

EUROPEAN HEALTH DATA SPACE: OBJECTIVES AND APPROACH

The European Parliament and the Council have published the **Regulation on the European Health Data Space (January 25)**



WHAT IS IT?

It is the European Union's (EU) first common data space in a specific sector and the only one that regulates primary as well as secondary data use.



GOALS

- Improving **people's access to and control over** their own health data.
- Facilitating **cross-border health data sharing** for safer, better quality, coordinated and more efficient healthcare.
- Promote **interoperability of electronic health record (EHR) systems** to facilitate the work of professionals and the mobility of individuals by fostering an internal market for these products.
- Promote the **reuse of health data** for research, innovation, entrepreneurship, training, public statistics and the design and evaluation of public policies.
- Define **organisational and technical conditions** for the processing of personal health data that ensure respect for the right to data protection and the security of the data themselves.

To achieve these objectives, the Regulation provides for **sector-specific rules**, considering the **special protection of health data**.



TWO AREAS OF ACTION

PRIMARY USE OF HEALTH DATA: interoperability of EU health records and availability of data, for healthcare delivery and self-monitoring

- **A common standard is adopted** to facilitate remote consultation and unified service across the EU.
 - » A European data sharing and traceability format will be established.
 - » The European interoperability platform for digital health "MyHealth@EU", which facilitates data sharing and complementary healthcare and services, will be extended.
- **New rights for citizens**, for example:
 - » They will be able to know when and from which centres their medical records have been consulted.
 - » They will be able to enter information in their own medical records, separate from the information of professionals.
 - » They will be able to limit access to their health data.
 - » They will be able to request portability of their data in a much simpler way than at present.



SECONDARY USE OF HEALTH DATA

- It defines the **categories of health data that can be re-used and the data holders**, public and private entities obliged to declare the health data they hold as data controllers.
- It sets out the **purposes for which electronic personal health data may be processed without the need for consent** such as:
 - » Public interest in the field of public health or occupational health (e.g. in a pandemic).
 - » Public policy formulation.
 - » Statistics related to the health or care sector.
 - » Training.
 - » Scientific research.
 - » Development and innovation for products or services, including training, testing and evaluation of artificial intelligence (AI) systems and digital health applications.
 - » Improving care delivery, treatment optimisation and healthcare delivery.
- It also defines **prohibitions on the use** of health data:
 - » As a general rule, anything that could harm or unfairly discriminate against natural persons.
 - » Harmful decisions in terms of provision of goods or services.
 - » Financial loan conditions.
 - » Health insurance or other conditions.
 - » Use of data for marketing or sales purposes of any kind.
 - » Development of products and services that may harm individuals, society at large, or public health.
- The **conditions** under which this electronic personal health data may be processed are defined:
 - » As a general rule, anonymised.
 - » In justified cases pseudonymised, in a secure processing environment and without the possibility of downloading or copying.
 - » For a purpose authorised and supervised by a "data access agency".
 - » For a limited period of time.

EU countries will have to establish:

- **A digital health authority (at least)** to implement the new provisions and guarantee people's rights.
- **Data access bodies (at least one)** to manage data catalogues, requests, their evaluation and granting or refusal and to oversee the re-use of data for secondary purposes, as well as the fulfilment of obligations of data holders and data users.



RELATED PROJECTS

The Commission is supporting these efforts by co-financing projects such as:



Xt-EHR Consortium
Direct grants to Member States for the development of systems and standards for interoperable EHR, which will enable the primary use of health data foreseen in the European Health Data Space.



European Oncology Imaging Initiative
Aims at oncology imaging to support cancer research and diagnostic improvements.



HealthData@EU Pilot
Technical infrastructure pilot for the secondary use of health data in the service of research, innovation, policy making and regulation.



European initiative "1+ million genomes"
Has the potential to improve disease prevention, enable more personalised treatments and support innovative research.



TEHDAS2 Consortium
Prepares the ground for the harmonised implementation of secondary use of health data in the European Health Data Space.



Cross-border eHealth digital service infrastructure (MyHealth@EU)
Ensures continuity of care for European citizens when they travel to another country. These are services that already allow access to clinical reports and electronic prescriptions for cross-border healthcare in the EU. It is being extended to cover all cases of use foreseen by the Regulation.



SHAIPED project
Leverages AI to improve medical devices by improving accessibility to health data, while prioritising strong data governance.



NEXT STEPS

- The Regulation shall enter into force **twenty days** after its publication in the Official Journal of the EU.
- Its general applicability will be **2 years after**, with additional deadlines for some aspects in both primary and secondary use.

Source: [REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space and amending Directive 2011/24/EU and Regulation \(EU\) 2024/2847](#)