An overview of national and EU health data developments

ICTD conference, RCSI

10 May 2023

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HRB Strategy 2021-25

Promote and enable the use of data to shape health policy, enhance healthcare delivery, and drive broader research and innovation initiatives

Trusted data

Health research – making an impact   19

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Trusted health data roles

Strategy 2021–2025

Health research – making an impact

Research. Evidence. Action.

- National role in information systems (NHIS) in health and social care for planning, policy, research and innovation

- National leadership role in delivering more impact through managed/FAIR/OPEN data

- Ethics and consent

European Union
Data related measures

Timeline (2016–2023):

- 2016 - General Data Protection Regulation (GDPR)
- 2018 – Regulation on the free flow of non personal data
- 2018 - Digital Health Strategy
- 2019 - Open Data Directive
- 2019 - Cybersecurity Act
- 2020 - Data Strategy
- 2020 - Data Governance Act (DGA)
- 2021 – 2030 Digital Compass
- 2021 - Artificial Intelligence Act
- 2021 - Digital Services Act
- 2021 - Digital Markets Act
- 2021 - Data Act
- 2022 – Chips Act
- 2022 – EHDS

GDPR enters in force May 2018

27.10.2021/22.3.2022

EU data strategy and Data Spaces

Rich pool of data (varying degree of accessibility)	• Technical tools for data pooling and sharing • Standards & interoperability (technical, semantic)

• Sectoral Data Governance (contracts, licenses, access rights, usage rights)

• IT capacity, including cloud storage, processing and services

Free flow of data across sectors and countries

Full respect of GDPR

Horizontal framework for data governance and data access

Health	Industrial & Manufac-turing	Agriculture	Finance	Mobility	Green Deal	Energy	Public Adminis-tration	Skills

Cross-sectoral Personal Data Space
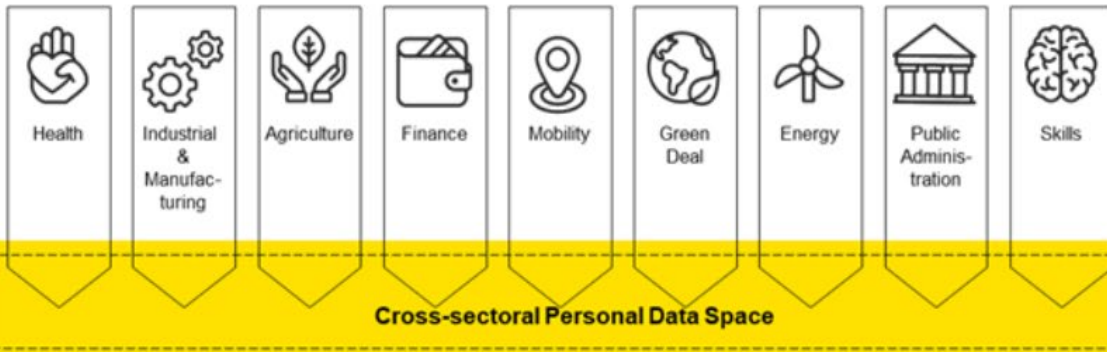
Services
• Collecting, combining, enriching and refining data into information and insights
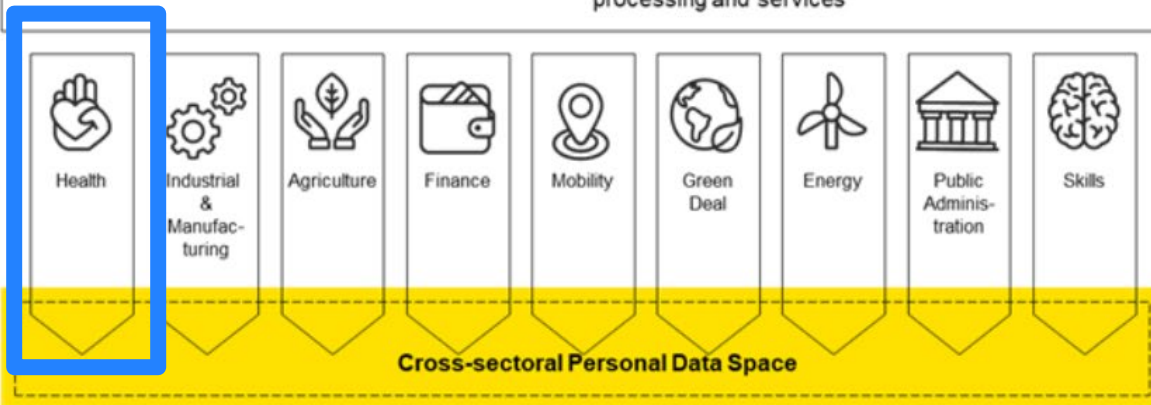
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Cross-sectoral Personal Data Space

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Joint Action Towards the European Health Data Space (TEHDAS)

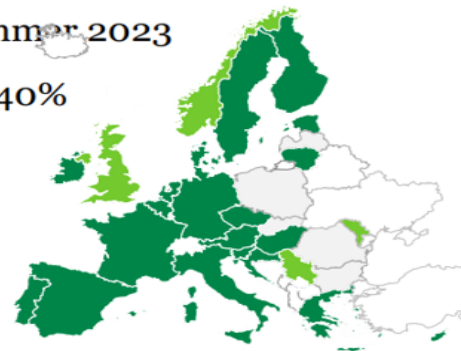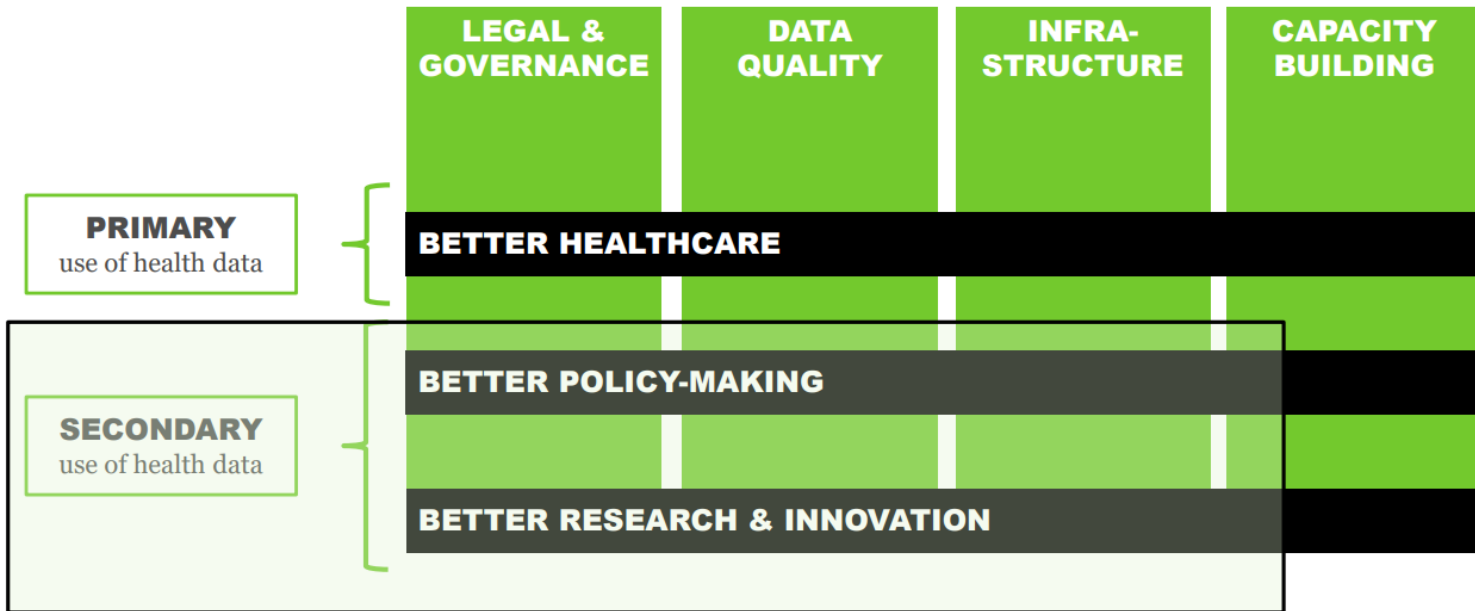|	
Joint Action	Supports the Members States and the Commission Develops and promotes concepts for sharing of data in secondary use
Participants	Nominated authorities from 25 European countries
Duration	30 months from February 2021 – Summer 2023
Co-funding	€4 million - EU 60%, Member States 40%
Project coordinator	Sitra, Finnish Innovation Fund

Health
Research
Board

Four pillars of the European Health Data Space

TEH DAS

	LEGAL & GOVERNANCE	DATA QUALITY	INFRA-STRUCTURE	CAPACITY BUILDING
PRIMARY use of health data	BETTER HEALTHCARE			
SECONDARY use of health data	BETTER POLICY-MAKING			
	BETTER RESEARCH & INNOVATION			

Co-funded by
The Health Programme
of the European Union

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Main provisions of the EHDS

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EHDS proposal areas

- General provisions (Arts 1-2)

- Primary use of electronic health data (Arts 3-13)

- EHRs and wellness applications (Arts 14-32)

- Secondary use of electronic health data (Arts 33-58)

- European governance and coordination (Arts 64-66)
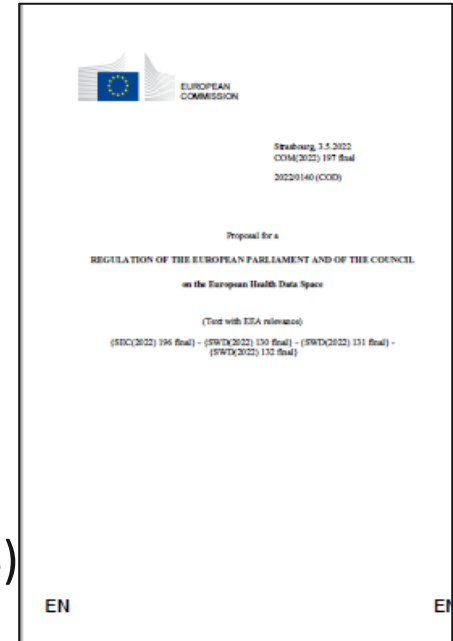
In general...

123 pages of text!

Will be a regulation rather than a directive

Broad definition of health data set out in the EHDS to be welcome

Covers primary and secondary use of health data and public, private, not-for-profit

Standardisation and interoperability

- Mandatory certification of EHRs
- Central platform for digital health to support and facilitate exchange of electronic health data between Member States
- Obligations on the manufacturers and distributers of EHR systems
- Common specifications and technical documentation
- No mention of identifiers like IHI!

Governance and structures

EHDS Board

MS cooperation and exchange

Digital Health Authority

Implementation of Regulation

Health Data Access Bodies

Access to data for sec use

Role of Health Data Access Bodies

- Decide on data access applications and issue data permits to access electronic health data for secondary use

- Permit authority

- Similar to those operating in Finland and Estonia

- Secure processing environments

Categories for secondary use (Art. 33)

(a) EHRs;

(b) data impacting on health, including social, environmental behavioural determinants of health;

(c) relevant pathogen genomic data, impacting on human health;

(d) health-related administrative data, including claims and reimbursement data;

(e) human genetic, genomic and proteomic data;

(f) person generated electronic health data, including medical devices, wellness applications or other digital health applications;

(g) identification data related to health professionals involved in the treatment of a natural person;

(h) population wide health data registries (public health registries);

(i) electronic health data from medical registries for specific diseases;

(j) electronic health data from clinical trials;

(k) electronic health data from medical devices and from registries for medicinal products and medical devices;

(l) research cohorts, questionnaires and surveys related to health;

(m) electronic health data from biobanks and dedicated databases;

(n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;

(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder

following a processing based on a data permit.

Categories for secondary use (ctd)

Genetic genomic and biobank

Patient registries

Clinical trials

Medical devices/wellness apps

Electronic health records

Purposes for secondary use (Art.34)

- Activities for reasons of public interest/public health surveillance or ensuring high quality and safety of health care
- To support public sector bodies in health and care sector to carry out tasks
- Official statistics
- Education or training activities
- Scientific research
- Development and innovation activities for products/services
- Medical devices, AI and digital health applications
- Personalised healthcare

Data quality and secondary use

- HDABs to set up metadata catalogue

- Commission to establish EU datasets catalogue

- Data quality framework/EU utility label (technical quality, quality management, coverage etc.)

EHDS benefits for researchers

Easier access to larger amounts of data, in a more effective and less expensive way

Knowing what data is available, where, and of what quality

Broad range of categories and uses included

EHDS in Ireland

- Health Information Bill to transpose EHDS in Ireland
    - Memo approved by Govt April 2022, published 4 May 2023
    - Provides a legal basis for sharing of health data
- Provision for a National Health Information Authority
- Roll out of Summary Care Record and EHRs
- Health Data Access Body – learning from existing trusted research environments
- PPSN as unique identifier

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Summary care record provisions

- SCR as 24/7 record for every individual and to include:

    - Personal and demographic details

    - Health status and health conditions

    - Medication and recent procedures

    - Allergies and immunisations

- Register of SCRs to be created

- Opt-out model

- Minister will develop Regulations as required for specific safeguards for research purposes aren't listed

National Health Information Authority

- Leadership role and functions

- Board and Director

- Standards

- Accountability and funding

- Development of a secure processing environment

- Establishment of a consultative forum

- Appointment of a National Health Information Guardian

- Enhanced information rights

Thanks for listening
Any questions?