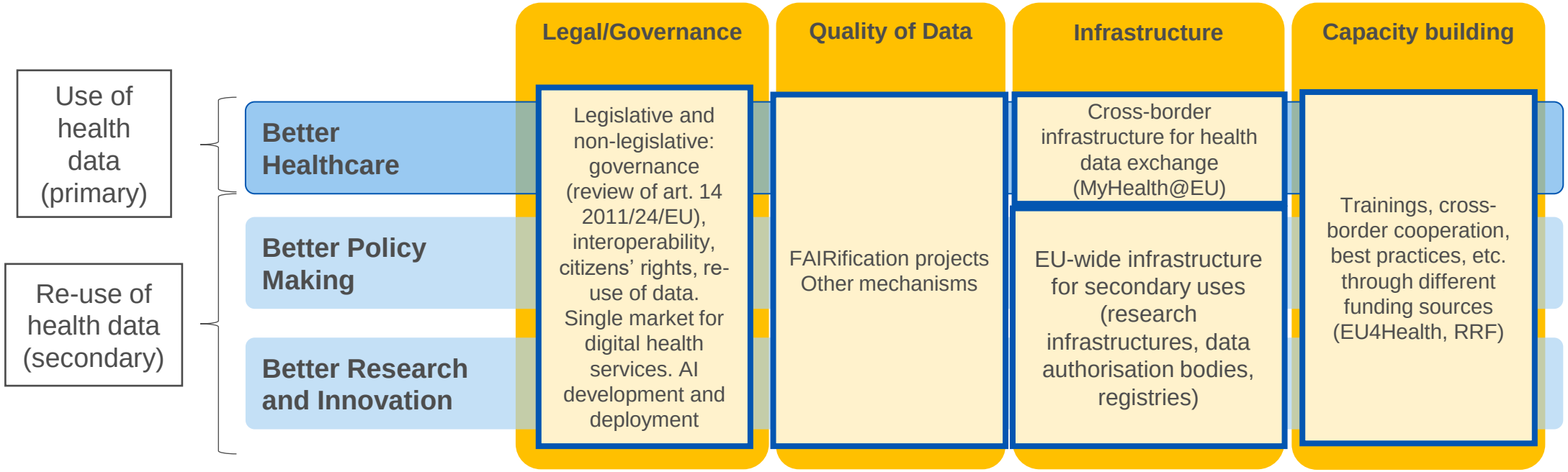
European Health Data Space

Primary and secondary uses of health data

- Timely and simplified *exchange of* and *access to* health data for different use cases:
  - Healthcare provision, access and control of patient over their data, (cross-border) exchange of health data;
  - Digital health services (including telehealth and m-health);
  - Research (eg on cancer, rare diseases, COVID-19 etc), pharmacovigilance, public health, policy making



European Commission

European Health Data Space

Use of data for healthcare (primary)

Sharing of health data for healthcare

Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Single market for digital health products and services

Problems

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

Areas of work

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

Re-use of health data (secondary)

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

Problems

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

Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

AI

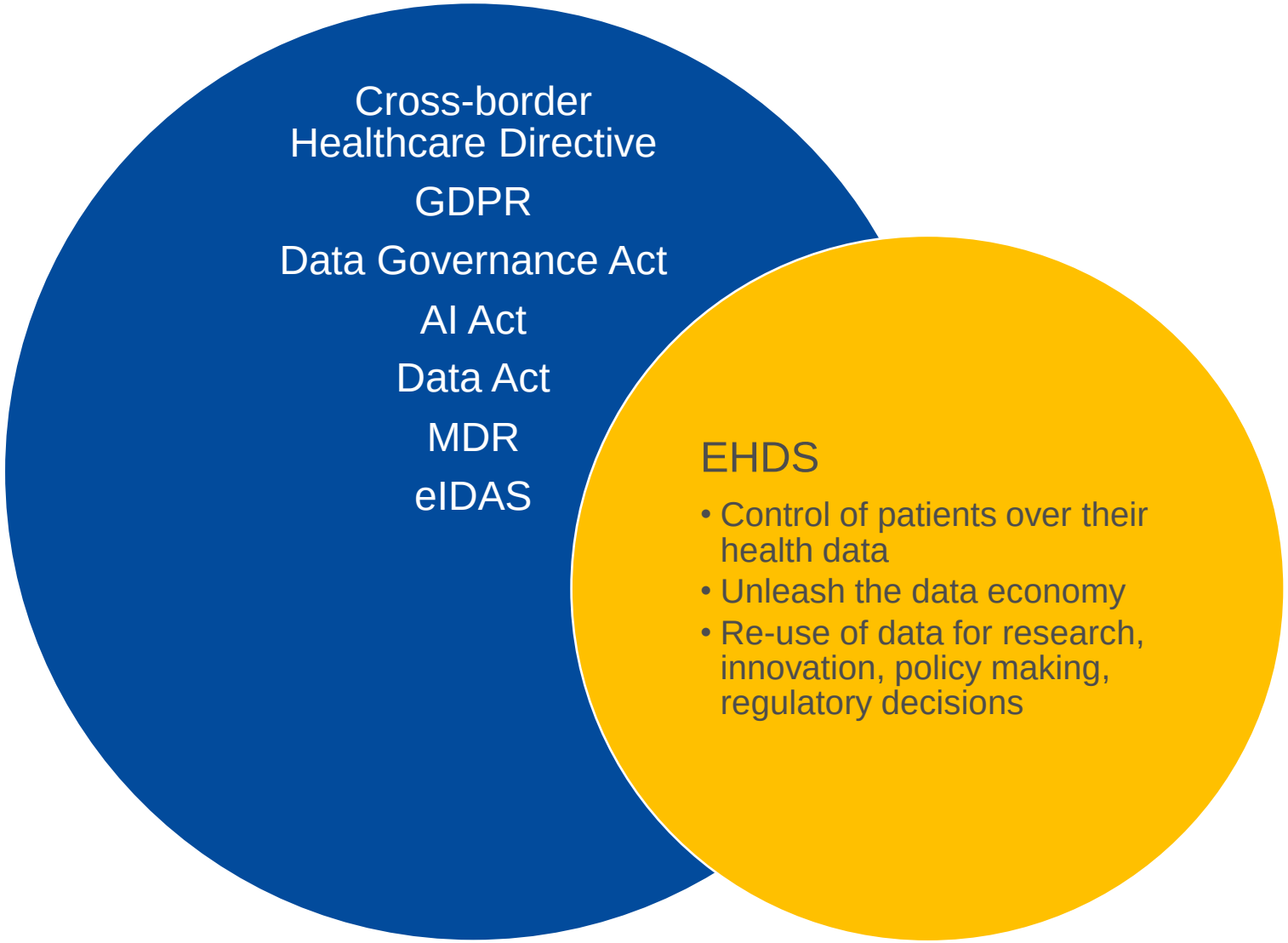
Problems

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

Areas of work

- Support for development and rollout of AI
- Data for AI
- Support for regulators

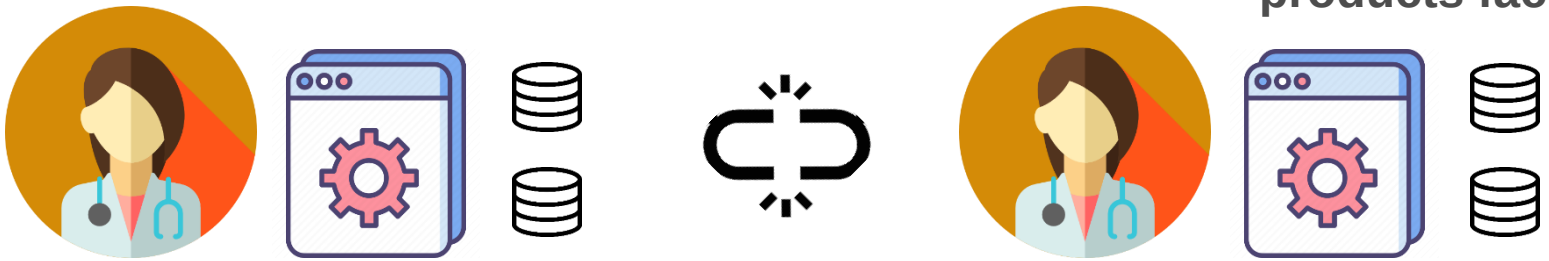
EHDS: articulation within EU regulatory framework



Individuals have difficulty controlling their health data

Providers of digital health services and products face barriers

Healthcare professionals have difficulty accessing health data



Policy makers and regulators cannot easily access health data

Limited innovation takes place on the basis of health data

European Commission

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 portability**.

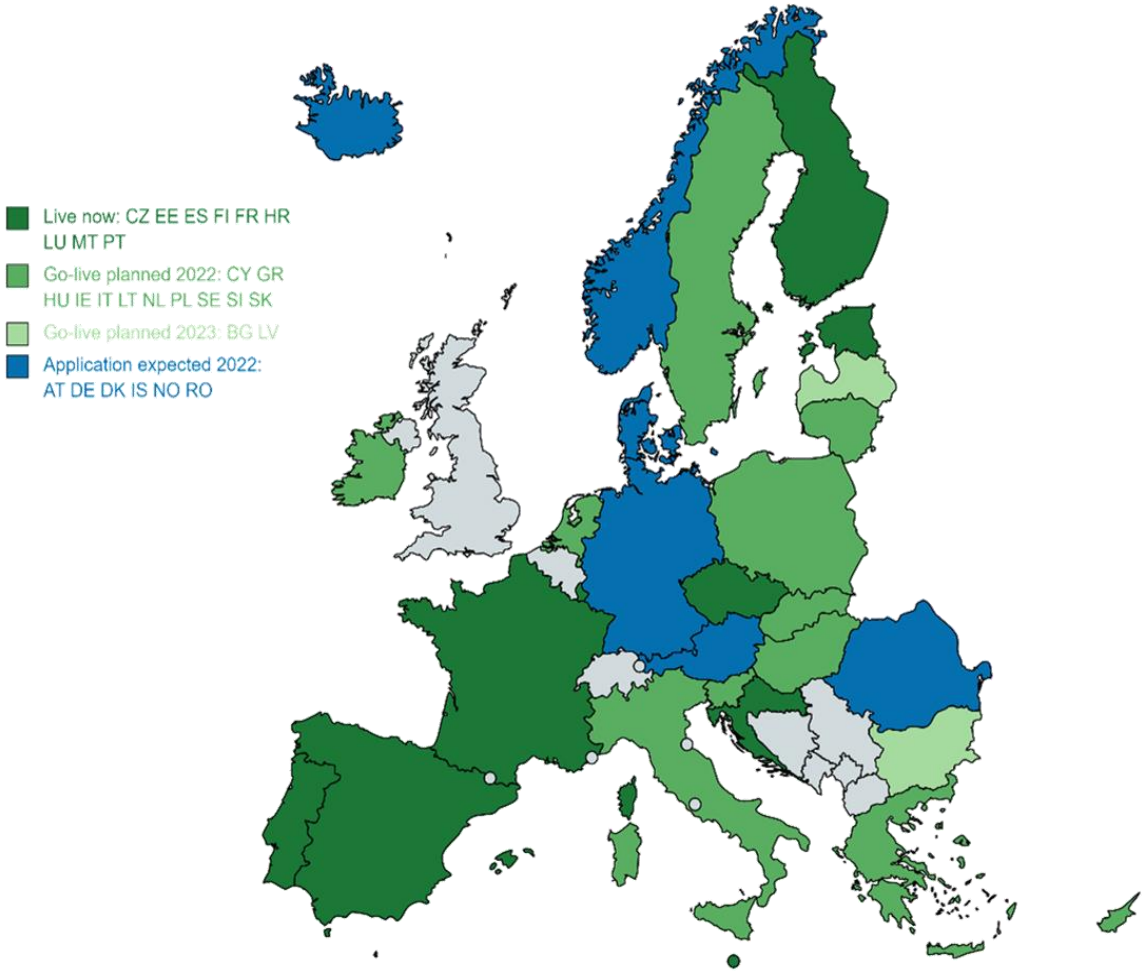
Tools and infrastructure

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. The Commission set up **MyHealth@EU infrastructure** to facilitate cross-border exchange of health data.

MyHealth@EU

Patient summaries and ePrescriptions: 10 MS live

> 2022: images, laboratory results, discharge reports; access of patients to their health data



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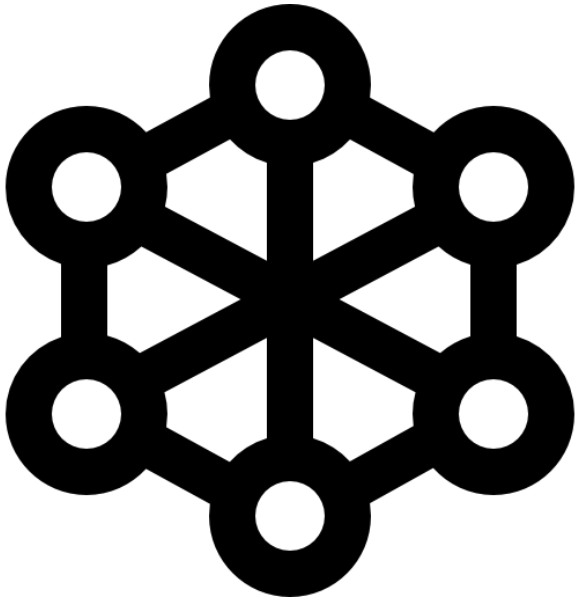
Primary use of health data

- The legislative proposal will focus on a number of areas:
- Expanding the rights of citizens to **access** and **portability** of health data
- Strengthening the eHealth **governance**
- Expanding the **MyHealth@EU** services
- Promoting **interoperability** of health software solutions (including EHR, apps, medical devices)

Secondary use in the EHDS

Reuse of health data by researchers, policy-makers and industry



Health data from patients and healthcare professionals

Rules, protocols and governance

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

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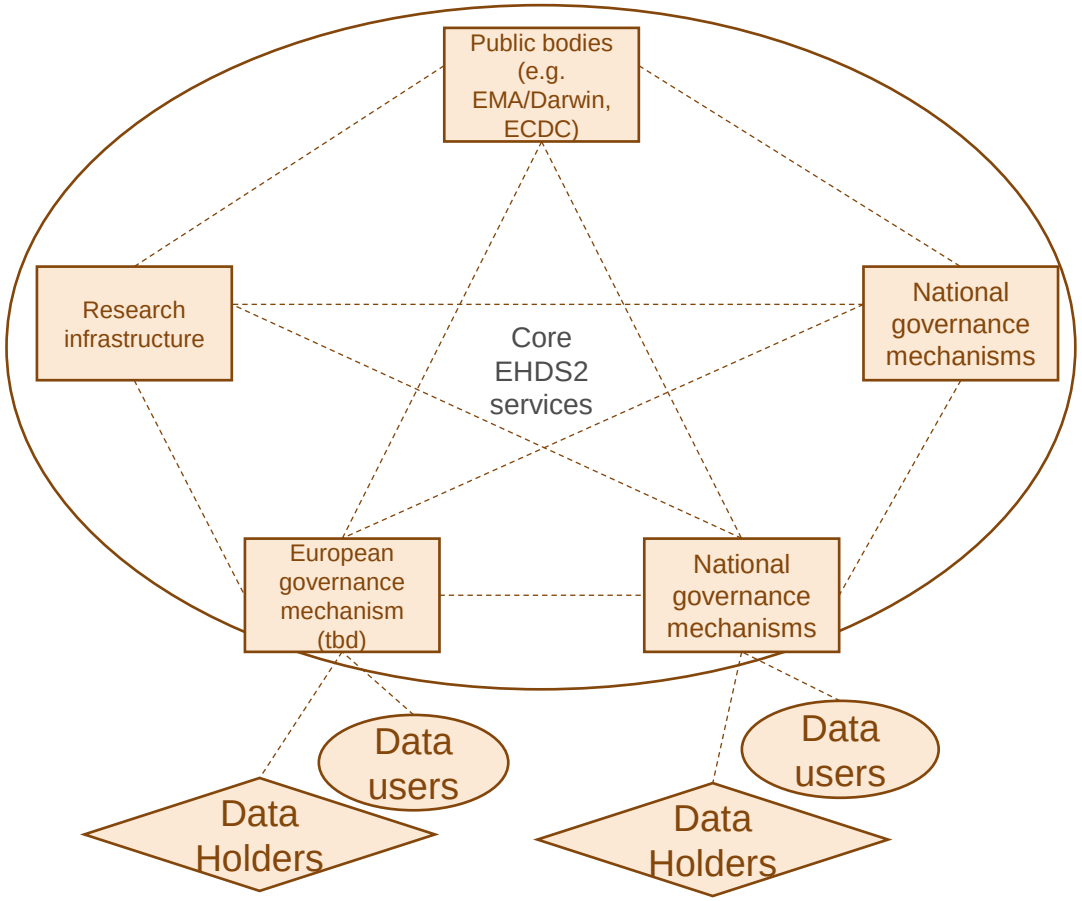
Access to data for research, innovation and policy making



- Creating a **network of nodes** as entry points into EHDS
- Nodes can be National **Data Authorisation Bodies** or European stakeholders (EMA, ECDC, Research Infrastructures)
- Rules are in place **governing the access** to health data (interoperability, data quality, privacy, security)
- Examples at national level are established in **Finland, Denmark, France and Norway**

TEHDAS

- On the secondary use of health data, the Joint Action TEHDAS has also published different recommendations:
- WP5: Report on barriers to cross border data sharing and potential governance mechanisms
- WP6: Report on regulating data quality
- WP7: Report on the user journey
- WP8: Literature review on data altruism, consent and access
- Please find the reports here: Results - Tehdas

Secondary use of health data

- The legislative proposal will focus on a number of areas:
- Expanding on the existing **infrastructure** in Member States (Health Data Authorisation Bodies)
- Introduce a European infrastructure
- Promoting **interoperability** and **data quality**
- Strengthening the **legal base** for the re-use of health data

Studies

The EHDS legislative proposal is being drafted on the basis of different sources of input:

- Public Consultation (May-July 2021)
- Study on the Assessment of rules in Member States on health data
- Study on the Interoperability of digital health systems in Member States
- Study on regulatory gaps (to be published)
- Study on the Infrastructure options (to be published)
- Study on the Impact Assessment (to be published)

- ms_rules_health-data_en.pdf (europa.eu); https://ec.europa.eu/newsroom/dae/redirection/document/79897
- Digital health data and services – the European health data space (europa.eu)

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Projects

EU4Health funds a number of relevant projects to further expand the European digital health infrastructure

- A pilot project to allow **patients access** their health data in MyHealth@EU
- **Expansion of MyHealth@EU**, both by allowing more Member States to establish National Contact Points and by expanding the amount of services
- A pilot project to understand the potential of a European **network of National Health Data Access Bodies** collaborating on secondary use of health data

RRF provides a further 12 Billion EUR in digital health funding

Next steps

- The next steps for the EHDS legislative proposal is to have approval from the Commission internally
- This includes approval from the Regulatory Scrutiny Board and Cabinet
- We expect the proposal to be published Q2 2022
- If you have questions, don’t hesitate to reach out: hugo.van-haastert@ec.europa.eu

Thank you

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