# The European Health Data Space and the Secondary Use of Data

The **European Health Data Space (EHDS)** is a European Union (EU) initiative aiming at **creating a common framework for securely and efficiently share and use electronic health data**. The main goals are:

**1** Promoting a single market for electronic health record (EHR) systems

**2** Enable citizens to access, control and share their health data in all EU Member States (MS) - **primary use of health data**

**3** Enable the secure and trustworthy reuse of health data for public interest purpose - **secondary use of health data**

## Use of health data under strong security safeguards for:

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| **Research** | • Support better medical diagnosis;<br>• Provide artificial intelligence systems to support medical practice; |
| **Development of technologies and innovation** | • Guide the selection of the most effective and appropriate treatments;<br>• Innovative solutions for better diagnosis and treatment;<br>• Remote patient monitoring technologies; |
| **Public health policies/ regulation** | • Identification of disease patterns, outbreaks, and risk factors for prevention;<br>• Better health planning and prevention (e.g. vaccination campaigns, efficient allocation of resources in the health system). |

**Examples of health data categories for secondary use:** EHR, social data (e.g. health insurance), environmental data (e.g. pollution), genetic data, data from wellness apps, data generated by medical devices.

## Advances in health through the controlled and restricted use of data

**Citizens:** control of their data

**The patient is considered the owner of their health data** and has the right to authorise or restrict its use, including the possibility of withdrawing consent.

**Users:** restricted access to data

**All requests for accessing health data will be carefully evaluated** according to established criteria, guaranteeing access only for the purposes set out in the EHDS regulation and for authorised persons.

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## The EHDS regulation (Regulation (EU) 2025/327) entered into force on 26th March 2025. What's next?

**March:**

**2027**

MSs must inform the European Commission (EC) about the national HDAB[1] and designate a national contact point for secondary use;
EC determines in **implementing acts**:

- The templates for data access application, data request, and the data permit;
- The technical, organisational, security, confidentiality, data protection and interoperability requirements for secure processing environments;
- The requirements, technical specifications, IT architecture, conditions and responsibilities of the cross-border infrastructure for data sharing, the 'HealthData@EU';
- The minimum elements that health data holders must provide about the datasets they hold (metadata);
- The visual characteristics and technical specifications of the data quality and utility label.

**2029**

Application of implementing acts. Start of secondary use for general categories of data.

**2031**

Entry into application for specific categories of health data (e.g. -omics, genetic data, etc).

**2035**

Connecting third countries to 'HealthData@EU'.

[1]**Health Data Access Body** (HDAB): legal and organisational body responsible for guaranteeing access to and use of health data for secondary use purposes in an efficient, simplified, reliable and secure way.

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# What does change?

**Citizens**

Citizens' data may, with their consent, be used to advance the understanding of diseases, prevent outbreaks, and provide better treatments and healthcare. This will comply with strict measures for accessing and processing health data, which guarantee confidentially and security, and restrict access to data: access only to the purposes defined in the regulation and to authorised persons (article 73). They will have control over their data and a simple and intuitive way to object (opt-out) to the use of their health data for secondary use purposes (article 71).

**Data holders**

Starting in 2029[1], health data holders will have to provide an updated description of the datasets they own on an annual basis (article 60). This description may contain a data quality and utility label (article 78). They will need to provide the datasets to the HDAB following the issuance of a data permit by the latter (article 68).

**Data users**

Starting in 2029[1], data users will be able to find the descriptions of datasets available for secondary use in national catalogues and in a central European catalogue. They will be able to submit data access applications or data requests at national or cross-border levels, through harmonised forms. In case of approved access, users will be able to process the data in a secure processing environment featuring high security control and confidentiality measures (article 73), and with the necessary tools for processing the data.

[1] for some categories of data only applicable from 2031 onwards (article 105).

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