



Potential impact of data regulation on service provision in health and care

June 9, 2022



This project has received funding from
the European Union's Horizon 2020
research and innovation programme
under grant agreement No 101017603

<http://ec.europa.eu/digital-single-market/ehealth>

Welcome

Piret Hirv

Tehnopol Connected Health Cluster
Coordinator of IN-4-AHA project

**Challenges in data
governance; synthesis of
stakeholder reflections**

Hille Hinsberg

Proud Engineers

Case studies on data sharing practices



Based on collected case studies and identified barriers to cross-border data sharing,

- **more than half** were legal-related barriers
- 30% were caused by data management
- 13% were technical issues
- 5% were trust-/transparency-related barriers.

Source: *Report on secondary use of health data through European case studies* (TEHDAS, 2022)

TEHDAS synthesis of challenges

- There is no common European interpretation of what is, and what is not, '**secondary use**' of data.
- European countries have national legislation/rules around health and research data **in addition to the GDPR**. Also, MS have different preferences as to the choice of legal basis for processing **under the GDPR**.
- No standardised **data sharing agreements** exist for tech solutions developed by private sector providers using public sector health data to (a) facilitate safe data sharing and (b) protect taxpayers' investment.
- Different **taxonomy and ontology codes** are used to label the same health condition, making comparisons between data sets challenging.
- Poor **data management procedures** reduce the ability to reuse data.

EIT Health analysis of challenges and enablers

Where several data controllers hold data in the context of one digital health solution, different legal bases for using data may apply. This limits the capacity for data collected for care to be reused for research.

RECOMMENDATIONS:

- The interaction between the Medical Devices Regulation and national level legislation should be screened to support the use of digital health solutions that are dependent on data use between several legal entities, including those in different jurisdictions.

Source: EIT Think Tank. *Learning from health data use cases* (2021)

EIT Health analysis of challenges and enablers (cont.)

RECOMMENDATIONS:

- Trust in the EHDS by data users will depend on the quality of the data to be accessed. To build such trust, the EHDS should develop a robust system for **certifying the quality of data**, which includes transparency on how it was acquired and all aspects of its format.
- As the EHDS will depend on shareable data, the Commission should incentivise the use of standards to make health data Findable, Accessible, Interoperable and Reusable. The EHDS should include common **guidelines on data meta-labelling** to allow for data to be found and aligned to governance and access policies of data providers.

EIT Health analysis of challenges and enablers (cont.)

RECOMMENDATIONS

- Data integration and use demands skills that are not abundant in Europe. More healthcare providers and solution developers need to be **trained in data science and data management**. The European Commission should earmark funds to support such training and make reference to certain levels of skills certification.
- Digital health creates new liability relationships between solution providers, users and patients. The European Commission should support Member States in exploring **new models of liability sharing** that more easily allows multiple actors to be involved in the provision on healthcare.

EIT Health analysis of challenges and enablers (cont.)

Digital health solutions which show a positive healthcare effect via a controlled study in one Member State, should be able to **enter reimbursement schemes** in other Member States.

RECOMMENDATIONS

- The European Commission should establish a European “**fast track**” for **digital health solutions**, looking to the experiences of different Member States, notably the DiGA example from Germany. This will help to support digital health innovation, improve patient care, treatment and diagnosis, and improve the resilience of healthcare systems.

Discussion



South-Eastern Finland
University of Applied Sciences



Slovenian Innovation Hub



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THANK YOU!

Looking forward to further
exchange:

hille.hinsberg@proudengineers.com

