European Health Data Space

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

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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
- Policy makers and regulators cannot easily access health data
- Providers of digital health services and products face barriers
- Limited research and innovation takes place on the basis of health data
Regulation provides rules, common standards and practices, infrastructures and a governance framework for the of electronic health data for healthcare, research, innovation and policy making – creation of European Health Data Space (EHDS)

- 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
Overview of a generic data access approval process

What health data is available to support my research?

Can I use this data for my research project?

Issue permit and make data ready for use, ensuring data quality and privacy.

Give access to Secure Processing Environment

Analyse and process data

Publish results, ensuring privacy and verifiability
What health data exists to support my research?

Researcher → Search in a trusted web portal → Dataset catalogue (contains only metadata, no health data is available) → Dataset descriptor (metadata, no health data) → Data sources (health data)

Responsible for:
- Health Data Access Body
- Health Data Holders

Data sources responsible for:
- EHRs
- Determinants of health claims data
- Genetic and genomic data
- Clinical trials data
- Medical devices data
- Research cohorts
- Biobanks data, ...

Art. 33 Minimum Categories

Classified as public by the European Medicines Agency
EHDS2 - Infrastructure

HealthData@EU Pilot

• Funded under EU4HEALTH
• Start: Autumn 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

* https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/eu4h-2021-pj-06
Data Quality & Utility Label

• Article 56 in EHDS proposal

• Elements: meta-data, data model, standards, provenance, completeness, timeliness, maturity, representativity of population sampled, average timeframe in which a natural person appears in a dataset

• Objectives:
  o To articulate the characteristics and the potential usefulness of datasets.
  o To support data holders in identifying and addressing areas of improvement which can, in turn, allow for wider and better use of these datasets

• Implementing act defining technical specifications of the data quality and utility label
Thank you

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