



Joint Action addressing differences in national General Data Protection Regulation (GDPR) implementation in the health sector, including the European Health Data Space and the health data use

Martin Dorazil

DG SANTE *ERNs and Digital Health*





EHDS – why?

“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

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.”

EHDS - what?

- Use of health data for:
 - Better healthcare
 - Better policy making
 - Better research and innovation

EHDS - how?

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



EHDS - governance

- Preparatory work:

Workshops & study on primary and secondary use of health data

(2020: 29 Jan, 11 Mar, 29 Apr)

- Mapping of GDPR implementation
- Governance structures for secondary use of health data
- Access of regulators to health data

Study on regulatory gaps in cross-border digital healthcare

(to be launched in Q1 2020)

- Digital services: telehealth/m-health
- AI – liability, regulators, rules, needs, standards
- Evaluation of article 14 of Directive 2011/24 (eHealth Network)

Governance: JA contribution

- Options for a **Data Governance model** for the European Health Data Space, complementing the European Data Spaces horizontal framework (also taking into account the mapping on GDPR)
- This should also include **functions and responsibilities** of the relevant actors
- Options for **guidelines on using health data for research and policy making**;
- Options for **guidelines on Ethical, Legal and Social** issues in the European Health Data Space;
- Options for **Economics models** focused on the sustainability of European Health Data Space.

Code of Conduct for secondary use of health data may be externalized from the JA in a **separate action**

EHDS: Data quality and interoperability

- Commission recommendation on Electronic Health Record Exchange Format
- Making data FAIR

JA contribution

- Options for a **Data Quality framework** encompassing semantic interoperability and FAIR principles relevant for the EHDS: mapping, metadata, vocabularies, data models
 - **Electronic health records** (taking into account **EHRxF**)
 - **Registries**
- **Anonymization and pseudomisation** techniques
- Use of **synthetic data**

EHDS: Infrastructure and technology

- What is being done:
 - MyHealth@EU
 - ERN
 - 1+ million genomes initiative
 - Existing research infrastructure
- New projects:
 - Upscale of MyHealth@EU
 - Use of data for policy making, research and innovation

Infrastructure: JA contribution

- Options for an Infrastructure architecture and technical interoperability guidelines/agreements to enable European Health Data Space services

JA budget

- EUR 1 500 000- 2 500 000
 - depending if the Code of Conduct is done within or outside the JA



European
Commission

Thank you!



DigitalSingleMarket@DSMeu
EU_Health@EU_Health

DG Health and Food Safety

http://ec.europa.eu/health/ehealth/policy/index_en.htm