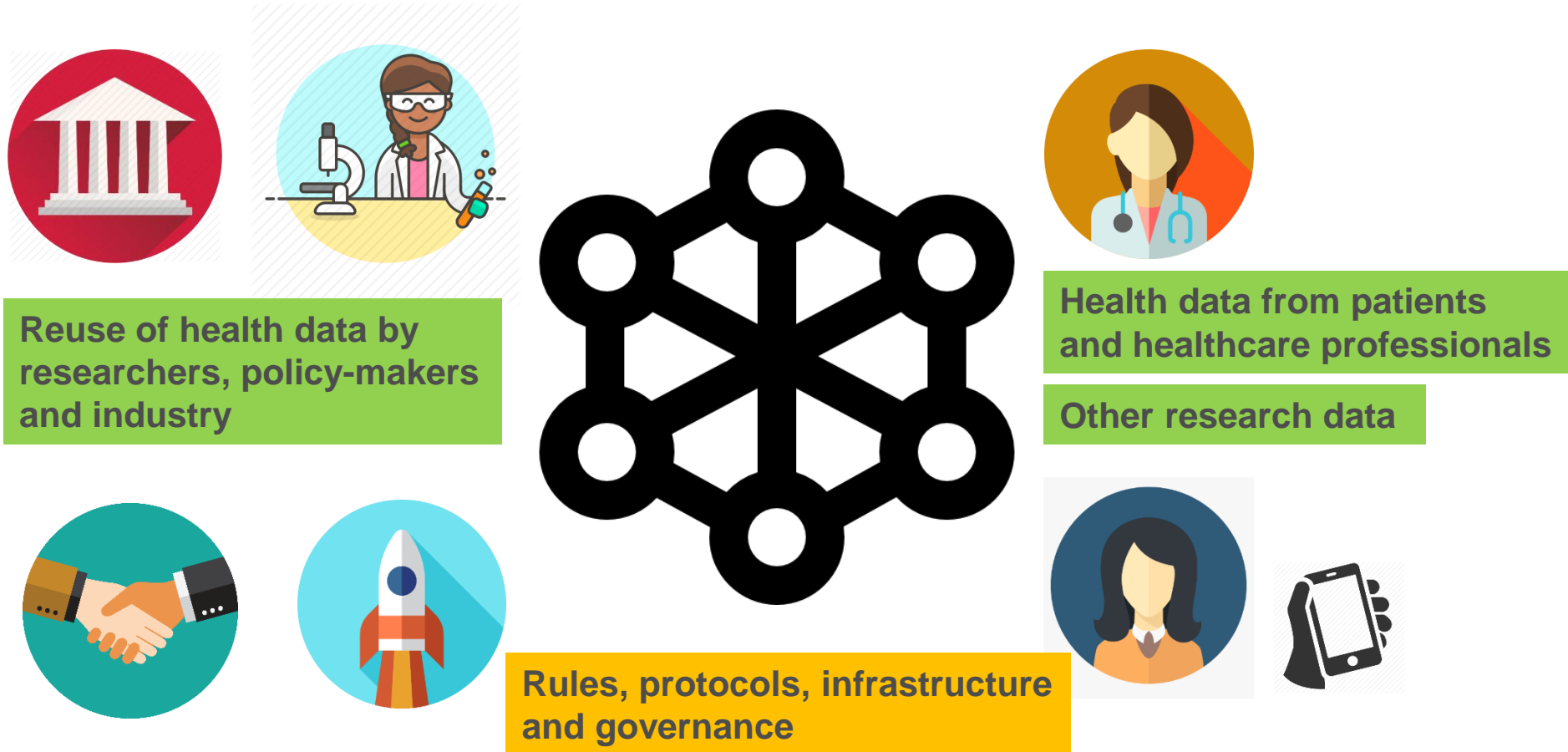
Incremental and selective approach

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

2. Use of data for research, policy making and AI

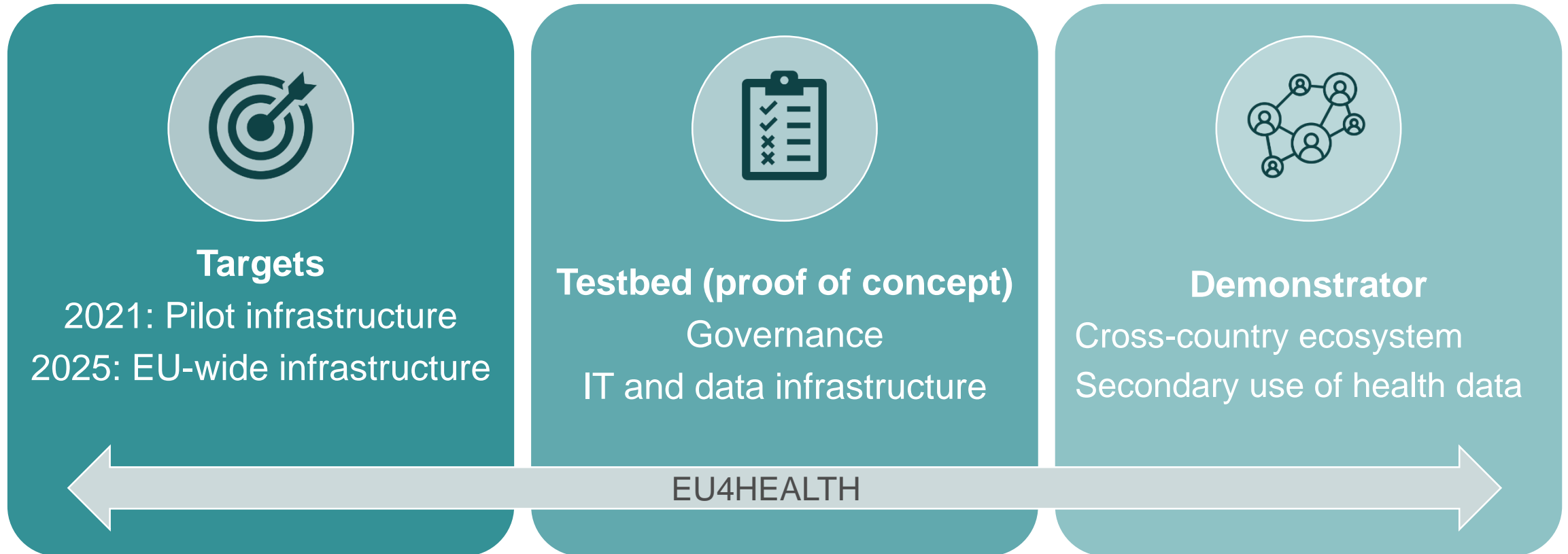
Secondary use of health data

Secondary use of data in the EHDS

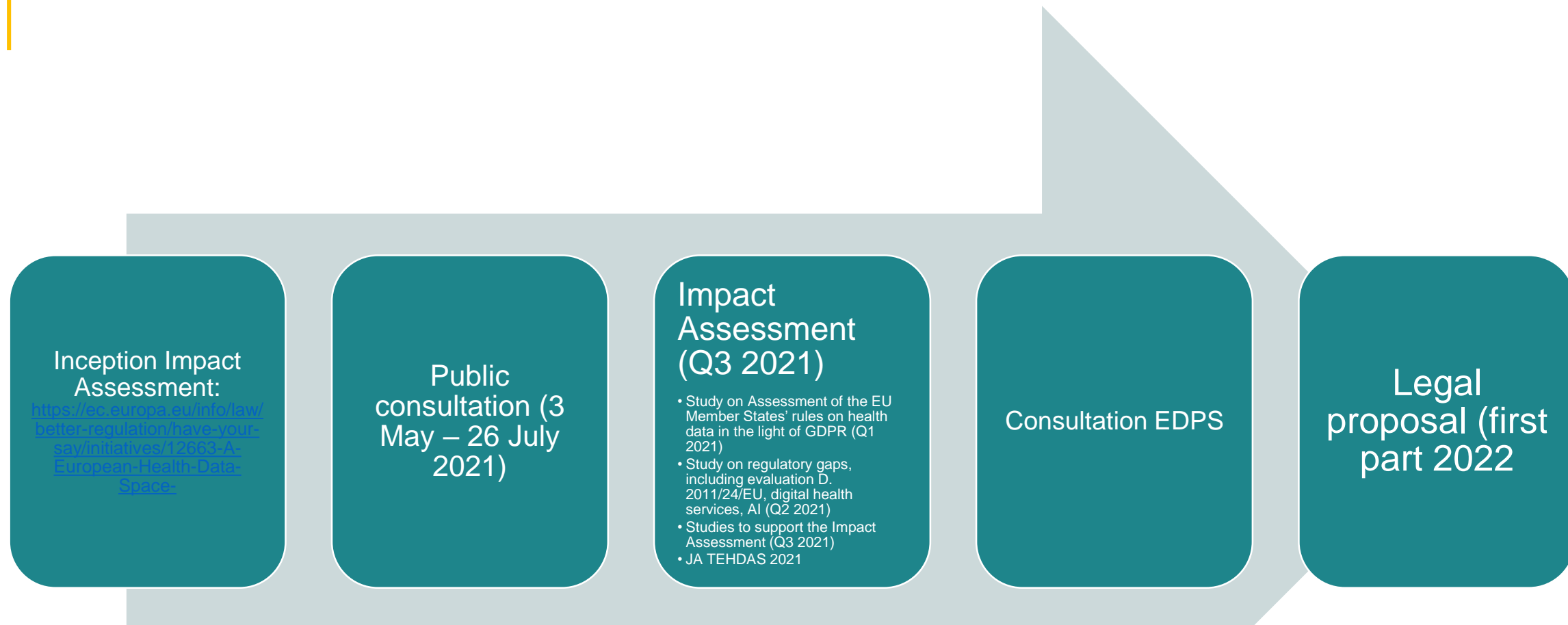


Granting researchers, policy-makers and industry access to health data across borders in an interoperable, digital format

Pilot project EHDS2: motivation



EHDS: next steps



Budget

National level investments

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

EU level investments

- EU4Health
- DEP
- Horizon Europe

Thank you



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