



Towards European Health Data Space

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Health Priorities in the Digital Single Market Strategy



Commission: Mid-Term Review of the Digital Single Market Strategy, May 2017



*“We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to **promote health-data exchange** and **support research on new preventive strategies**, as well as on **treatments, medicines, medical devices and outcomes**. As part of this, you should ensure **citizens have control** over their own **personal data**.”*

*Mission letter of Stella Kiyriakides
Commissioner for Health*



European Health Data Space



- Adopted in February 2020
- Announced work on sectoral Common Data Spaces

Common European data spaces

Rich pool of data
(varying degree of
accessibility)

Free flow of data
across sectors and
countries

Full respect of GDPR

Horizontal
framework for data
governance and data
access



Health



Industrial &
Manufacturing



Agriculture



Finance



Mobility



Green Deal



Energy



Public
Administration



Skills

- 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

European Health Data Space

What?

Use of health data for:

- Better healthcare
- Better policy making
- Better research and innovation

How?

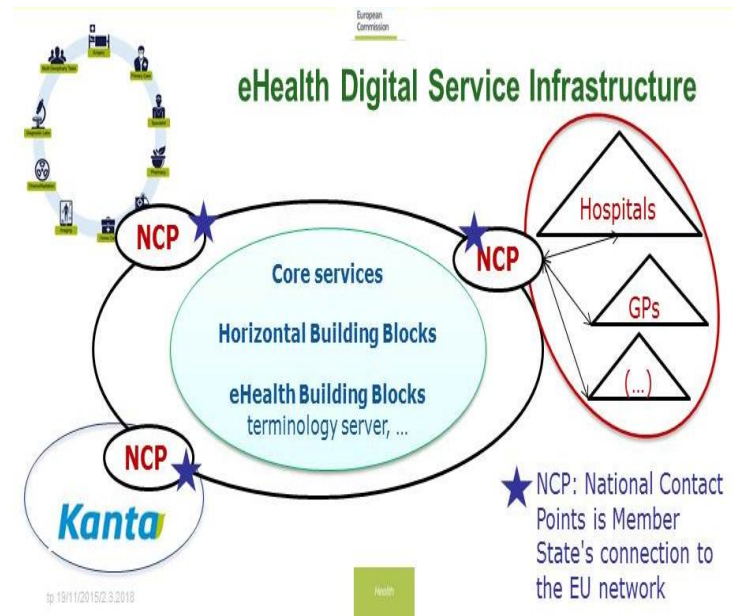
4 pillars of action:

- Data governance and rules
- Data quality and interoperability
- Infrastructure and technology
- Capacity building

European Health Data Space

	Governance	Quality of Data	Infrastructure	Capacity building
Better Healthcare	Legislative and non-legislative measures on governance and rules for primary and secondary use of health data	Increase uptake and develop the EEHRxF	MyHealth@EU CPMS (ERNs) 1+mil genomes	Support for digitalisation of healthcare systems
Better Policy Making	Free movement of digital health services	FAIR-ification of health data for primary and secondary use	Darwin (regulators) Link different repositories (e.g. cancer, ERN, transplantation, image databases)	NCPeH Tele-health
Better Research and Innovation	Regulatory framework for AI (including safety and liability)		Link data permit authorities	AI Digital skills

Digital tools and infrastructures



Expert workshops and study: Assessment of the Member States' rules on health data in the light of GDPR

- **5 expert Workshops in first half of 2020**
- **Main areas examined:**
 - Mapping of national GDPR implementation in health sector
 - National health data rules and governance structures
 - Use of health data for research and innovation
 - Use of health data for policy making and regulatory purposes, access of regulators to health data
 - Access of citizens to health data and portability of data,
 - Patients rights, including right to be forgotten

Study on regulatory gaps in cross-border digital healthcare

- Kicked off in 08/2020, to be completed in Q1 2021
- Areas to be covered:
 - eHealth (including mHealth and Telehealth) services and products
 - AI in health (including liability issues)
 - Economic analysis of national health data governance structures
 - Evaluation of Article 14 of Directive 2011/24 on eHealth (including Mandate of the eHealth Network)

Joint Action on EHDS

- **To start in early 2021**
- **Expected Results:**
 - Options for a Data Governance model for the EHDS;
 - Options for guidelines on using health data for research and policy making;
 - Options for guidelines on Ethical, Legal and Social issues in the EHDS;
 - Options for a Data Quality framework encompassing semantic interoperability and FAIR principles relevant for the EHDS, as well as anonymization and pseudomisation techniques;
 - Options for an Infrastructure architecture and technical interoperability guidelines to enable EHDS services;
 - Options for Economics models focused on the sustainability of EHDS.

EU4Health programme for a healthier and safer Union

- Commission Proposal adopted on 28 May 2020
- Building on the lessons learned from the COVID-19 crisis, EU4Health is an ambitious and dedicated funding programme for 2021-2027 to build resilient health systems in the EU to better equip us for the future.
- Specific objectives: “...(4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, **including by supporting digital transformation, the uptake of digital tools and services**, systemic reforms, implementation of new care models and universal health coverage, and address inequalities in health”
- Initial proposed budget EUR 9.4 billion, European Council of July 2020 reduced to EUR 1.67 billion
- Negotiations in the European Parliament and the Council ongoing



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