

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 organsiation?
 Distrution 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





National European **Policy European vision and policies National vision and policies** interoperability **Organisational** Governance strategies Governance strategy technical semantic Digital health data Digital health data interoperability strategies strategy Legal inter-**European laws National laws** operability



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

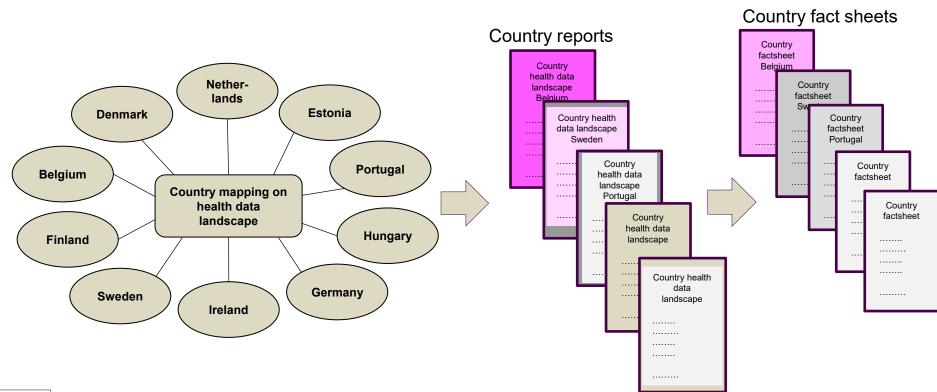
Basic data domain - health, care and welfare

 Pilot study on creating a governmental national data space for diagnostic imaging





Tehdas "country visits" - mapping national healthdata landscapes





SITRA

Data Data collection Data governance and data governance sources Legal Approach to Data infra-Health European structure Mapping the information **Data quality Health Data** systems Space Data storage Swedish (EHDS) health data Data infralandscape Resources Training structure (human, opportunities financial and Data interand needs technical) operability Data infrastructure Data access

@ eHälsomyndigheten



National governmental inquiries





National Board of Health and Welfare



Statistics Sweden



Senomic Medicine Sweden

National Life Sciences Coordinator









Analytic Imaging Diagnostics Arena (AIDA)











The Swedish Association of the **Pharmaceutical Industry**







Stockholm Center for Health Data







Government Offices of Sweden Department of social affairs and health







Medtech4Health





Confederation of Regional Cancer Centres in Sweden

