

European Health Data Space

loana Gligor, Isabelle Chatelier DG SANTE, Unit B3

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Problems

Access to health data for healthcare in cross-border context

- Patients cannot access and share their health data cross-borders
- Limited digital interoperability of health care providers

Access to health data for secondary purposes (research, policy making)

- Low re-use of health data for research and policy making
- Cross-border access to health data for secondary purposes is unclear and cumbersome
- Fragmented infrastructure for data use in research and policy making
- Limited output of eHealth Network of Member States on processing of health data for secondary purposes

Limited free movement of digital health services (e.g. tele-health, mhealth)

- Uneven legislative framework
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

Slow roll-out of AI in health care

- Knowledge gaps and access to data to be used in Al applications
- Uncertainty on Al liability in health



European Health Data Space

Legislative proposal 2021

Quality of data

Infrastructure

Capacity building and digital skills

Better Healthcare

Governance and rules, interoperability, infrastructure (primary and secondary use of health data)

Digital health services

Regulatory framework for AI and liability

Electronic Health Record Exchange Format

FAIR-ification of health data

MyHealth@EU

CPMS (ERNs)

1+mil genomes

European Health Data Space infrastructure

Pilot project 2021 (EMA, ECDC)

Digitalisation of healthcare systems - RRF

Trainings of public administration

Sharing best practices

Digital skills

Better
Research
and
Innovation

Better

Policy

Making

https://ec.europa.eu/health/ehealth/dataspace_en

EHDS: building up

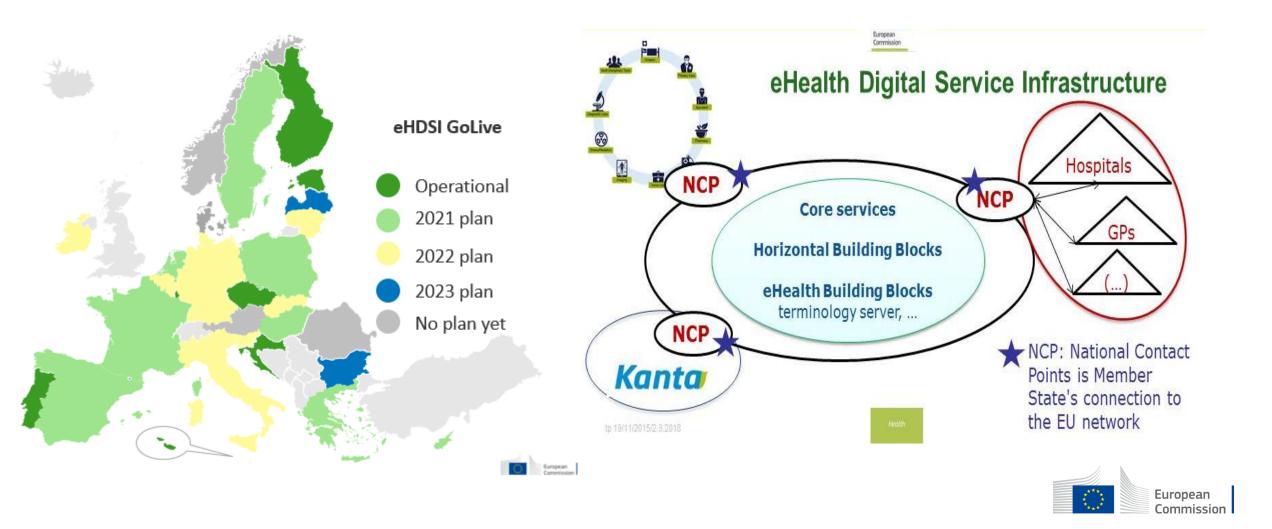
Data Governance Act
Al framework

EHDS

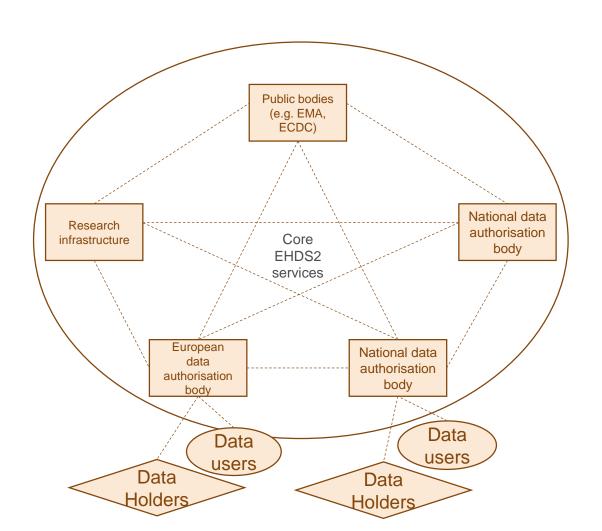
- Use of health data for healthcare
- Control of patients over their health data
- Use of data for research, policy making, regulatory decision
- Provision of tele-health and m-health, including cross-borders
- Clarifying use of AI in health



EHDS1: MyHealth@EU: cross-border exchange of patients' data



EHDS2: access to data for research and policy making (secondary use of health data)



EHDS2 NODEs are the entry point for stakeholders into the EHDS

EHDS2 NODEs can be established by National or Trans-national stakeholders

EHDS2 NODEs follow common policies and interoperability specifications

DATA Holders make health data available for research and policy making

DATA Consumers use data for research or policy making



EHDS: next steps

Inception Impact Assessment:

Public consultation (Q1-Q2 2021)

Impact Assessment (Q3 2021)

- Study on Assessment of the EU Member States' rules on health data in the light of GDPR (Q1 2021)
- Study on regulatory gaps, including evaluation D. 2011/24/EU, digital health services, AI (Q2 2021)
- Studies to support the Impact Assessment (Q3 2021)
- JA TEHDAS 2021

Consultation EDPS and data protection authorities/EDPB

Legal proposal (Q4 2021)



Thank you!

Questions?

