

The European Parliament has just adopted the European Health Data Space (EHDS) regulation



The European Parliament has just adopted the European Health Data Space (EHDS) regulation, marking a historical moment for digital health in the EU. This monumental step will have a profound impact on the rights of natural persons to their electronic health data and on the possibilities for the secondary use of such data.

Konstantin Hyppönen, Programme Officer at European Commission emphasises that the EHDS will empower individuals to access their electronic health data through patient portals or apps. This is aligned with the goals of the Digital Decade policy programme 2030 to reach the target that 100 % of EU citizens should have access to their electronic health records. Furthermore, the regulation will ensure that electronic health data follows patients when they seek care from different healthcare providers within their own Member State or across the EU.

Through the European Electronic Health Record Exchange Format (EEHRxF), the regulation will promote further harmonisation of structures in data exchanged by electronic health record systems. In addition to structured data, the format should also support the exchange of unstructured clinical documents, to ensure the implementation of the rights of natural persons. The electronic health record systems will be certified to guarantee their compliance with interoperability and logging requirements.

To ensure secure access to electronic health data for secondary use purposes, the regulation will establish a network of health data access bodies in each Member State. This will accelerate research and innovation in the EU, contributing to the development of new treatments and advanced health solutions.

Two key infrastructures, MyHealth@EU and HealthData@EU, will be established to support the implementation of the EHDS. While the creation of these infrastructures is a significant undertaking, progress is well underway. The main components of MyHealth@EU are already operational, and pilots are ongoing in HealthData@EU.

National Directorate General for Hospitals is proud to be involved in the coordinated efforts of transforming the European healthcare system, and contribute to the establishment of the European Health Data Space (EHDS) by participating in different joint actions and projects like: **XpanDH Project**, **#XtEHR EHDS2pilot.eu** **XDSI NS** which enhance the development and testing of cross-border digital health solutions to build a more resilient and digitally empowered healthcare across Europe.

The European Health Data Space regulation signifies a major leap forward, enabling seamless flow of health data for the benefit of all of us.