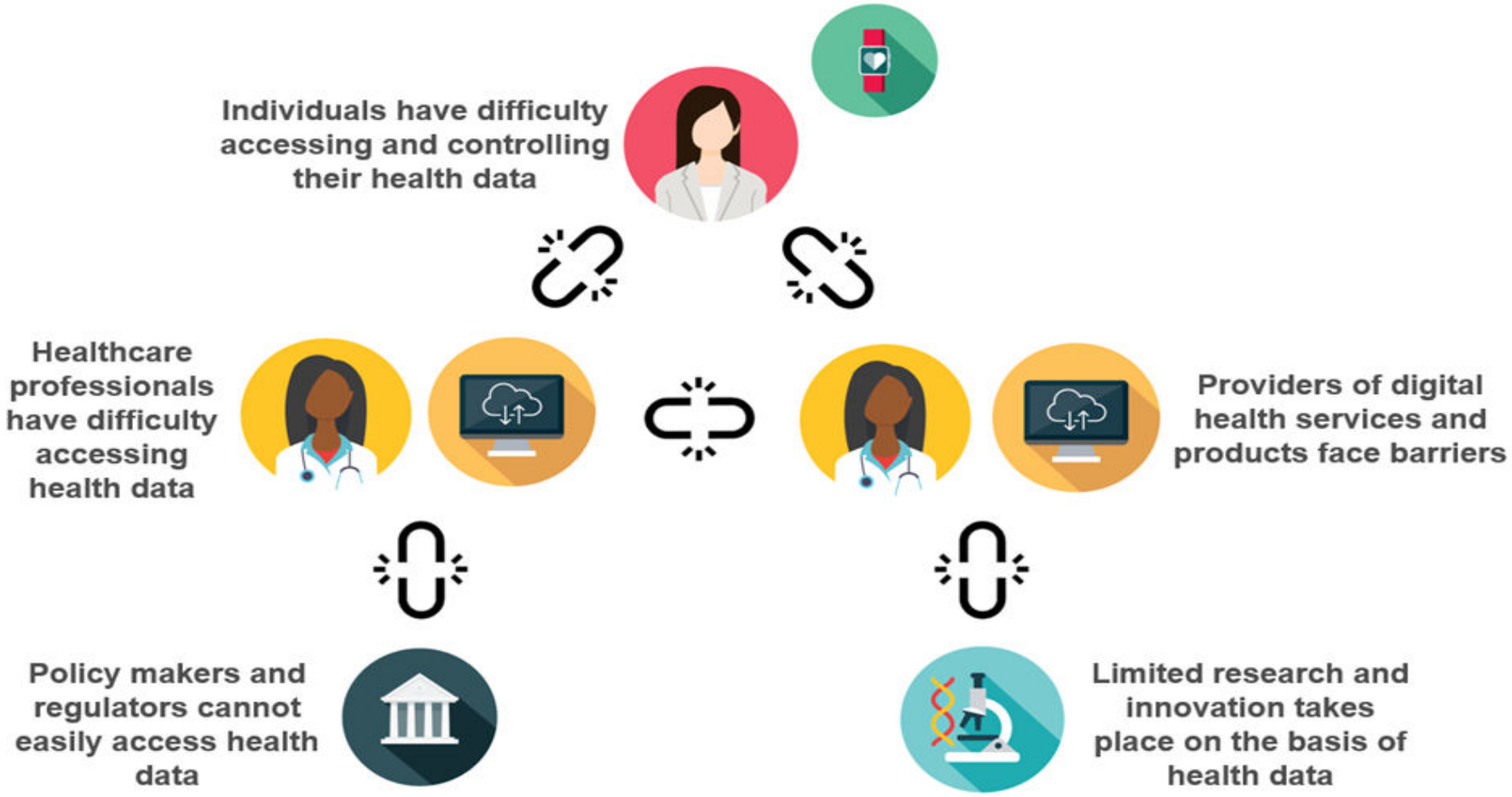
European Health Data Space

Harnessing the power of health data for people, patients and innovation

October,24th, 2023

Policy context

Main challenges in harnessing the power of health data



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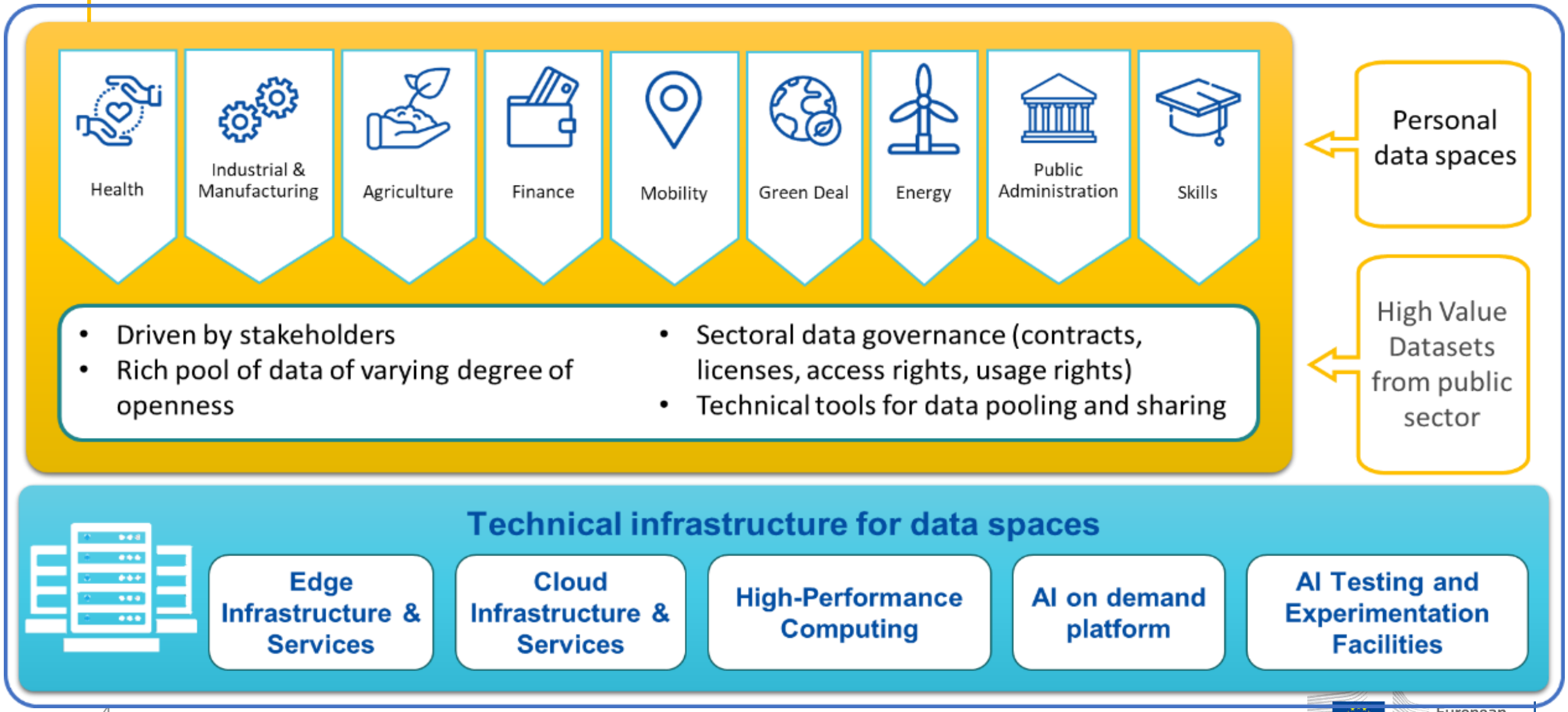
EHDS – **the first** sector specific European Data Space



European Health Data Space (EHDS)

OBJECTIVES

Effective use of health data

SCOPE & EXPECTED IMPACT

Use of health data (primary, MyHealth@EU)	• Empower individuals to control their data • European Electronic Health Record Exchange Format • Standardization and mandatory certification of EHR systems • Labelling of wellness apps	→ Single market for health data, data protection, free movement of people, digital goods and services
Re-use of health data (secondary, HealthData@EU)	• Health data access bodies • Purposes for use and forbidden use • Data permits, secure environments, no identification	→ Facilitated Research & Innovation → Better Policy Making

MEANS

- **Legal / Governance**
- **Quality of data**
- **Infrastructure**
- **Capacity building/digitalisation (MFF)**

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Primary Use of health data

For healthcare purposes

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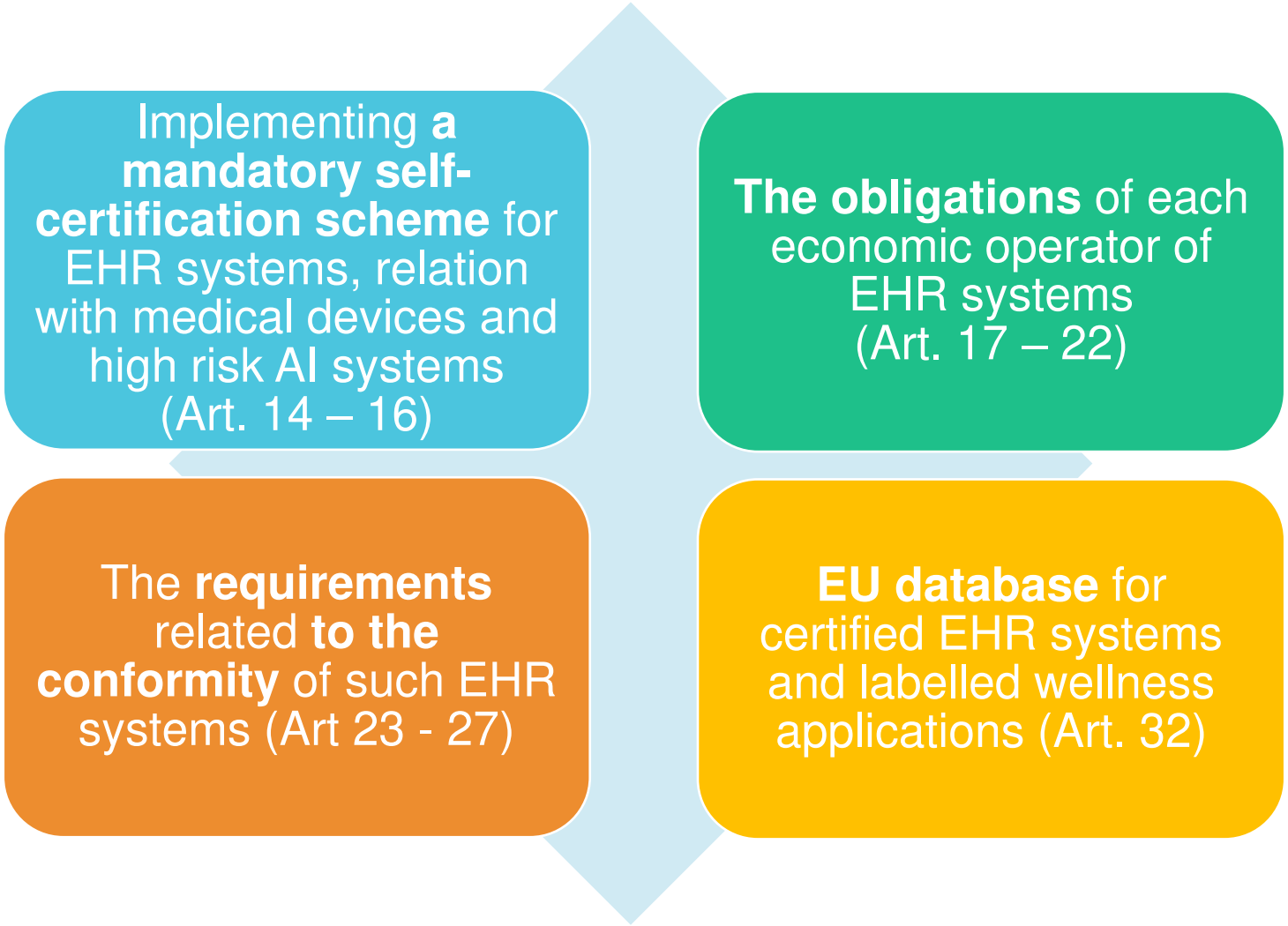
Chapter III
EHR systems and wellness applications



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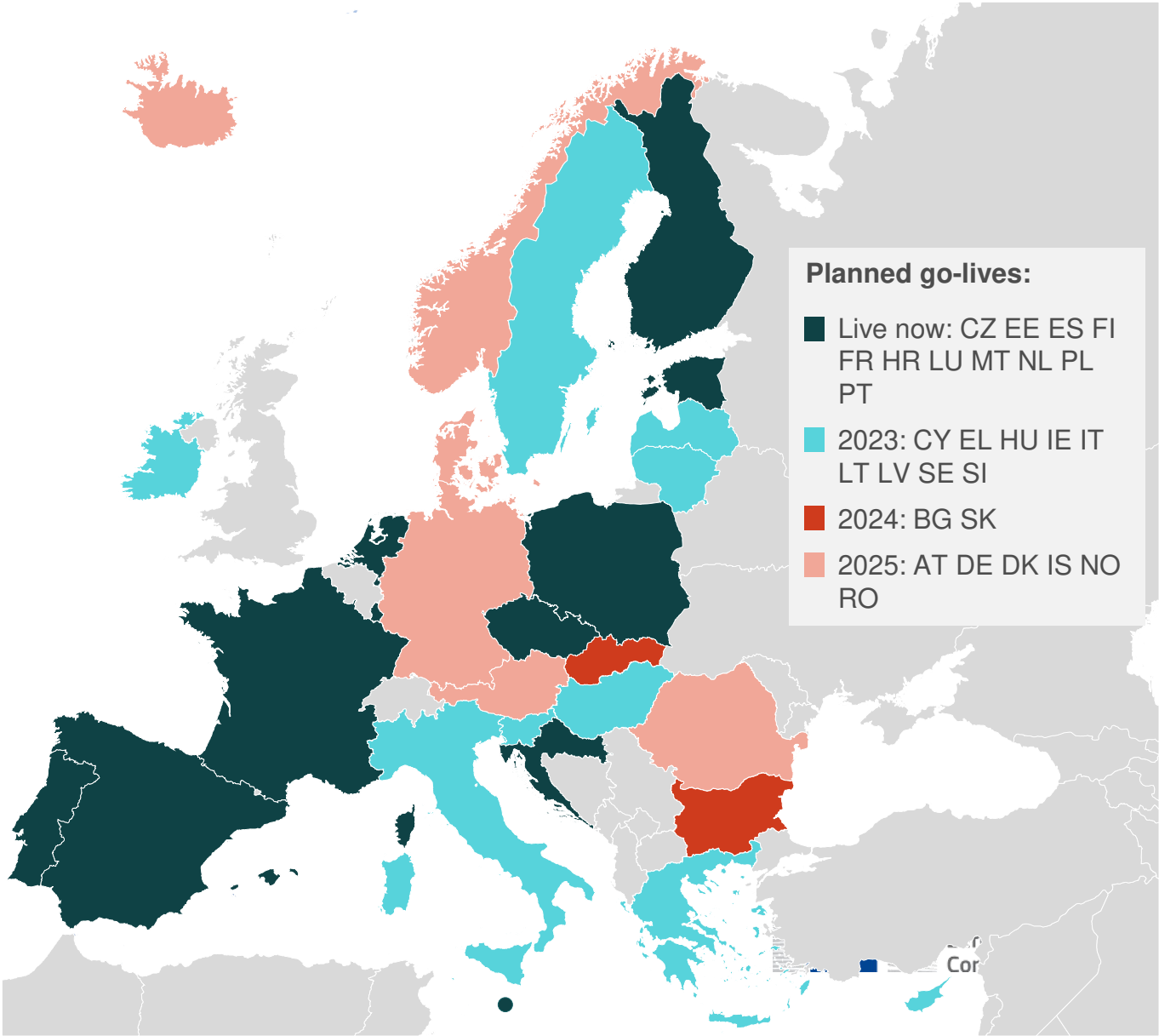
MyHealth@EU

MyHealth@EU is the existing infrastructure that connects healthcare providers in 11 Member States. It allows them to exchange health data such as Patient Summaries and ePrescriptions. These services will be expanded to include lab results and other types of health data.



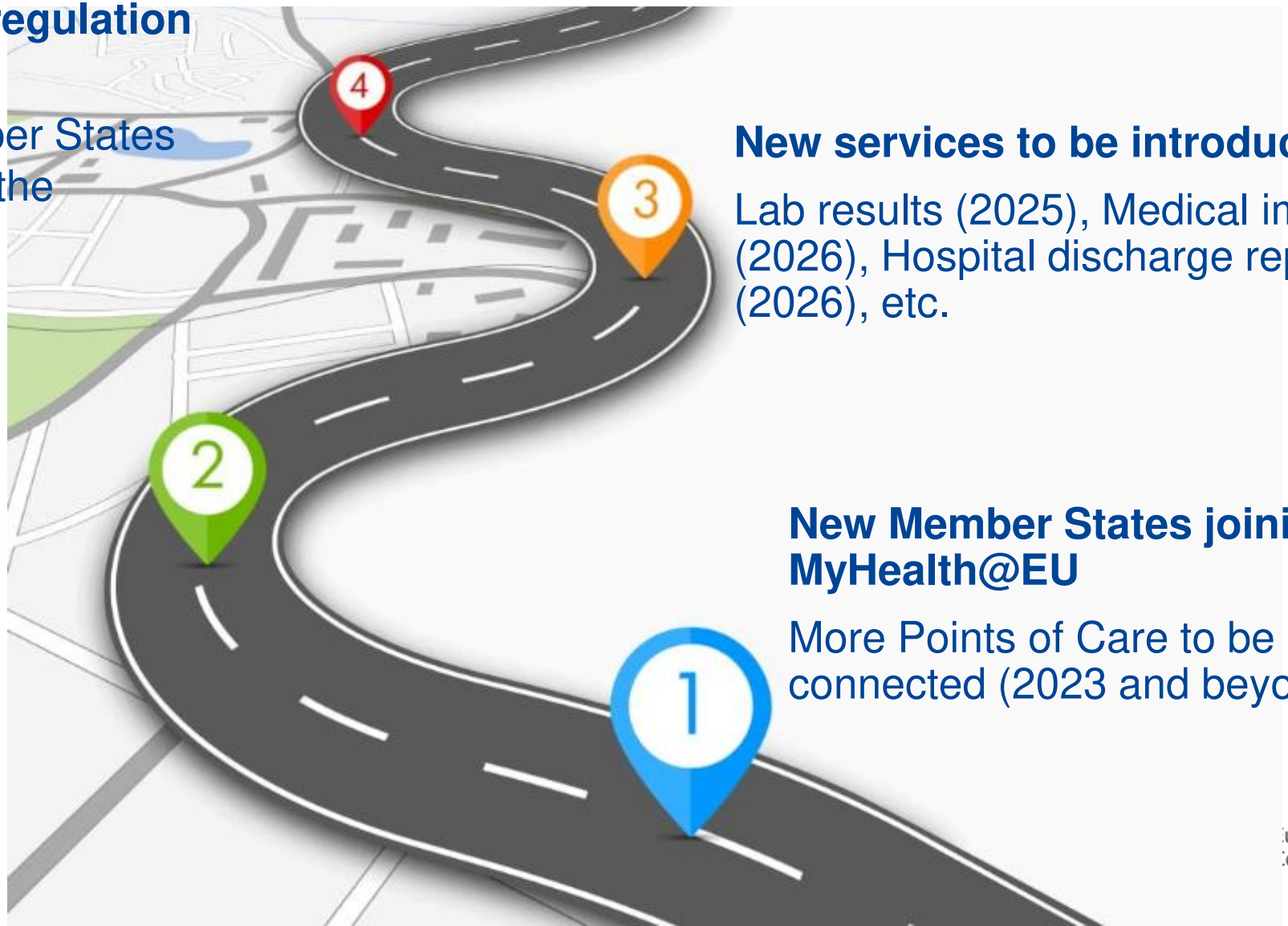
MyHealth@EU roadmap

Entry into force of EHDS regulation

Mandatory participation in MyHealth@EU for all Member States with transitional periods for the different services

Pilot on Patient Access

to enable citizens to access health data in MyHealth@EU (kick-off in January 2023).



New services to be introduced

Lab results (2025), Medical images (2026), Hospital discharge reports (2026), etc.

New Member States joining MyHealth@EU

More Points of Care to be connected (2023 and beyond)

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Secondary Use of health data

for policy making, regulatory activities, research, innovation and personalised care

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Chapter IV Secondary use of health data I

Defines **a set of minimum categories** of electronic data **for secondary use** that can be used for defined **purposes** (supporting policy making, regulatory activities, research, innovation and development of health products, training of AI algorithms eg for medical devices).

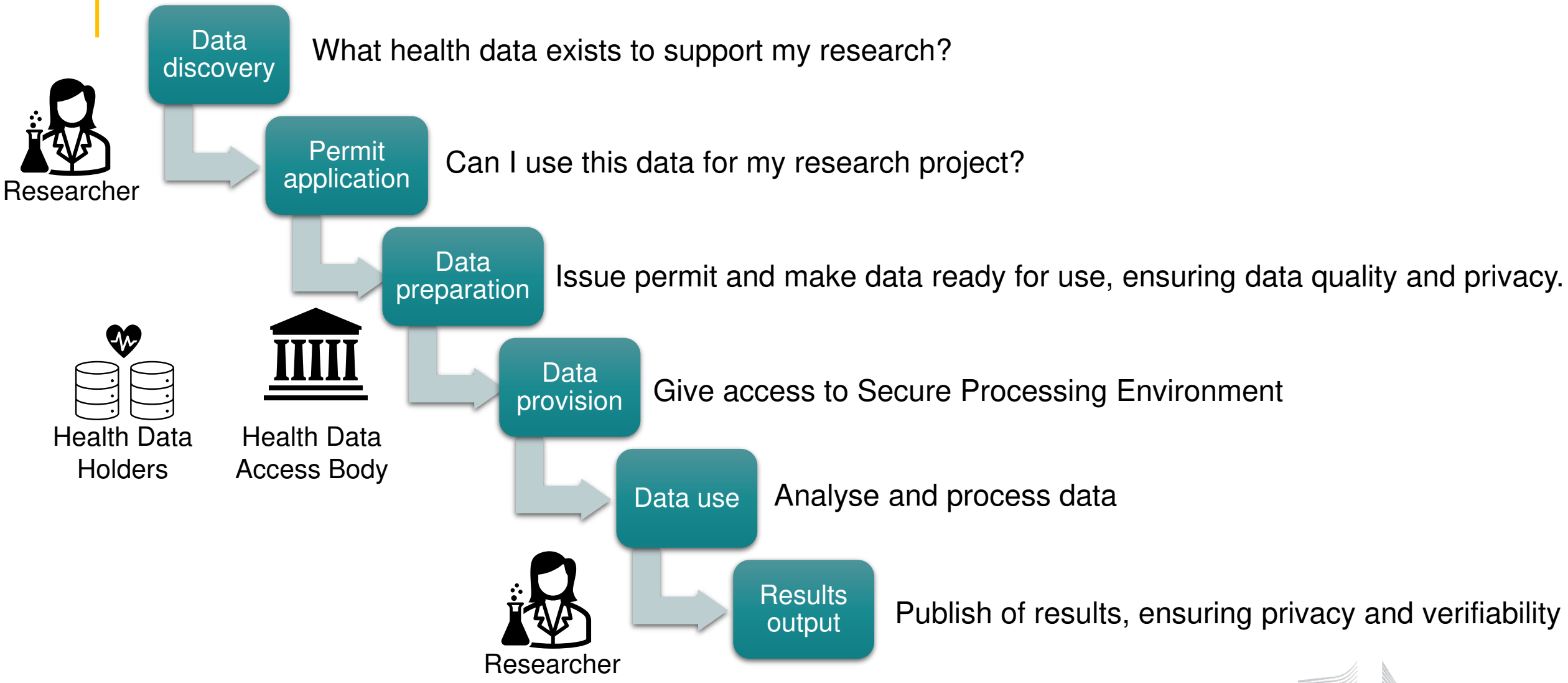
Defines **prohibited purposes** (eg use of data against persons, commercial advertising, increasing insurance, develop dangerous products) (Art. 33, 34, 35)

Set up a **health data access body/bodies** for secondary use of electronic health data (Art. 36) – *building upon the Data Governance Act*

The tasks and obligations of the health data access body, the data holders and the data users (Art. 37, 38, 39)

Sets **the duties for data holders** (Art. 41)

Overview of a generic data access approval process



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HealthData@EU

- **Pilot**
  - Kick-off: Oct 2022
  - Duration: 24 months
  - Budget: 10M€
  - Partners (17)
    - **HDABs**: FR, BE, DK, DE, NO, HU, HR, FI
    - **EU Health Agencies**: EMA; ECDC
    - **Data Holders and Data Users**: IACS, BBMRI, eBrains, Elixir, Orphanet, EUPHA
- **Scale up (HDABs set-up grants)**
  - **Applications deadline**: 31 Jan 2023
  - Kick-off: 2023 Q3
  - Duration:~ 36 months

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EHDS Webinars with researchers

- Secondary use of health data for research purposes (June 2023)
  - 1st webinar on “Data user journey / case specific for researchers: Summary of the presentations”
  - 2nd webinar: “Data discoverability & data access application process: Summary of the presentations”
  - 3rd webinar: “Secure processing environment & Governance: Summary of the presentations”

- Link to webinar recordings (available shortly):
  https://vimeo.com/channels/1618632/videos

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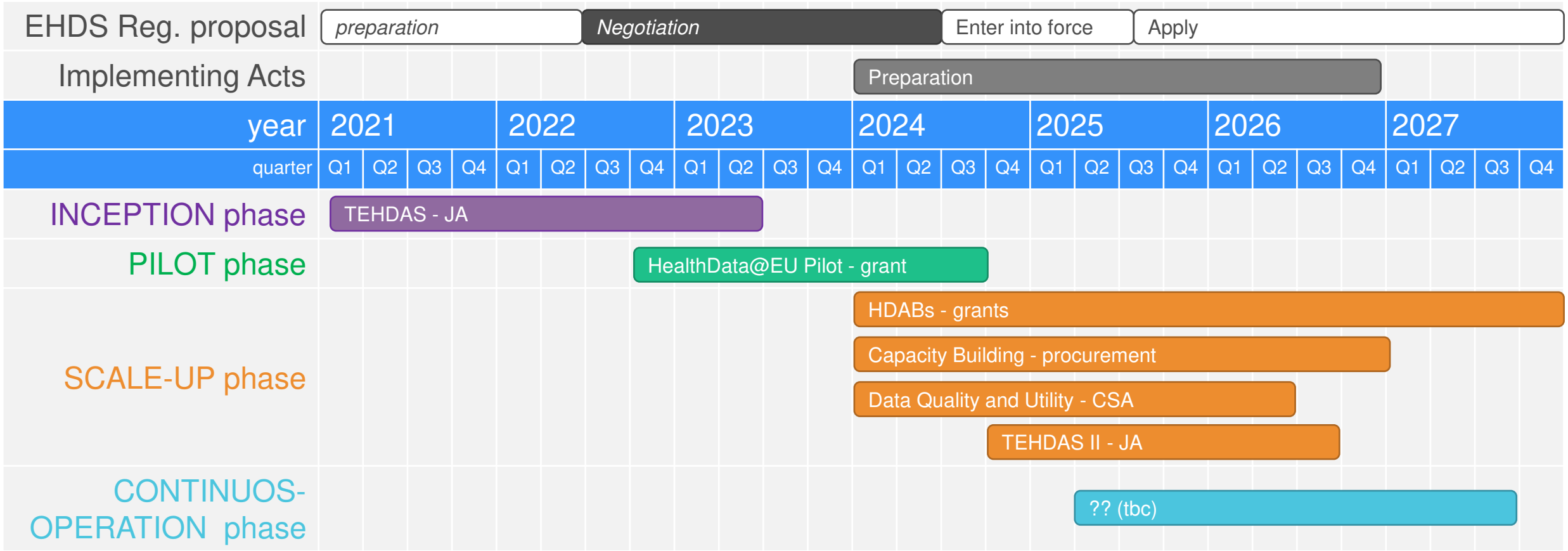
EHDS2 initiatives – landscape and timeline



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Thank you

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