Towards the European Health Data Space: Challenges and opportunities

A Swedish perspective
Main challenges

- Fragmented health data landscape
- Lack of national infrastructure
- Legal challenges
- Interoperability
**EHDS – for Sweden**

- Increase standardisation/inter-operability work
  - EU
  - Domestic
- Major impact on e-prescriptions, cross-border patient overviews, and new categories of information and services
  *National autonomy decreases?*
- (Initial) costs
- Constitutional amendments?
- New authority organisation?
  *Distribution of role and responsibilities*
- How to harmonize the legislative train - DGA, DA, AI, MDR, etc
Preparation for primary use of health data

A national "e-Health authority" (*Digital Health Authority*) will be selected by the government:

- Ensure implementation of rights and requirements in the regulation, monitor compliance - for example for interoperability!
- Contribute to the work at EU level
- Offer telemedicine services!
- Additional tasks through delegated acts
- The member states must ensure resources for the above
Preparation for secondary use of health data

Health Data Access Body

• One or more (one should be coordinator)

• Tasks:
  • Manage applications
  • Support EU authorities in their tasks
  • Collaborate with data holders and secure data quality
  • Provide meta catalogue

Member state shall select a national contact point for secondary use of health data to be connected with Healthdata@EU
The national process

• The proposal has been sent out for consultation

• Openness around the referral responses
Preparation for EHDS
New EU-projects: EU4Health

Swedish e-Health Agency is selected competent authority:

- Joint Action – Primary use
- Direct Grant – Primary use
- Direct Grant – Secondary use
Three national inquiries regarding health data

- Health data as a national resource for future healthcare
- Investigation about e-prescriptions and patient overviews within the EEA
- Health data as a national interest – legislation for interoperability
Government assignments

• Carry out a pilot study on creating a digital national infrastructure for national quality registers

• Basic data domain - health, care and welfare

• Pilot study on creating a governmental national data space for diagnostic imaging
Tehdas "country visits" - mapping national health data landscapes

Country mapping on health data landscape

Country reports

Country fact sheets

Tehdas WP 4.1 Sciensano, Belgium
Mapping the Swedish health data landscape