EUROPEAN HEALTH DATA SPACE

Policy briefing

Weblink	https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
Relevance	☐ National policy ☐ EU policy x other: EU regulation
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Short summary of the policy

The European Health Data Space (EHDS) Regulation establishes a legal framework for the use and exchange of electronic health data across the EU. It aims to empower individuals with more control over their health data, while facilitating its use for research, innovation, public health, and policymaking, all within strict regulatory frameworks.

The EHDS defines two distinct purposes for health data: primary and secondary use.

- **Primary use** involves direct patient care, allowing individuals immediate and free access to their electronic health records. They can share this data with health professionals of their choice, both within and across borders, and have the right to add information, request corrections, restrict access, and monitor who has consulted their records. This is supported by the European cross-border digital infrastructure MyHealth@EU, which enables secure and interoperable data exchange among healthcare providers in different Member States.
- **Secondary use** refers to the use of anonymised or pseudonymised data for scientific research, statistics, policy development, and health system planning. This access is strictly regulated and must occur in secure processing environments (SPEs) managed by national Health Data Access Bodies (HDABs). These bodies evaluate data access requests and ensure compliance with regulations. Uses that could harm individuals, such as for advertising, discriminatory profiling, or creating harmful products, are explicitly prohibited. Individuals have the right to opt out of the secondary at any time.

To support these objectives, the regulation also lays down requirements for **electronic health record** (EHR) systems, mandating that they meet common interoperability and security standards. A dedicated governance structure is established to oversee implementation, comprising national digital health authorities, the EHDS Board, and coordination mechanisms for both primary and secondary use infrastructures.

The EHDS Regulation entered into force in March 2025, with a phased implementation timeline that extends to 2031. By then, all Member States are expected to ensure the interoperability of their systems and to participate fully in both primary and secondary use frameworks.

Main objectives of the policy

- **Transforming healthcare through data**: maximising the use of health data to improve patient care, foster innovation, and support policymaking based on evidence.
- **Seamless cross-border health data access**: enhance data exchange to securely share individual medical history, facilitating accurate diagnosis and treatment.
- **Advancing digital healthcare**: providing electronic health record access for individuals and healthcare providers and enabling data-driven research and innovation to improve efficiency and reduce costs in medical advancements.

Context and relation to the Digital Europe Programme (DEP)

DEP plays a crucial role in supporting the various elements necessary for the effective implementation of the EHDS Regulation. Examples of past DEP call topics and their impact on different EHDS features:

- **Infrastructure and services deployment**: set up and scale the technical infrastructure that enables primary and secondary use of health data.
    - DIGITAL-2022-CLOUD-AI-02-CANCER-IMAGE: deployment of federated infrastructure for cancer imaging data
    - DIGITAL-2024-CLOUD-AI-06-HEALTHACCESS: deployment of MyHealth@EU across Member States and integrating EU Digital Identity

- **Training and capacity building**: to ensure that the involved workforce, including healthcare professionals, technical staff, and data governance experts, has the required digital and data-related skills.
    - DIGITAL-2022-CLOUD-AI-02-CANCER-IMAGE: training materials and testing facilities for capacity-building in AI and data management
    - DIGITAL-2021-SKILLS-01-SPECIALISED: the project DS4Health, funded under this topic, designs and delivers an international Master's programme in digital health

- **Interoperability and standards**: support the development and adoption of common technical standards, formats, and semantic interoperability tools required for EHDS implementation.
    - DIGITAL-2024-CLOUD-AI-06-HEALTHRECORD: real-world deployment of the EEHRxF and validation in clinical settings

- **Use cases and pilots:** involving real-world cross-border health data exchange through pilot implementations, covering both primary and secondary use cases.
    - DIGITAL-2024-CLOUD-DATA-06-HEALTHCARE-AI: AI use cases in healthcare that rely on secondary use of data

- **Stakeholder coordination and community building**: EHDS relies on collaboration between Member States, health authorities, researchers, industry, and civil society. DEP funds platforms and actions that bring these stakeholders together, for example, through multi-country projects such as EDICs, expert groups, and stakeholder engagement activities.

Activities in the DEP Work Programme 2025-27 contributing to the objectives of the policy

In general, DEP actions funded under Specific Objective 5 (SO5) primarily focus on Chapter III (EHR systems), while SO2 and SO4 actions mainly contribute to the objectives of Chapter II (primary use) and Chapter IV (secondary use) of the EHDS regulation.

Specific Objective 2 – AI Continent

Health: Data ingestion capacities and data services for the European Genomic Data Infrastructure in the European Health Data Space: Improve the European Genomic Data Infrastructure by supporting the deployment of advanced data curation and tools, aligned with the EHDS.

Deployment of cutting-edge multi-modal AI-based solutions in medical imaging: Accelerate the adoption of EU AI-driven solutions for deployment in healthcare settings for patient care.

Virtual Human Twins and Artificial Intelligence in health: Platform validation and uptake incubator: Validate and confirm that the platform for advanced VHT models is effective across various use cases and is ready for deployment as planned.

Apply AI: Piloting AI-based image screening in medical centres: Establish pilot project(s) to deploy a cloud-based AI/GenAI system using European trustworthy and safe AI/GenAI algorithms that have been developed, trained, and validated with large patient datasets.

Specific Objective 4 – Advanced Digital Skills

Excellence in higher education and training programmes in key digital areas and applied technologies | Second work strand: Advanced Digital Skills for Digital Health: Expand the education and training opportunities in digital health.

Specific Objective 5 – Accelerating the Best Use of Technologies

Building capacity to deploy the EEHRxF and digital health services and systems to support the rights of citizens and reuse of health data under EHDS: Capacity building of public authorities and healthcare providers to deploy, at a large-scale, services and systems that support the rights of natural persons foreseen under the EHDS.

Related policies and further information

EHDS Webinar Series: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds/european-health-data-space-ehds-webinar-series_en

Summary on the EHDS: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

Strategy for European Life Sciences: https://research-and-innovation.ec.europa.eu/strategy/strategy-research-and-innovation/jobs-and-economy/strategy-european-life-sciences_en

The EHDS builds on key existing horizontal EU frameworks, including:

- General Data Protection Regulation (GDPR)
- Data Governance Act
- Data Act
- Network and Information Systems Directive

Please note, that these frameworks may be affected by the Digital Omnibus Regulation.