European Health Data Space

Harnessing the power of health data for people, patients and innovation

December, 2022
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**

**Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities**

**Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)**
**European Health Data Space (EHDS)**

**OBJECTIVES**

**Effective use of health data**

**SCOPE & EXPECTED IMPACT**

**Use of health data**  
*primary, MyHealth@EU*

- Empower individuals to control their data
- Standardization and mandatory certification of EHR systems
- Voluntary labelling of wellness apps
- European Electronic Health Record Exchange Format

**Re-use of health data**  
*secondary, HealthData@EU*

- Health data access bodies
- Purposes for use and forbidden use
- Data permits, secure environments, no identification

**Means**

- Legal / Governance
- Quality of data
- Infrastructure

**Endnotes**

- Single market for health data, data protection, free movement of people, digital goods and services
- Facilitated Research & Innovation
- Better Policy Making

Classified as internal/staff & contractors by the European Medicines Agency
User perspectives

Empower citizens to have control over their health data

Enable healthcare professionals to have access to relevant health data

Health data from apps and medical devices

Electronic health records

Health data in registries

Assist policy makers and regulators in accessing relevant health data

Facilitate access to health data for innovators in industry

Grant access to health data for researchers

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Better health policy, greater opportunities for research and innovation
HealthData@EU
(secondary use of health data)

- EMA
- ECDC
- Data Sharing Infrastructures
- Core Services
- Health Data Access Bodies
- Health Data Access Body
- Secure Processing Environments (SPE)
- GENERIC Services
- LOCAL Services
- CORE Services
- Data Users
  - Researcher
  - Health Professional
  - Public Health Authority
  - Regulator
  - Innovator
- Data Holders
  - Electronic Health Records
  - Health Data Registries
  - Administrative Data
  - Claims Data
  - Genomics

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Overview of a generic data access approval process

1. **Data discovery**: What health data is available to support my research?
2. **Permit application**: Can I use this data for my research project?
3. **Data preparation**: Issue permit and make data ready for use, ensuring data quality and privacy.
4. **Data provision**: Give access to Secure Processing Environment
5. **Data use**: Analyse and process data
6. **Results output**: Publish of results, ensuring privacy and verifiability
EHDS2 - Infrastructure

HealthData@EU Pilot

• Funded under EU4HEALTH
• Start: October 2022 (duration 2 years)
• Budget: EUR 5M (+ EUR 5M Central services)

• Objectives:
  • design, develop, deploy and operate a network of nodes federated by central services, enabling reuse of health data
  • investigate and establish the value of an infrastructure for the reuse of health data
  • assess the feasibility to scale towards a Union-wide infrastructure
  • validate the infrastructure through 5 complementary use cases

* https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/eu4h-2021-pi-06
Thank you