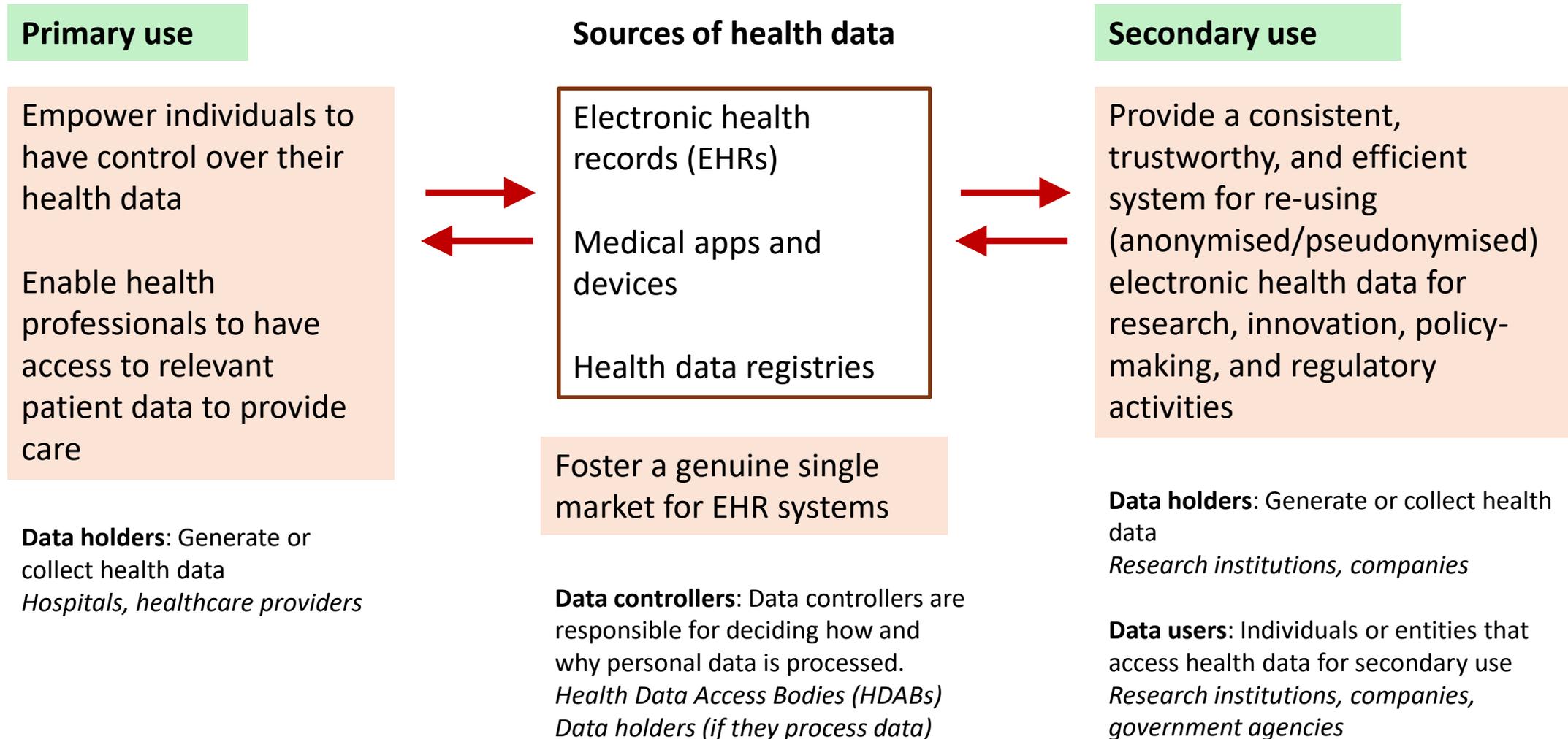


**Session 2: Leveraging data and new technologies for
evidence generation and decision-making**

EHDS Nordic Approaches – Case Sweden

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European Health Data Space, EHDS, is a common framework and data infrastructure to support the use and exchange of electronic health data across the EU.



EHDS timeline

- March 2025: The EHDS Regulation entered into force.

2025 -2027: Member states' transition period; planning and preparations

- March 2027: EHDS becomes applicable; Deadline for European Commission to adopt key implementing acts, providing detailed rules for the regulation operationalisation

2027 – 2029: Implementing period: preparing to start the data exchange

- **March 2029: Key parts of the EHDS Regulation enter into application.**
Primary use: The exchange of the first group of priority categories of health data (Patient Summaries, ePrescriptions/eDispensations) in all EU Member States. Rules on secondary use start to apply for most data categories (e.g. data from electronic health records).
- March 2031: Primary use: the exchange of the second group of priority categories of health data (medical images, lab results, and hospital discharge reports) should be operational in all EU Member States. Rules on secondary use start to apply for the remaining data categories (e.g. genomic data).
- March 2034: Third countries and international organisations will be able to apply to join HealthData@EU, for the secondary use.

National e-health infrastructure

The **Swedish eHealth Agency** has been tasked by the government with coordinating and facilitating the development of a national e-health infrastructure that facilitates healthcare organisations to store, exchange and reuse information to enable efficient and seamless integration and coordination of healthcare services across various systems and platforms.

As part of this work, the **National Council for interoperability** was established in September 2024. The Council's task is to identify priority areas for standardization, and work for the development and use of implementation related specifications in health care. The focus is on primary use.

Technical interoperability: Common technical specifications, standards and platforms are used.

Semantic interoperability: Information can be exchanged, interpreted and reused uniformly, while retaining meaning and content.

Organizational interoperability: Common descriptions of activities and their needs are used, as well as work processes are coordinated between different organizations.

Legal interoperability: Legal frameworks support the technical and organizational aspects of interoperability, and information is exchanged in accordance with applicable legislation.

Council members represent

- Government agencies
- Regions and municipalities
- Private healthcare providers
- Standardization organizations
- Service providers; Medical technology companies
- Academia
- Professional associations

Prioritized areas for standardization and specifications

- Clinical information
- Technical information
- Basic information – Area of activity and organisation
- Basic information – Range of care services

Task groups were established in Spring 2025

Status reports in May and October

Final report in November

Developing and implementing digital infrastructure

The developing activities are mainly funded by government and government agencies. Estimated costs vary depending on the range of the provided services and pace of development.

Year	Estimated cost – Low MSEK	Estimated cost – High MSEK
2025	356	548
2026	433	1000
2027	428	1490
2028	453	1442

The implementing phase will be mainly funded by care providers, which will create great costs for Sweden's regions and municipalities. There are no estimates for this cost yet, but it is expected to be several 100 MSEK.

EHDS-implementation poses obligations for regions and municipalities as data holders: They must access and use the national digital infrastructure and make electronic health data available for primary and secondary use.

The municipal financing principle may apply in this case, i.e., government may not impose new responsibilities on municipalities and county councils without providing them with adequate funding.

SENASH - Sweden National services for Access to Swedish Health data for secondary use; Project period Feb 2024 – Jan 2027

- A feasibility study to analyse the Swedish national context and the challenges posed by the EHDS Regulation regarding the secondary use of health data
- Five Swedish governmental authorities collaborate: The Swedish eHealth Agency (leads and coordinates the project) the Public Health Agency of Sweden, the National Board of Health and Welfare, Statistics Sweden, and the Swedish Research Council
- A Steering Board and an Advisory Board with representatives from the health data sector
- The EU4Health Work Programme co-finances the project (60%)
- During the project, two systems will be developed in pilot versions:
 - A national **metadata catalogue** that improves the findability of health.
 - A centralized system that facilitates **data access** applications and **data requests** for health data to multiple dataholders.

Secondary use - HDABs

- Health Data Access Body (HDAB) is a national entity responsible for granting access to health datasets for secondary use
- The data can only be accessed and processed in closed secure environments to be provided by the HDABs with clear standards for cyber security
- A decentralised infrastructure for secondary use of health data (HealthData@EU) will connect health data access bodies across EU
- HDABs facilitate data discovery through national metadata catalogues, process access requests, enforce EHDS Regulation compliance, and promote collaboration between member states via working groups like the HDAB Community of Practice (CoP)

Secondary use – Preparations in Sweden

Start May 2025 Final report June 2026

- The National Board of Health and Welfare has been tasked by the government with preparing to be the responsible agency for processing requests and granting access to health datasets for secondary use
- Statistics Sweden has been tasked by the government with investigating how secure environments for secondary use can be organized and developed
- The Health and Social Care Inspectorate (IVO) has been tasked by the government with preparing to be the responsible agency for monitoring and controlling EHDS Regulation compliance
- The Swedish eHealth Agency has been tasked by the government with facilitating the implementation of the national e-health infrastructure

Some challenges in implementing EHDS

- GDPR compliance
- Opt-out implementation
- Interoperability issues
- Protection of intellectual property (IP) and trade secrets
- Sweden: Digital maturity varies across regions and municipalities

Thank you for your attention

Questions?

Appendix: Key actors

- The eHealth Agency (Ehälsomyndigheten)
- The National Council for Interoperability (Nationellt råd för interoperabilitet)
- The National Board of Health and Welfare (Socialstyrelsen)
- The Public Health Agency of Sweden (Folkhälsomyndigheten)
- Statistics Sweden (Statistikmyndigheten SCB)
- Swedish Research Council (Vetenskapsrådet)
- The Health and Social Care Inspectorate (Inspektionen för vård och omsorg, IVO)