

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?*
 - Distruption 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

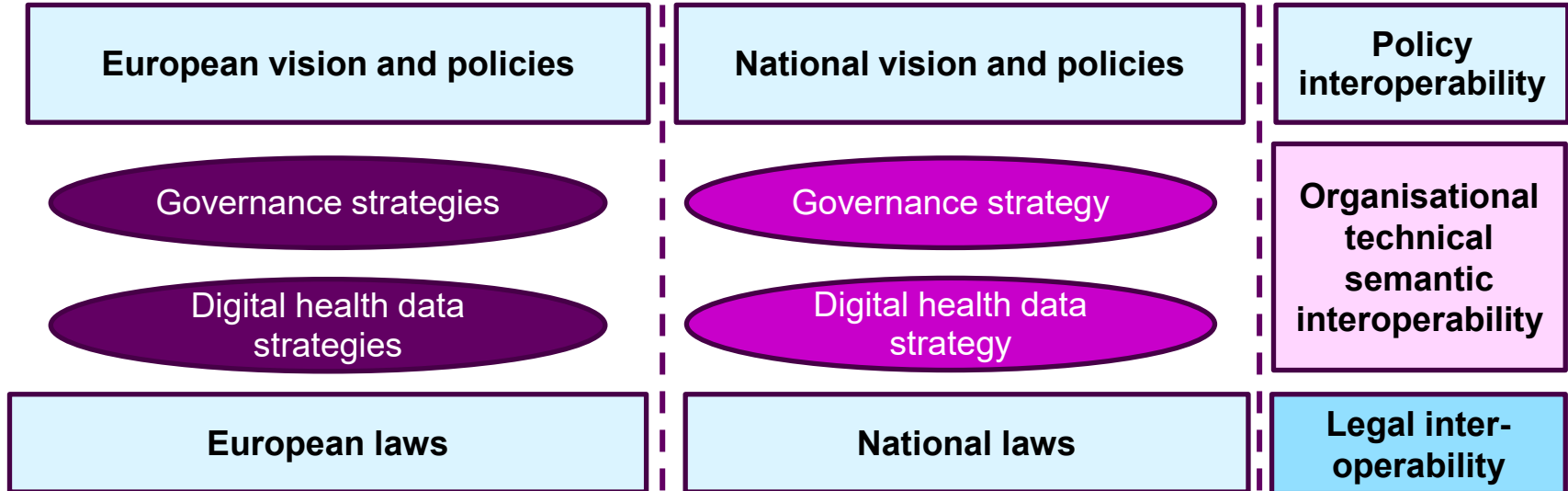


Preparation for EHDS



European

National



New EU-projects: EU4Health

Swedish e-Health Agency is selected competent authority :

- Joint Action – Primary use
- Direct Grant – Primary use
- Direct Grant – Secondary use



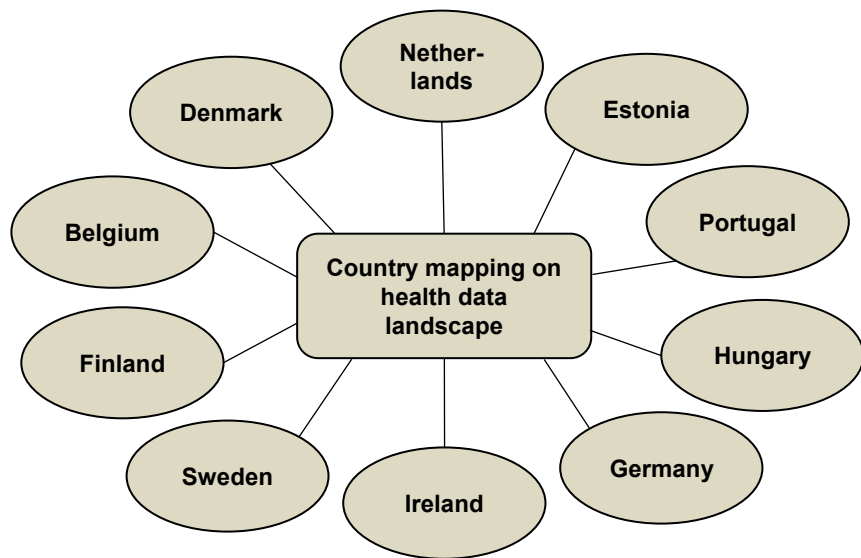
Three national inquiries regarding health data

- 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

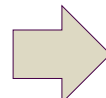
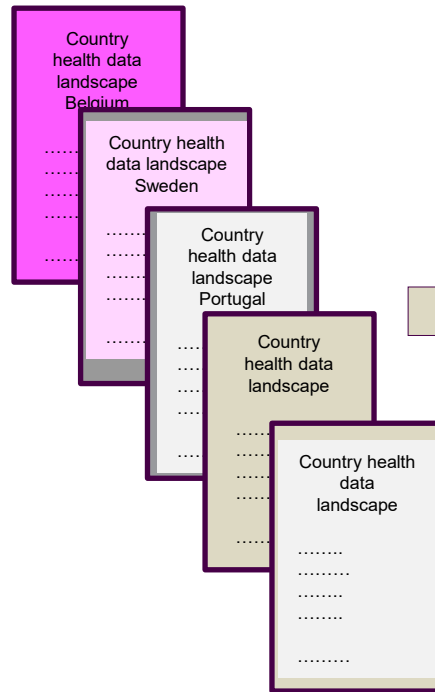
Government assignments

- 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

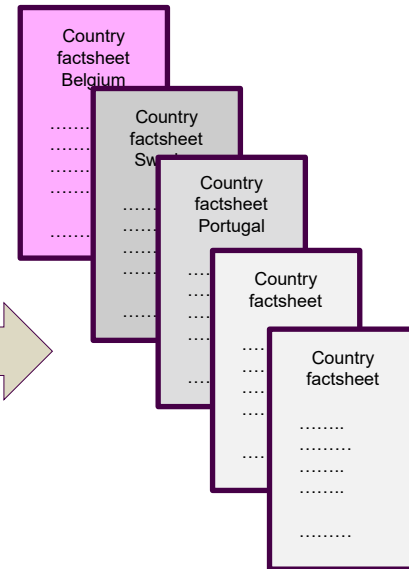
Tehdas "country visits" - mapping national healthdata landscapes



Country reports

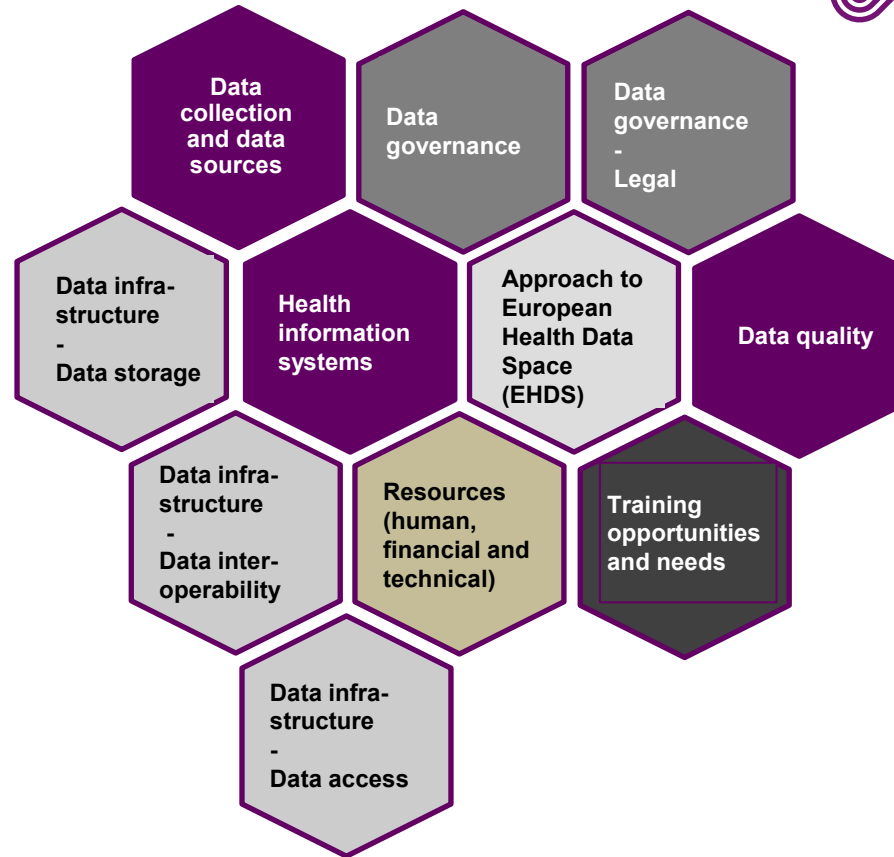


Country fact sheets



Tehdas WP 4.1 Sciensano, Belgium

Mapping the Swedish health data landscape





National governmental inquiries



National Life Sciences Coordinator



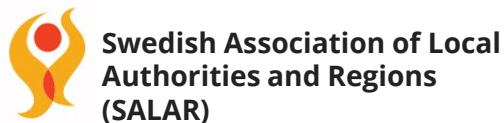
Analytic Imaging Diagnostics Arena (AIDA)



The Swedish Association of the Pharmaceutical Industry



Medtech4Health



Confederation of Regional Cancer Centres in Sweden

