European Health Data Space

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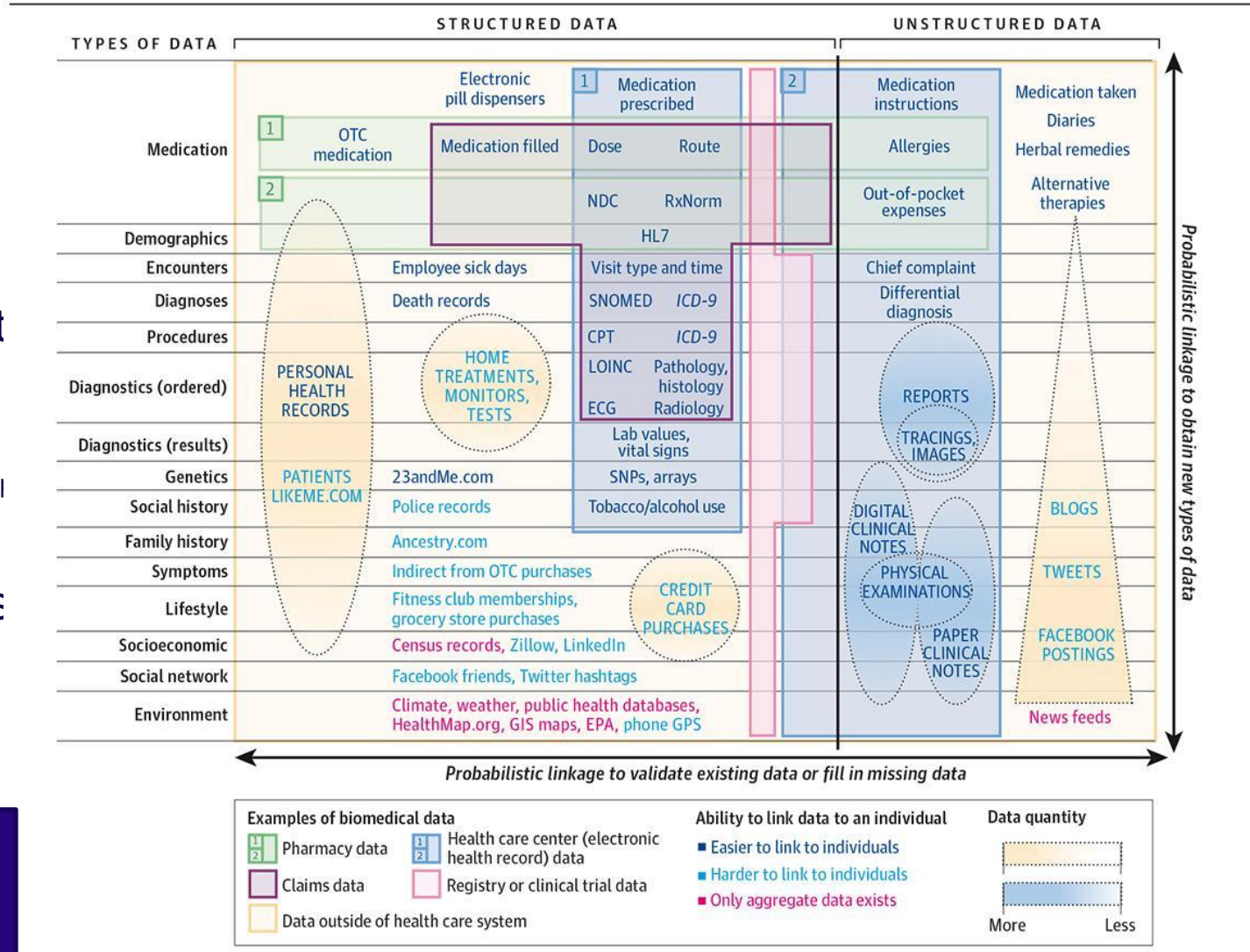
Professor with 20+years of experience in teaching and researching in Digital Health, Leadership and Management education for Medical Students and Health Professionals. He is past president of Portugal's Digital Health Agency (7 years), and former Member States co-chair of the EU eHealth Network, the highest policy body on eHealth in the Union. Currently he works as an Academic, on individual consulting projects in Digital Health. He is the Director of BRU-DHI at Iscte University and coordinator of the recently-ended XpanDH and recently-started XiA and i2X projects, among other initiatives such as the General-Secretariat for iH10 initiative (collaborating under Samsung Medical Center)

Health Data…

- Data about the individual's healt
- Secondary use data
  - National Registries
  - Data about health professionals capacity/system ca
- Public Health Data / Indicators
- World/Regional level data that is healthcare, world health

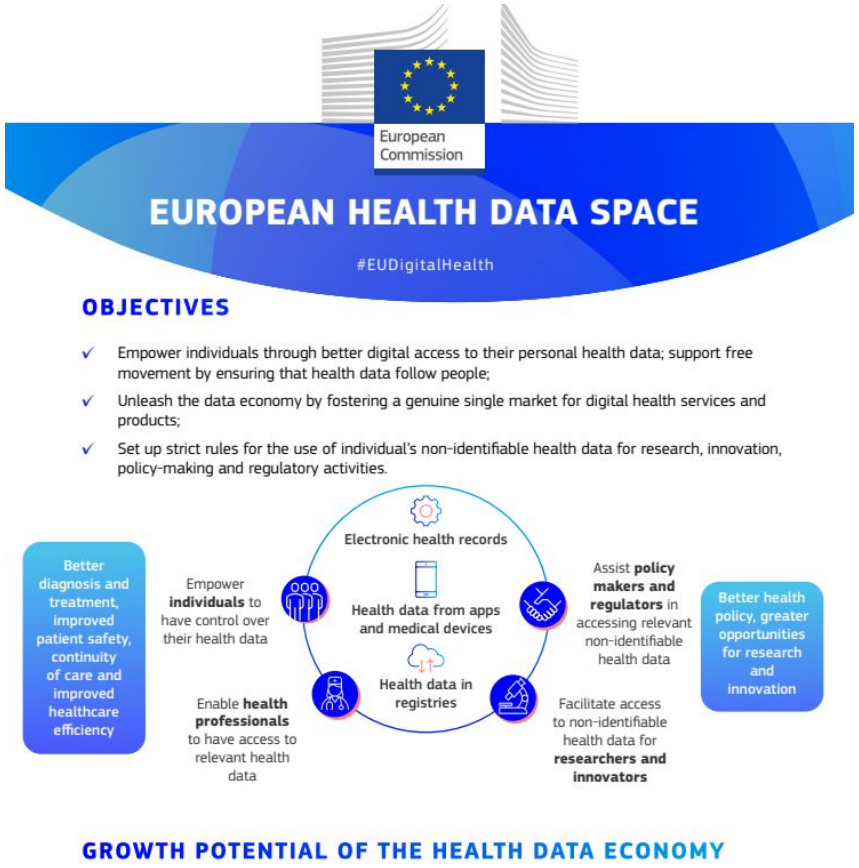
DATA LEVEL *Broad (public health) Data Types*

*Data on Communicable Disease (DCD)
*Data on Non-Communicable Disease (DNCD)
*Data on Health System (DHS)
*Data with Public Health Relevance (DPHR)



Source: https://www.openaccessgovernment.org/european-infrastructure-and-health-data-space/83393/

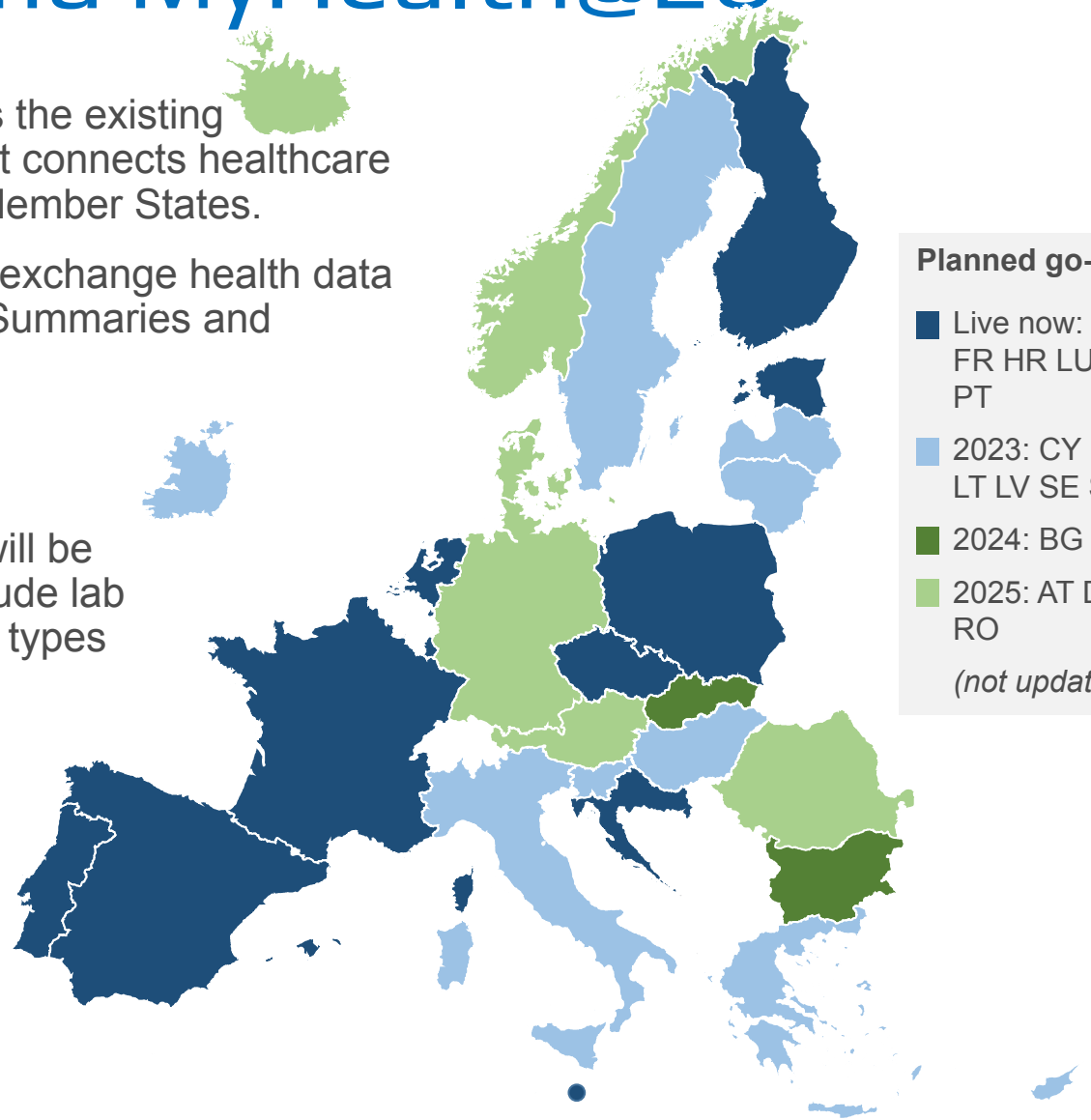
The proposal for EHDS and MyHealth@EU



MyHealth@EU is the existing infrastructure that connects healthcare providers in 16 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.



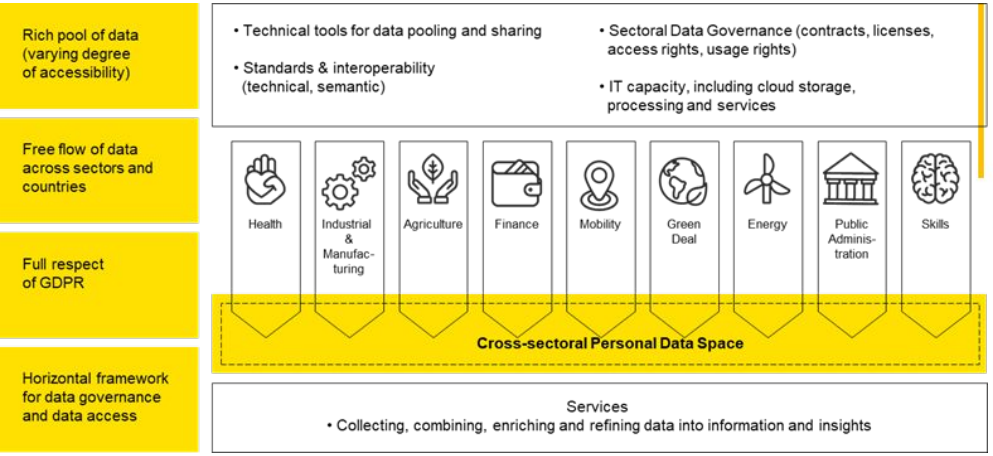
Planned go-lives:

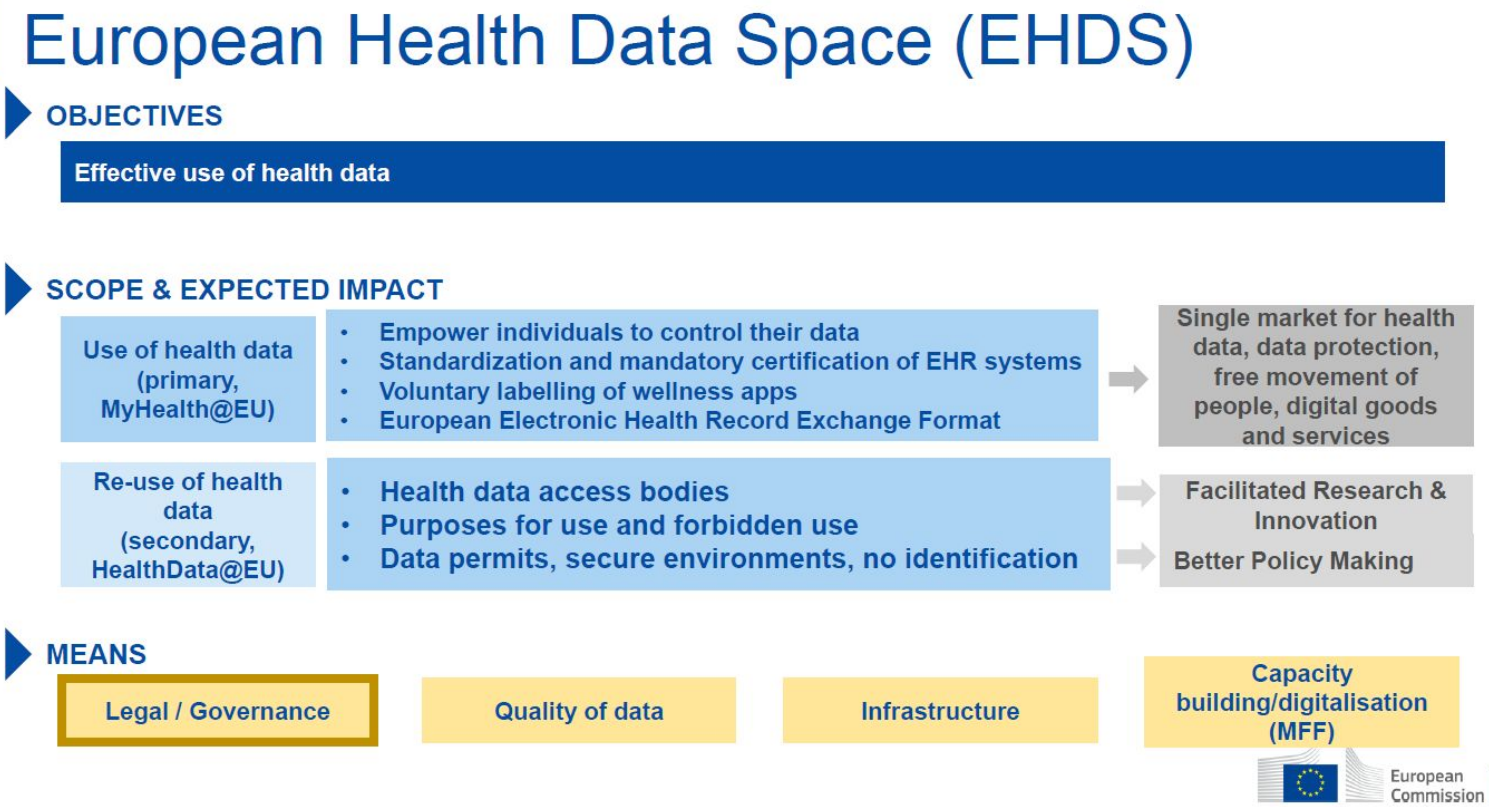
- Live now: CZ EE ES FI FR HR LU MT NL PL PT
- 2023: CY EL HU IE IT LT LV SE SI
- 2024: BG SK
- 2025: AT DE DK IS NO RO

(not updated)

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework

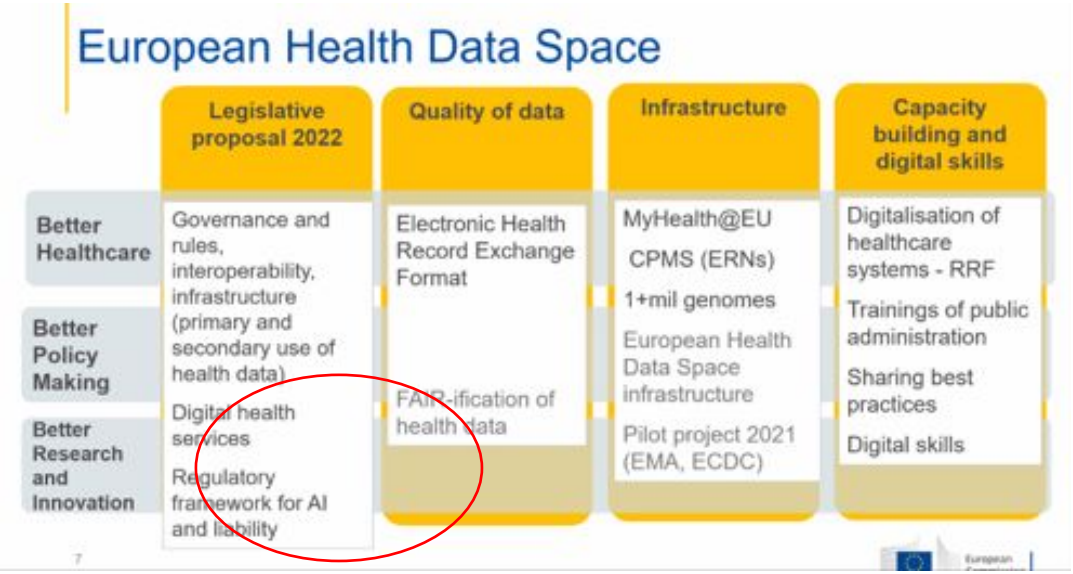
EHDS Proposal published 03/05/2022

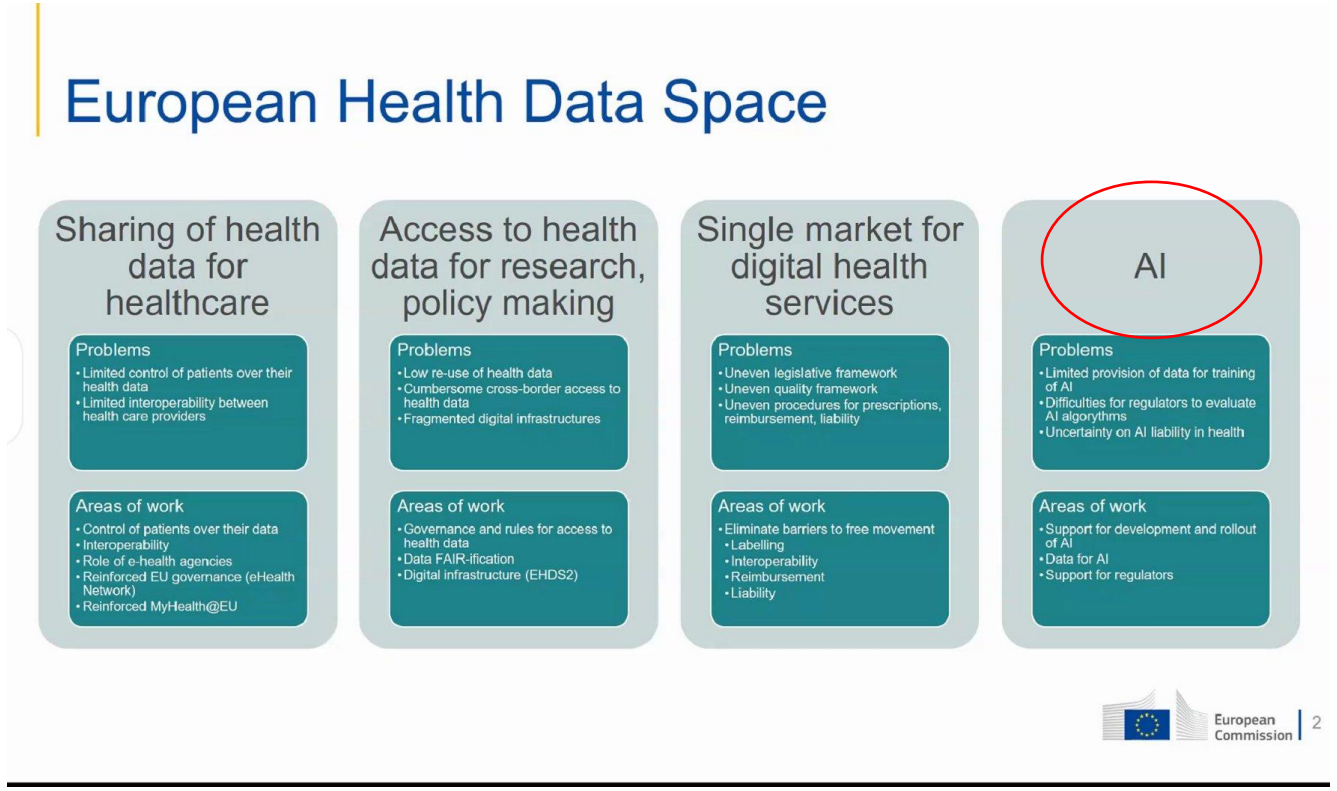




"Health" Data Space was the first to be legislated, much also because of previous work and COVID-19

EHDS and AI (and the AI Act)





EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare

- Improving patients' access to their health data;
- Ensuring seamless exchanges for continuity of healthcare – also across borders

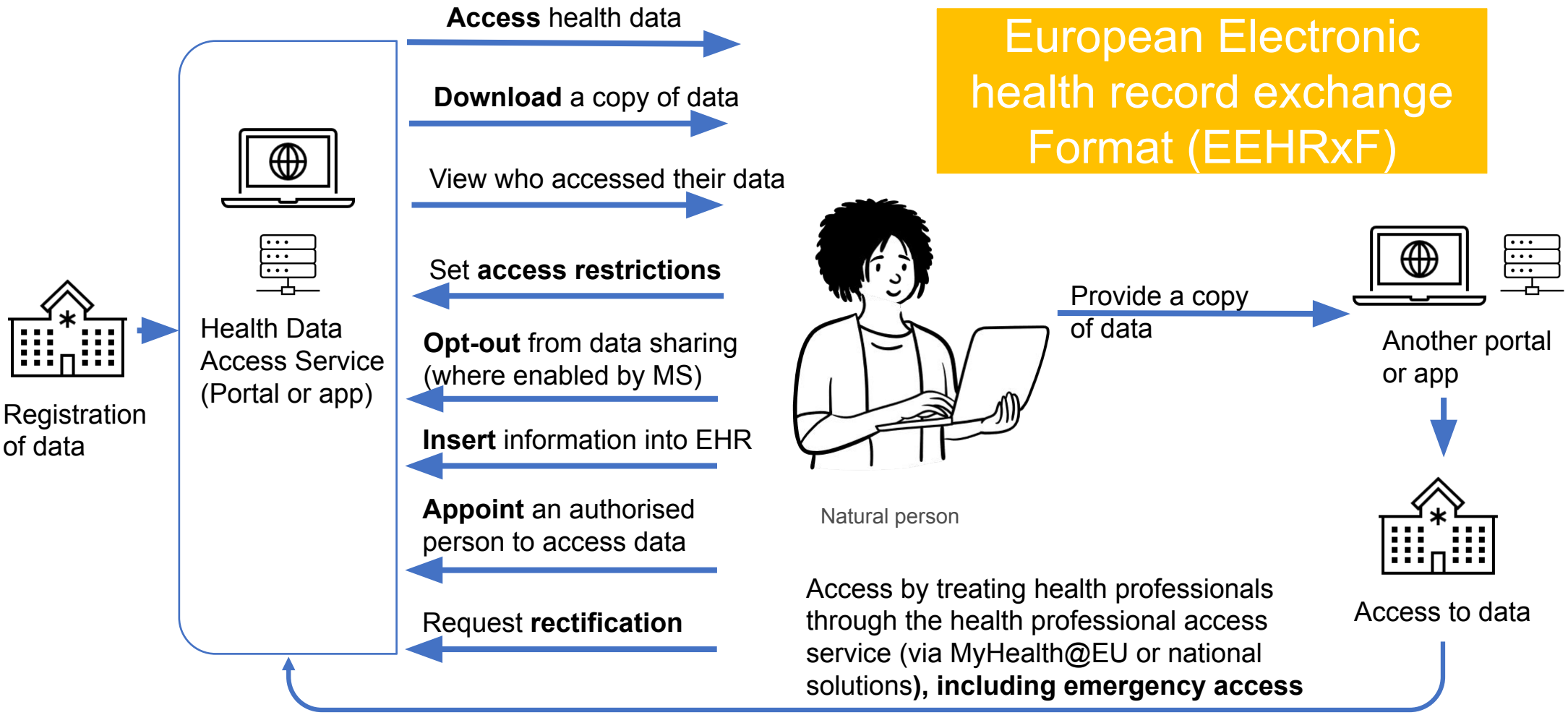
2. Secondary use = use of data for research and public interest purposes

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

3. Requirements for electronic health record (EHR) systems

- Creating a single market for electronic health records systems, supporting both primary and secondary

Rights of natural persons in primary use



Scope of harmonisation

EHR systems must contain **two harmonised components**, starting 2028/2030 depending on which kind of data they process:

Interoperability component

- Provides capability to import/ export data in EEHRxF

Logging component

- Provides capability to generate the logs of access

Member States remain free to have requirements on other parts of EHR systems, provided they do not interfere with the harmonised components

The exchange format (EEHRxF) – Art. 15

Article 15

European electronic health record exchange format

1. By … [two years from the date of entry into force of this Regulation], the Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 14(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. Such format shall support transmission of structured and unstructured health data and shall include the following elements:

   (a) harmonised datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;

   (b) coding systems and values to be used in datasets containing electronic health data;

   (c) technical interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles.

   The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).

2. The Commission shall, by means of implementing acts, provide regular updates of the European electronic health record exchange format to integrate relevant revisions of the healthcare coding systems and nomenclatures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

3. The Commission may, by means of implementing acts, lay down technical specifications to extend the European electronic health record exchange format to additional categories of personal electronic health data referred to in Article 14(1), third subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

4. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 14 are issued in the European electronic health record exchange format referred to in paragraph 1 of this Article. Where such data are transmitted by automated means for primary use, the receiving provider shall accept the format of the data and be able to read them.

Priority categories

- Group 1

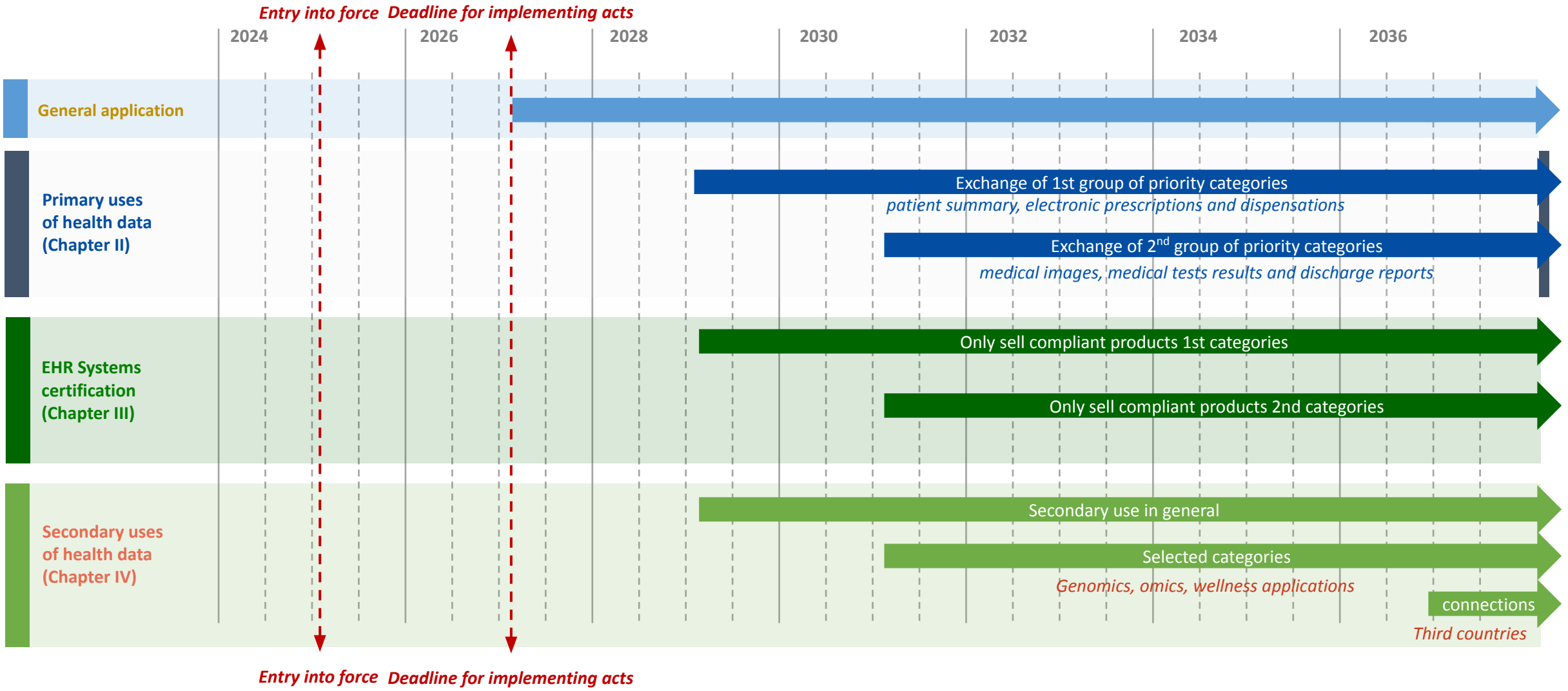
- Patient summaries
- Electronic prescriptions
- Electronic dispensations

- Group 2

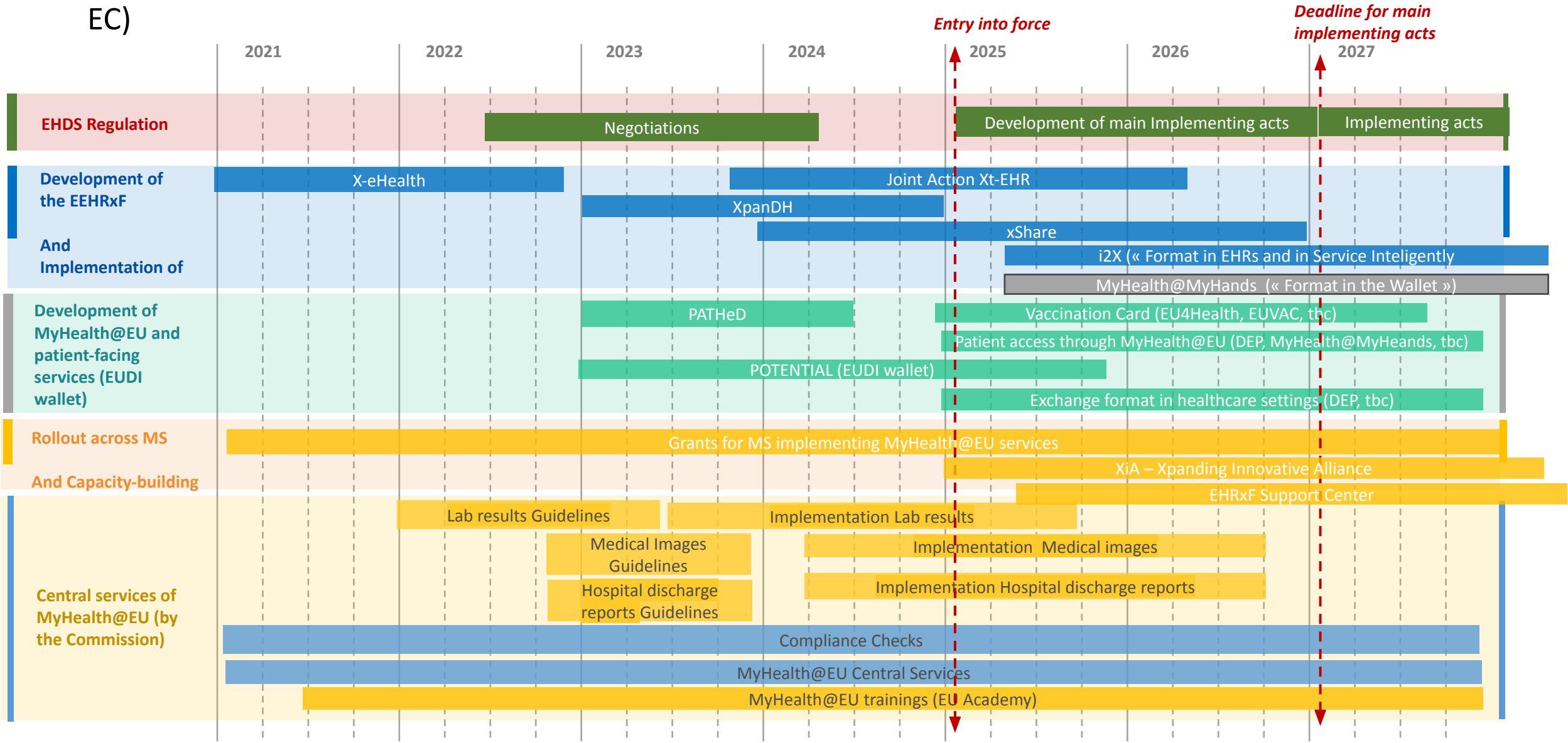
- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

Implementation of the EHDS Regulation

Timelines are indicative.



Primary use of health data: Implementation (adapted from EC)



Three key actors in the secondary use

- Data user:
  - *A data user is someone or some organisation that has been granted permission by a health data access body to use certain health data for specified purposes*
- Data holder:
  - *Any public or private entity that has the right or obligation to make electronic health data available. Micro- and small enterprises are excluded.*
- Health Data Access Body:
  - *National authority in each EU Member State responsible for managing access to electronic health data for secondary use*

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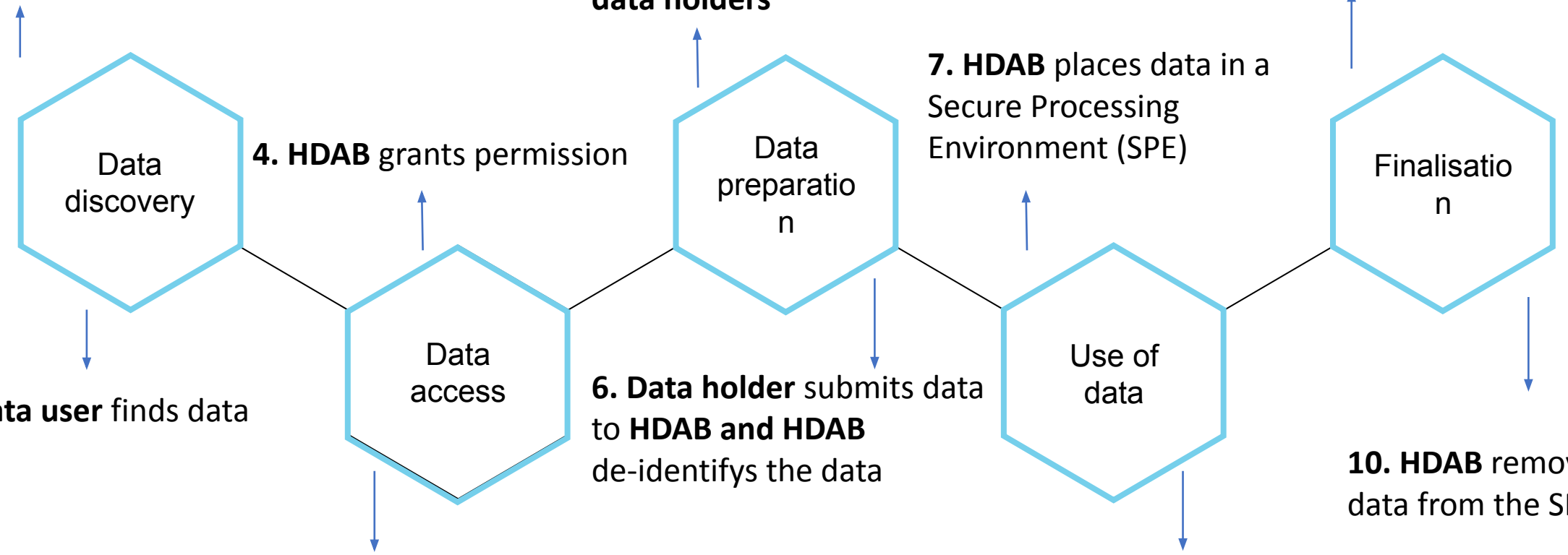
EHDS 10-step user journey



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