

IHE[®] | EXPERIENCE | 3-4 EUROPE | DAYS | JUNE 2024

EU Initiatives in Digital Health

Sponsored by



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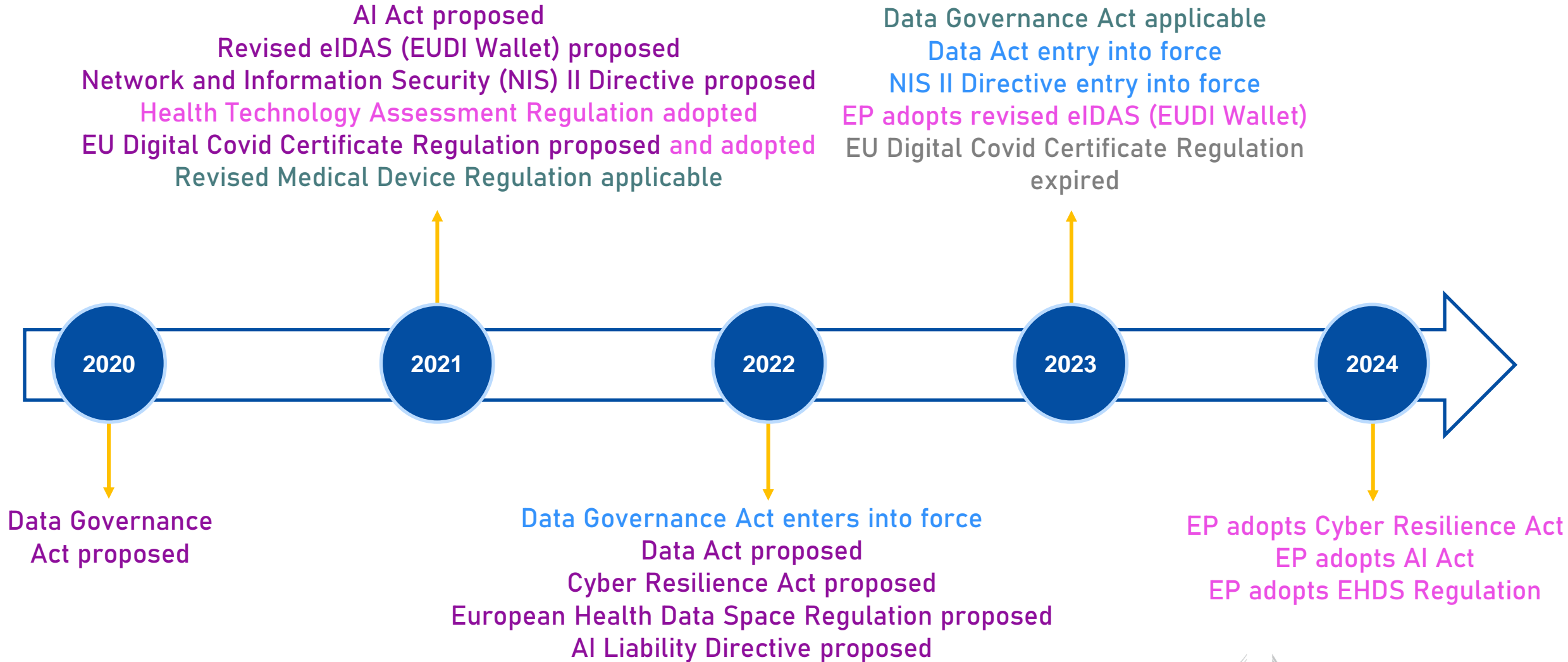
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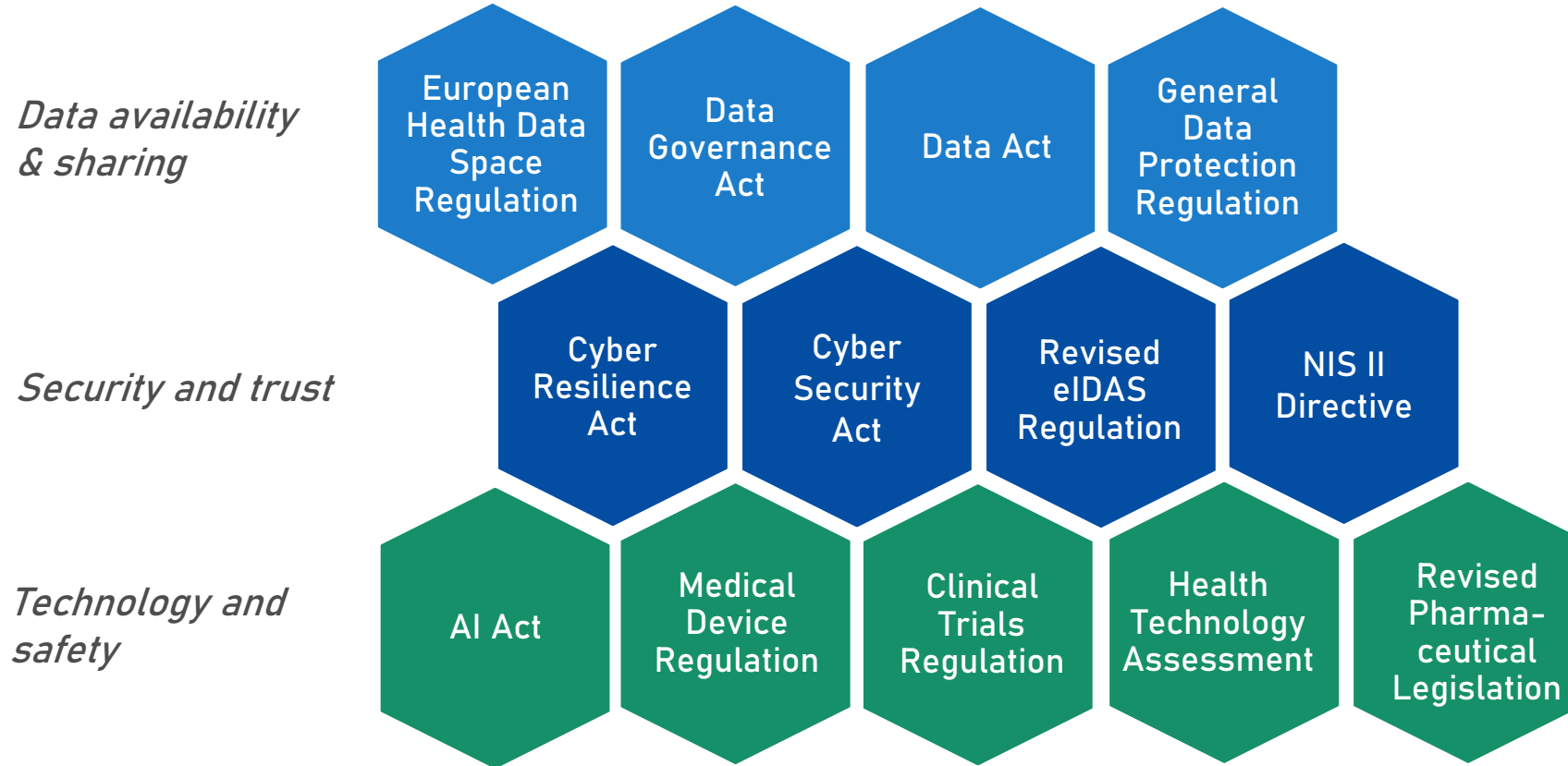
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Legislative developments & funding





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e-Health target: 100% of EU citizens access to **electronic health records** by 2030

Horizon Europe (2021-2024)

€549m



Digital Europe (2021-2024)

€129m



EU4Health (2021-2027)

€270m



Innovative Health
Initiative (IHI) 2021-2027

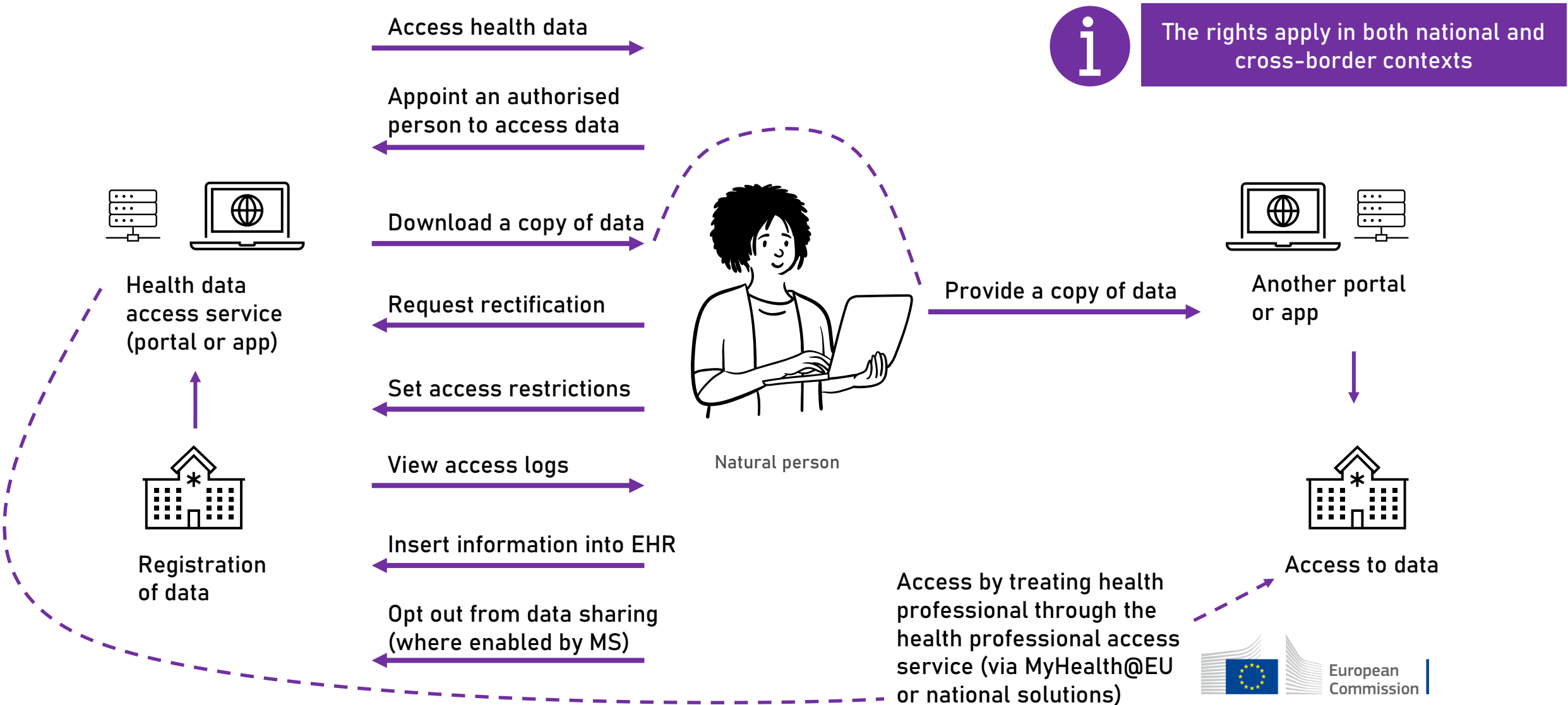
€351m under Horizon
Europe to date

European Health Data Space

- 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.
- 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.
- 3. Requirements for EHR systems**
 - Creating a single market for electronic health record systems.



The rights apply in both national and cross-border contexts



Priority categories

- Patient summaries
- Electronic prescriptions
- Electronic dispensations
- Medical imaging: studies and reports
- Medical test results: laboratory, other diagnostics, related reports
- Discharge reports

Full implementation of the rights of natural persons *shall* be ensured.

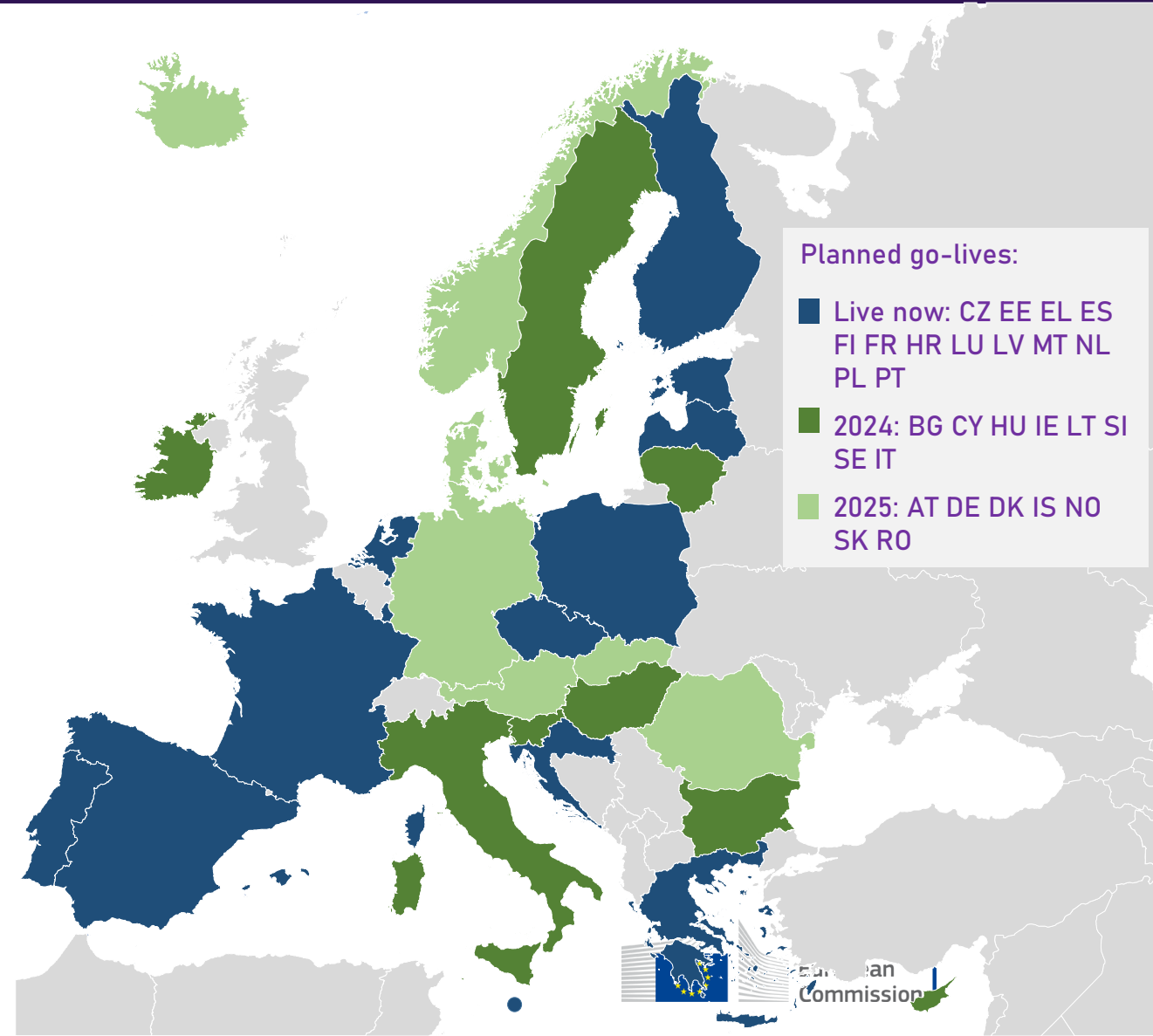
Additional data categories

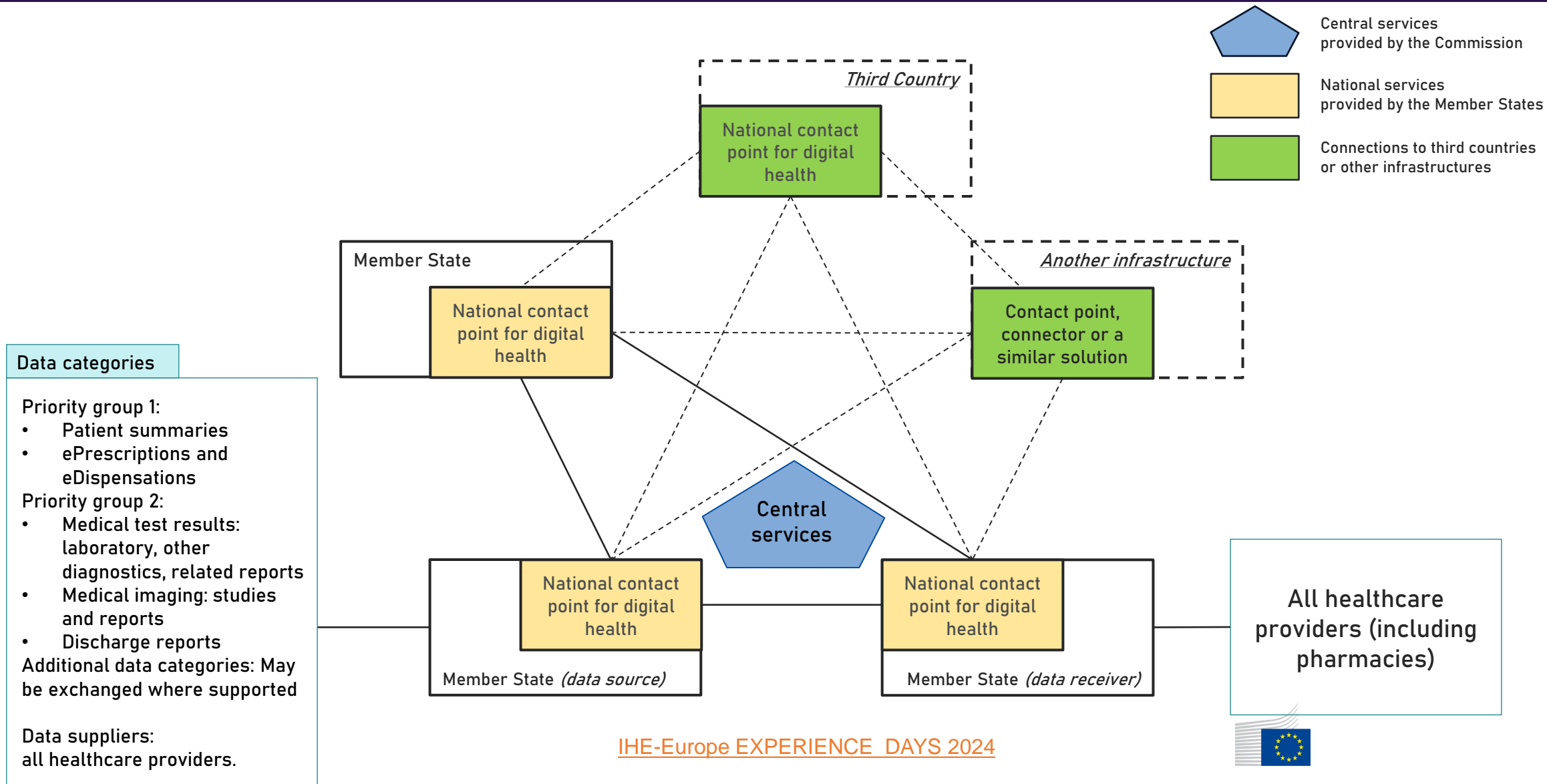
- *May* be defined by MS
- When defined, all rights of natural persons *shall* be implemented at national level in respect to these
- Support *may* be included in the European format
- *May* be exchanged through MyHealth@EU (where supported)

MyHealth@EU is the existing infrastructure that connects healthcare providers in 13 Member States.

The current live services are: (1) Patient Summaries and (2) ePrescription and eDispensation.

These services will be expanded to all priority data categories in EHDS.





EHDS Article 6:

Shorter version:

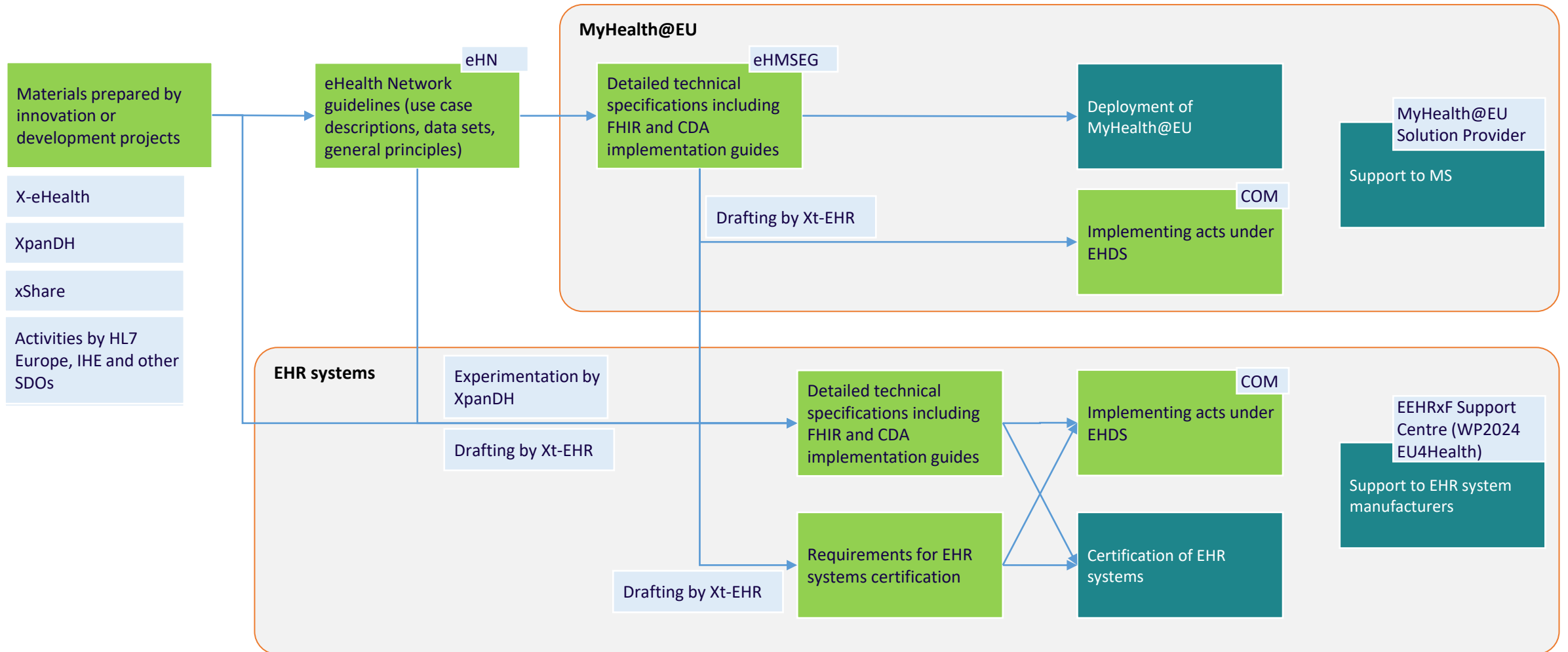
The EEHRxF is a set of technical specifications targeted at ensuring the interoperability of electronic health record systems used on the Union market

- ...
- 1a. The Commission shall provide regular updates of the European acts to integrate relevant revisions of the healthcare coding system
 - 1a. The Commission may, by means of implementing acts, lay down the health record exchange format to additional categories of electronic health records. Implementing acts shall be adopted in accordance with the examination procedure referred to in Article 66(2).

lay down the technical specifications for the priority categories of electronic health records, laying out the European electronic health record exchange format. The format should allow transmission of personal electronic health data between Member States. The format should support transmission of structured and unstructured data elements:

The European electronic health record exchange format is a powerful tool.

Common specifications (implementing acts under Article 23) are to further define the requirements for EHR systems regarding the support of the format (among other requirements).



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

Interoperability component

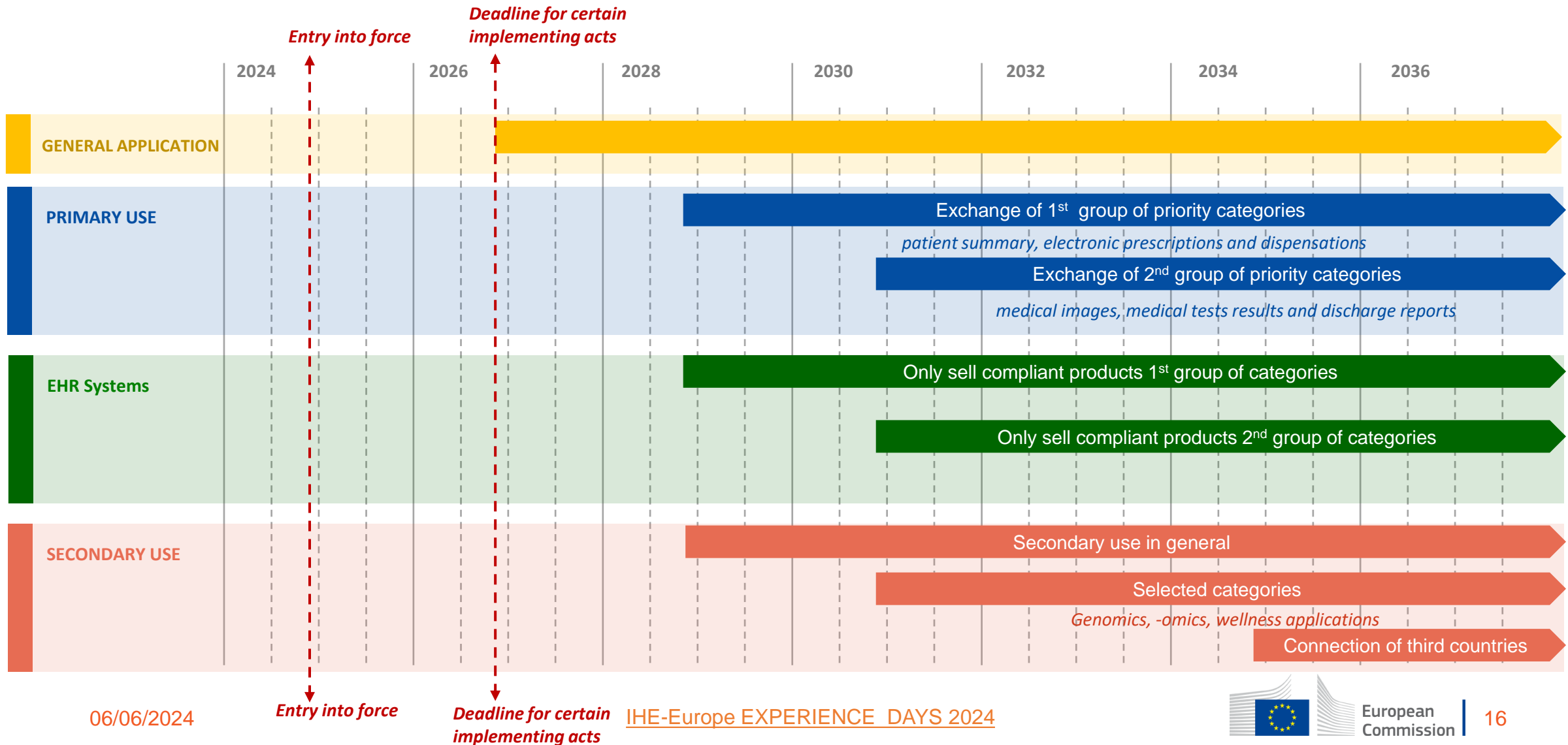
- Provides capability to issue and accept data in EEHRxF as per Art. 6

Logging component

- Provides capability to generate the logs of access as per Art. 8f

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

EHDS – Overall timeline for application



Research infrastructures

1+ Million Genomes Initiative



Cancer Imaging Initiative



Virtual Human Twins Initiative



Access to **genomics** and the corresponding **clinical data** across Europe for better research, **personalised healthcare** and health policy making

- 1+ Million Genomes Declaration (2018), 25 EU countries, the UK and Norway
- Digital Europe co-funding EUR 20 million for the Genomic Data Infrastructure (GDI) (+ EUR 20 million from Member States)
- Currently GDI includes organisations in 24 European countries
 - Technical readiness of 15 countries by 2026



Genome of Europe

- High-quality European network of **national genomic reference cohorts**, representative of the European population
- A **unique genomic reference** for biomedical research, healthcare and public health, covering 100 000 whole genomes
- **EUR 20 million** co-funding from the Digital Europe programme (+**EUR 25 million** from Member States)



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1+ Million Genomes: sustainability and uptake

- Coordination and Support Action under the **Digital Europe Programme (EUR 2 million)**
- Support towards **healthcare implementation** of genomic medicine
- Support preparatory work for the creation of an **EDIC** (European Digital Infrastructure Consortium)

- Harness the potential of **cancer imaging** data and **Artificial Intelligence** to combat cancer
- Digital Europe co-funding (EUR 18 million)
- Link resources and databases to establish an **open infrastructure** of cancer images
- Foster innovation and deployment of digital technologies, including **AI tools**, for better clinical **decision-making**, **diagnostics**, **treatment** and **prediction**

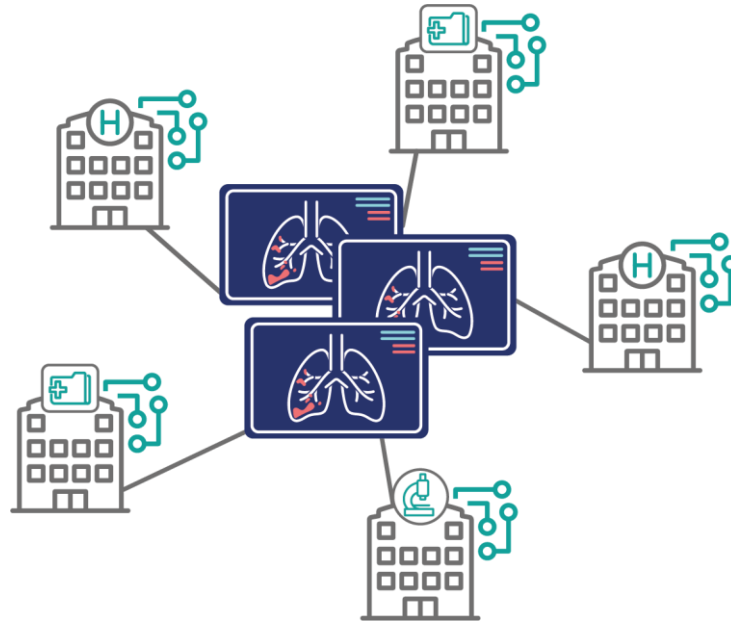


Public catalogue of 39 datasets

From the "AI4HI" network of EU-funded projects

Approx. 20 000 subjects
> 200 000 image series*

9 cancer types
breast, colon, lung,
prostate, rectum, liver,
glioma, neuroblastoma,
glioblastoma



21 clinical sites from 12 countries

30+ data providers from 15 countries by 2026

EDIC for the Cancer Image Europe Platform – working group *launched*

- An EU framework supporting the emergence, market entry and clinical adoption of virtual human twin solutions in healthcare
- Virtual Human Twins Manifesto – December 2023
- European Virtual Human Twin EDITH project, DIGITAL
- 8 actions on integrated, multi-scale VHTs for personalised disease management, Horizon Europe (EUR 80 million)
- State-of-the-art digital platform for advanced VHT models integration and validation, DIGITAL (EUR 24 million)



Artificial Intelligence – shaping the future of digital health

Communication on boosting startups and innovation in trustworthy artificial intelligence (January 2024)

Foster an innovative European AI ecosystem for startups and innovators, including in health

- Strategic investment framework for **trustworthy AI**
- Financial support for **GenAI** through Horizon Europe and Digital Europe Programme
- Initiatives to boost up **skills** on GenAI

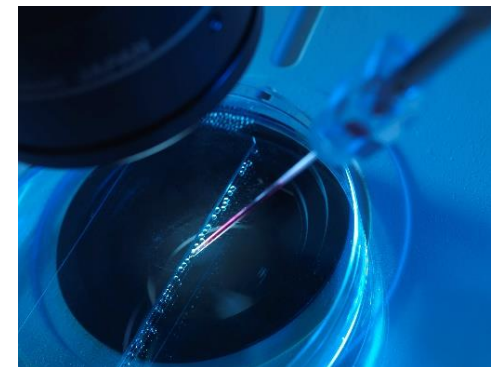


06/06/2024

Communication on boosting Biotechnology and Biomanufacturing in the EU (March 2024)

Push the application of AI, in particular GenAI, in health biotech and biomanufacturing

- Biotech and biomanufacturing companies using AI benefit from the “**AI innovation package**”
- Support the development of advanced **GenAI models**, through health data **infrastructures** & **Euro HPC supercomputing**



GENAI4EU

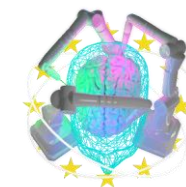
- Stimulate the uptake of **GENAI** in key sectors – including healthcare
- Development of **novel use cases** and emerging **applications**
- **Collaboration** between AI startups, industry, public sector

AI Factories

- Privileged access to **supercomputers** to AI startups – including in healthcare
- **One-stop-shops** to test & validate large-scale AI models and solutions
- Linked to **TEF-Health** for pre-market validation



- Launched January 2023, co-funded under DIGITAL (EUR 60 million over 5 years)
- Support developers in healthcare AI and robotics **bring their solutions to the market**
- Assisted **validation** and **certification** of AI and robotics in medical devices
- **Regulatory sandboxes** to test AI solutions in controlled real-world environments



TEF-Health

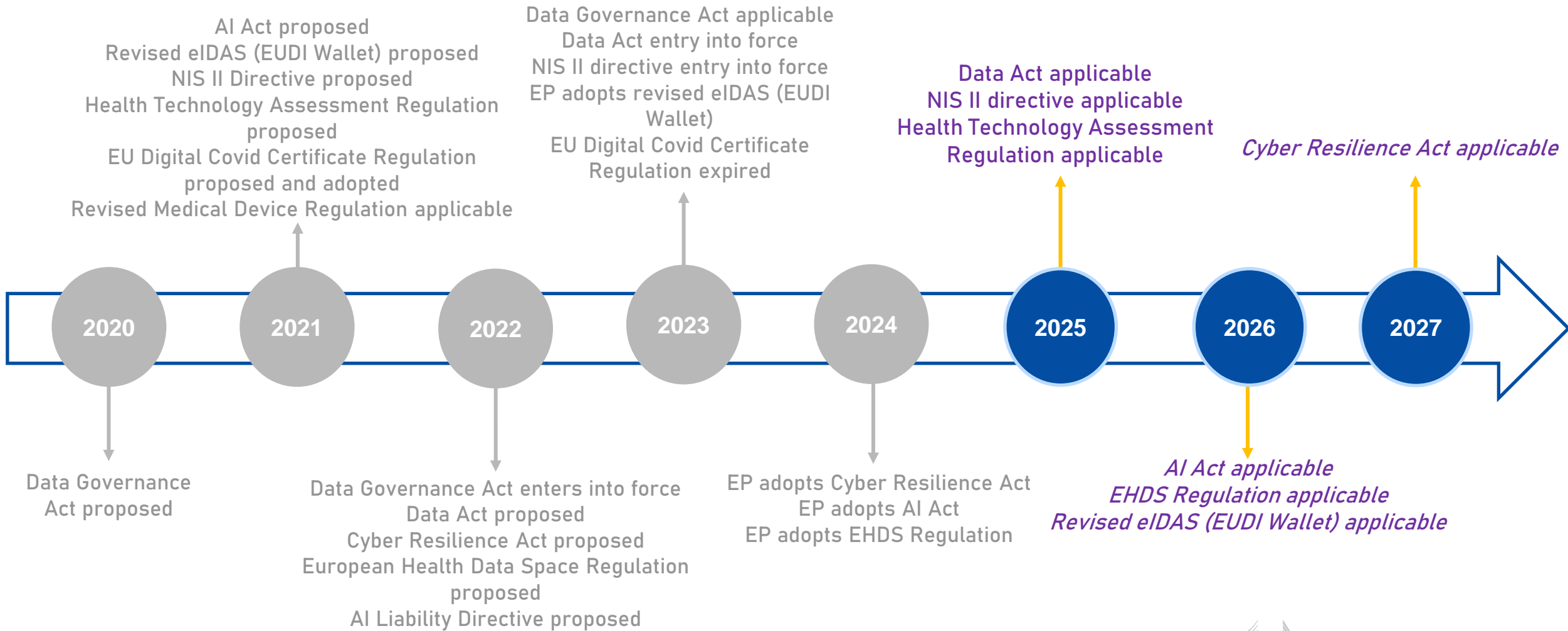
Testing and Experimentation Facility
for Health AI and Robotics

- AI innovators can test their solutions in a controlled environment, in compliance with the AI Act
- Priority access to SMEs
- At least one sandbox in each Member State
- Leverage TEF-Health facilities



What's next?

Ensuring timely and effective implementation



Thank you!



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