European Health Data Space

Digital health in Germany's Presidency

Nick Schneider

Division 511 – New technologies and data use
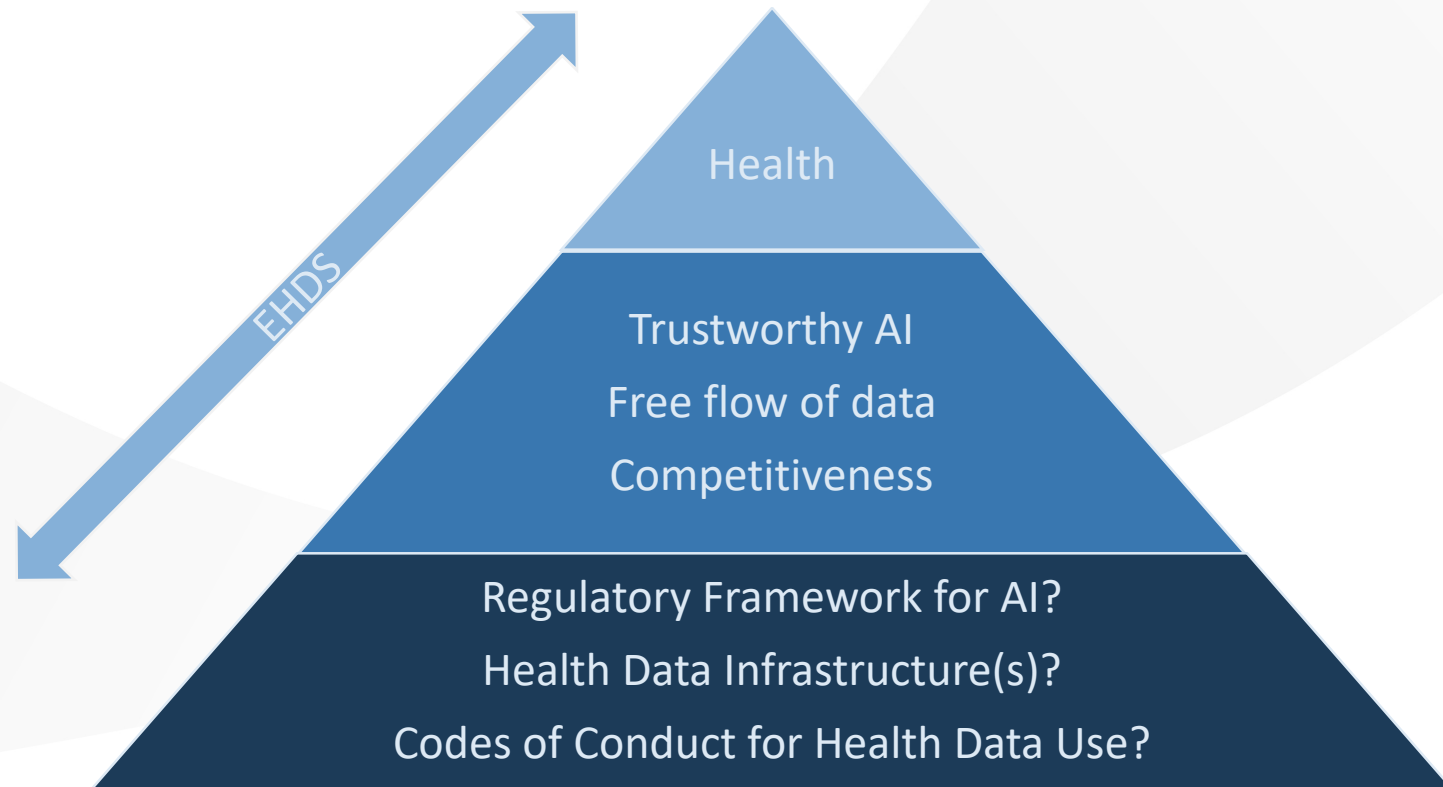
German Federal Ministry of Health

Agenda

- Looking back - the road to the EHDS

- Building political momentum - actions within Germany's Presidency

- Moving forward – Joint Action and Code(s) of Conduct

Roadblocks to secondary data use in the EU

- No real free flow of health data
  - Highlighted by COVID-19 pandemic

- GDPR-regime too complex for researchers
  - Different legal layers (EU, federal, state)
  - GDPR vs. sectorial health law

- Lack of consensus in the MS on e.g.
  - Scope of national derogations
  - Definition of anonymisation / pseudonymisation, primary / secondary use of data
  - Legal base for data collection for scientific research purposes
  - Rights of data subjects
  - Technical and organizational measures
  - Semantics and data quality

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A strategic approach to the European Health Data Space

EHDS

Health

Trustworthy AI

Free flow of data

Competitiveness

Regulatory Framework for AI?

Health Data Infrastructure(s)?

Codes of Conduct for Health Data Use?

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Mapping GDPR implementation in the health sector

- EUHealthSupport study "Assessing the Member States' rules on health data in light of the GDPR"
  - Assess MS rules on processing of health data for
    - provision of health and social care
    - public health purposes
    - research
  - Identify possible areas for European action

- Workshops with experts, MS, data protection supervisory authorities and stakeholders

- Final report to be presented in Fall 2020

German Presidency committed to take the EHDS forward

- Learn from the mapping study

- Discuss at ministerial level
  o Information point at Informal Meeting of Health Ministers, 16 July 2020
  o Preliminary results of EUHealthSupport Study presented

- Explore cross-border data access and exchange
  o High Level Conference "Digital Health 2020 – EU on the Move", 11 November 2020

- Reflect proposed actions together with other MS
  o Political debate on technical level (Public Health WP)
  o Consideration in potential Council conclusions

- Prepare Joint Action on the EHDS

  ➢ **Build political momentum for the EHDS**

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Joint Action – Towards the European Health Data Space (TEHDAS)

- Four main pillars:
  - Governance
  - Quality of data
  - Infrastructure
  - Capacity building for MS

- 22 MS and MDA, NOR, SRB, GBR involved

- Align with ongoing initiatives, e.g. eHN, GAIA-X, CoC

- Start: Q1 2021

Code(s) of Conduct

- Tailored Codes of Conduct for specific categories of data processors and processing situations needed (acc. article 40 GDPR)

- Provide legal clarity and guidance

- Could be applied where EU legislative action is less feasible

Cooperation between MS

- Reduce differences in the interpretation and implementation of the GDPR by exchanging best practices

- Enhance data quality and make data findable, accessible, interoperable and reusable (FAIR)

- Foster use cases of health data spaces for specific research topics

Thanks a lot!

Contact details

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