

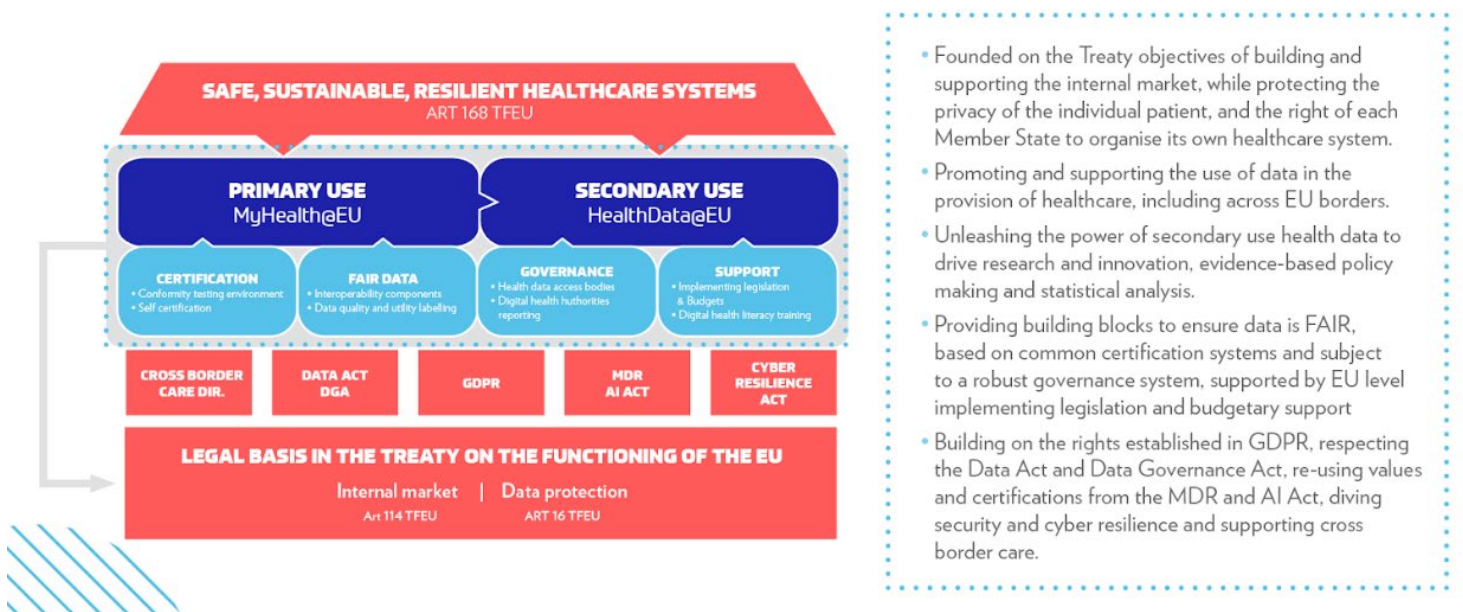
Policy Briefing on the European Health Data Space (EHDS)

- The EHDS is the European Union’s groundbreaking initiative to **unleash the full potential of health data to make healthcare systems more sustainable and resilient**. It supports **individuals to take control of their health data** so that health data follow people within and across the EU borders. The EHDS is an **ecosystem of national health data spaces** which can interact through EU level platforms (MyHealth@EU and HealthData@EU)
- The **EHDS Regulation** is an EU level legislative Act which sets the rules, common standards and practices, infrastructures and a governance framework for **primary use of health data to improve care delivery** and for **secondary use to support research, innovation and policies**. It is the **first common EU data space** to emerge from the European strategy for data. Other spaces including agriculture, manufacturing, energy, mobility, and financial will follow.
- The proposal is backed by a **substantial budget: €12 billion for Member States** to digitise healthcare under the Recovery and Resilience Facility and **€810 million to support the EHDS at EU level**. It is expected to **save the EU around €11 billion over ten years**: €5.5 billion from better access and exchange of health data in healthcare and another €5.4 billion from better use of health data for research, innovation and policy making.

This briefing note consists of two pages drafted in May 2024. It is based on the political agreement reached by the European Parliament and Council in spring 2024.

The EHDS Regulation is expected to be formally adopted in mid 2024 and enter into force in the fall of 2024. Once it has entered into force, it will be gradually implemented in the EU Member States. The first elements are due to be operational by fall 2026, with full implementation extending over a 10 year timeline.

THE EUROPEAN HEALTH DATA SPACE REGULATION



MyHealth@EU – Primary use of health data to improve care delivery

- The cross-border infrastructure **MyHealth@EU will be rolled out gradually to allow the data held in Electronic Health Records (EHR)** to be accessible across the EU for the use of ePrescriptions, patient summaries, medical images and reports, laboratory results and discharge reports wherever the patient may need care. **Currently, eleven EU countries support the sharing of ePrescriptions, eDispensation reports and patient summaries** but most of the other Member State have plans to join by 2025, with the availability of ePrescriptions, eDispensation and patient summaries being required under the EHDS Regulation by fall 2028.
- The EHDS will **support EU citizens in exercising their rights to data access, control, portability, rectifying errors** and to allow them to more easily add data from wellness apps, and other digital health information sources. Individuals will be able to **restrict access to their data**. EU countries may allow patients to opt out of data being made available for primary use by a healthcare professional other than the one(s) who collected it.
- The EHDS is designed to **support care in the patient’s home country** – the country where they hold their health insurance - as well as **facilitation care across borders**, both when the patient travels, but also when telemedicine solutions are used. This has been hailed as **especially important for patients with rare diseases** who may need to travel to other countries to receive care or use telemedicine services.
- **Interoperability** sits at the heart of the EHDS, with the new Regulation requiring all EHR systems to conform to **common interoperability and data logging standards** which providers must self-certify using a common EU level testing environment. The details of the standards and certification will be set out in secondary legislation to be adopted by 2026.

HealthData@EU - Secondary use of health data to support research, innovation and policy making

- The ‘**HealthData@EU**’ platform will be established to connect national health data hubs for secondary use of electronic health data across the EU. As of May 2024, thirteen countries have started to put forward national systems to provide access to data for secondary use, but there is no link between them. There are already **Health Data Access Bodies** such as Findata in Finland, the Health Data Hub in France and the German Forschungsdatenzentren.
- The objective of the EHDS is to **simplify access to data sets within and across borders**, setting up common standards for data quality and use labelling, which will ensure that the **data catalogues to be published annually** make it easy for researchers to identify the data sets they may want to use.
- Patients will have the **right to opt out of their anonymized or pseudonymized health data being made accessible for secondary use** in an easy and reversible way. However, for certain important public interests and under strict safeguards data may still be used. Researchers, industry or public institutions will be able to access to health data **only for specific purposes that benefit individuals and society**.

EHDS IMPLEMENTATION TIMELINE

