Summary of the European Health Data Space Regulation

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Health data drives innovation
European Strategy for Data

A common European data space, a single market for data

Data can flow within the EU and across sectors

Availability of high quality data to create and innovate

European rules and values are fully respected

Rules for access and use of data are fair, practical and clear & clear data governance mechanisms are in place
Main challenges in harnessing the power of health data

- Individuals have difficulty accessing and controlling their health data.
- Healthcare professionals have difficulty accessing health data.
- Providers of digital health services and products face barriers.
- Policy makers and regulators cannot easily access health data.
- Limited research and innovation takes place on the basis of health data.
Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making.

- Empower individuals to access and control their personal health data
- Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)
- Ensure a consistent framework for the use of individuals’ health data for research, innovation, policy-making and regulatory activities
EHDS – the first sector specific European Data Space

- Driven by stakeholders
- Rich pool of data of varying degree of openness
- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

Technical infrastructure for data spaces

- Edge Infrastructure & Services
- Cloud Infrastructure & Services
- High-Performance Computing
- AI on demand platform
- AI Testing and Experimentation Facilities

Personal data spaces
- High Value Datasets from public sector
Primary Use
For health, care, wellness
Primary Use
For health, care, wellness

• Aims:
  • Natural persons in the EU have increased control in practice over their electronic health data
  • Better exchange and access to different types of electronic health data, including electronic health records, genomics data, patient registries etc. to support healthcare delivery
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

- Aims:
  - Researchers, innovators, policy-makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well-informed policies
  - Support health research, innovation, policy-making, regulatory purposes and personalised medicine purposes
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

Quality checked, Interoperable: EEHRxF

HEALTH

DATA
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

Health Data

Consolidated, Free, Writable, Portable

Quality checked, Interoperable: EEHRxF
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

National Contact Points, Certified EHR systems, Apps, MyHealth@EU
Consolidated, Free, Writable, Portable
Quality checked, Interoperable: EEHRxF

HEALTH DATA
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

HEALTH DATA

Personally controlled access

Consolidated, Free, Writable, Portable
National Contact Points, Certified EHR systems, Apps, MyHealth@EU

Quality checked, Interoperable: EEHRxF
Primary Use
For health, care, wellness

Secondary Use
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Secondary Use
For research and strategy
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

HEALTH DATA
Quality checked, Interoperable: EEHRxF
Quality labelled, FAIR metadata, Catalogued

Consolidated, Free, Writable, Portable
National Contact Points, Certified EHR systems, Apps, MyHealth@EU

Personally controlled access

Data Access Bodies, Audited safe havens, HealthData@EU
Data Purposes, Fees, Anonymised/pseudonymised

Transparency to the public
The EHDS Regulation, May 2022

- The EHDS Regulation has been broadly welcomed by many stakeholder representative bodies and associations, and by multiple European initiatives.
- Some of its provisions are expressed at a high level (e.g. citizen control over data access for primary use, the certification of EHR systems, decision making by data access bodies) and will need more detailed work.
- It has an ambitious time line for implementation of many of its provisions, which some Member States may find challenging.
- However, it provides a much valued direction of travel for the landscape of health data access and use across Europe, and is already stimulating a powerful momentum and commitment towards achieving its vision.