Towards European Health Data Space

Martin Dorazil
Deputy Head of Unit
European Reference Networks and Digital Health
DG SANTE, European Commission
Health Priorities in the Digital Single Market Strategy

- Give citizens better access to their health data, everywhere in the EU
- Use digital services for citizen empowerment and person-centred care
- Connect and share health data for research, faster diagnosis and better health outcomes

“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 Kyriakides 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

- 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

Health, Industrial & Manufacturing, Agriculture, Finance, Mobility, Green Deal, Energy, Public Administration, Skills
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**
- Legislative and non-legislative measures on governance and rules for primary and secondary use of health data
- Free movement of digital health services
- Regulatory framework for AI (including safety and liability)

**Quality of Data**
- Increase uptake and develop the EEHRxF
- FAIR-ification of health data for primary and secondary use

**Infrastructure**
- MyHealth@EU CPMS (ERNs)
- 1+mil genomes
- Darwin (regulators)
- Link different repositories (e.g. cancer, ERN, transplantation, image databases)
- Link data permit authorities

**Capacity building**
- Support for digitalisation of healthcare systems
- NCPeH
- Tele-health
- 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
Towards European Health Data Space

Martin Dorazil
Deputy Head of Unit
European Reference Networks and Digital Health
DG SANTE, European Commission

3 June 2020 - Brussels, Belgium