

European Health Data Space regulation

EHDS

2026-03-25 Johanna Holm, PhD

National Board of Health and Welfare

Outline of talk

1. Brief EHDS overview
2. EHDS2 roles and time line
3. How are Swedens government agencies preparing for EHDS?



EHDS - European Health Data Space

- Introduces a single market for health data within the European Union (EU)
- A new EU regulation becoming a corner-stone of the European Health Union
 - *Regulation (EU) 2025/327*
- EHDS is the first common EU data space as part of the European strategy for data
- Aims to establish a common framework for the use and exchange of electronic health data across the EU.



Foreseen benefits of the EHDS

- Empower individuals to access, control and share their electronic health data across borders for the healthcare delivery (primary use of data)
- Enable the secure and trustworthy reuse of health data for research, innovation, policy-making, and regulatory activities (secondary use of data)
- Foster a single market for electronic health record (EHR) systems, supporting both primary and secondary use.

Today's focus



EHDS

Primary use

Patients gain access to and control over their data

Healthcare staff gain access to patient information

Exchange of health information across borders

Secondary use

Access to health data for research, innovation, statistics and policy making

Health data processed in secure processing environments

Cross-border access to health data

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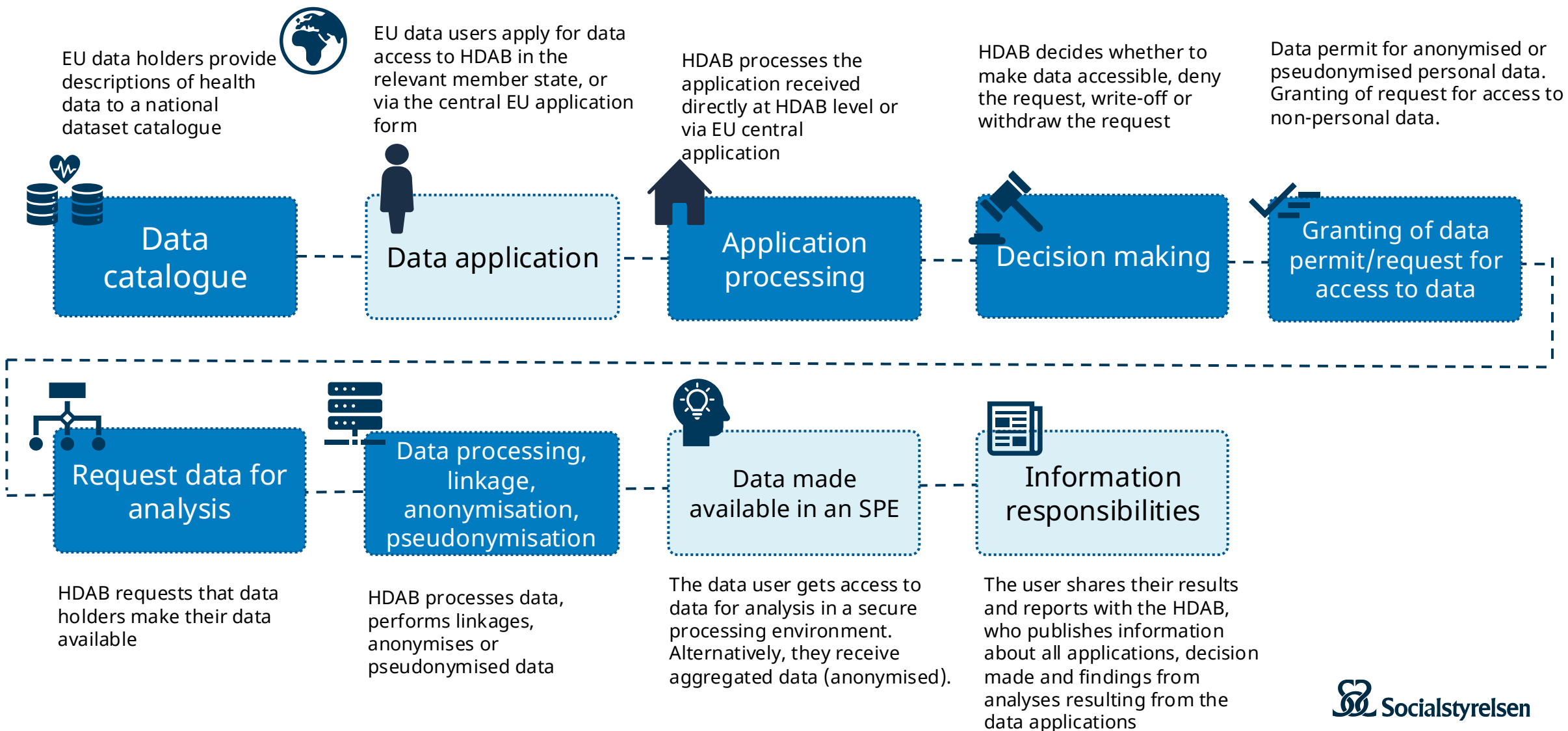
Secondary use

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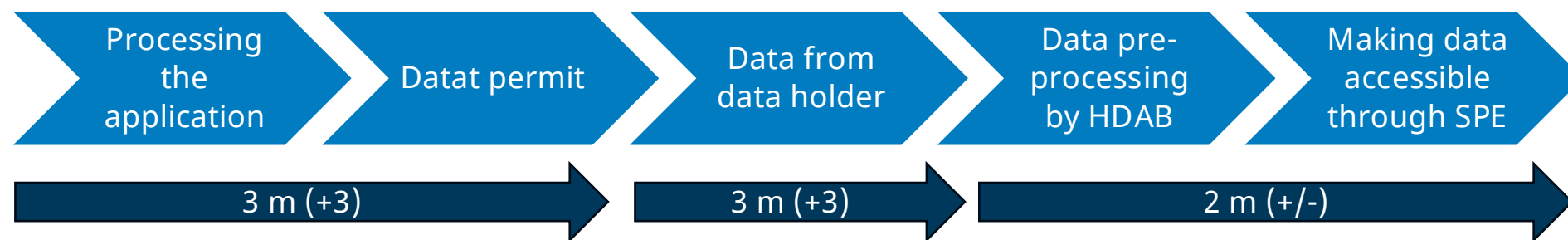
Cross-border access to health data

Secondary use EHDS



Application for data permit - timelines regulated in the EHDS

Time from complete application



Allowed and prohibited purposes

- **Public interest in the area of public and occupational health**, such as activities for protection against serious cross-border threats to health and public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;
- **Policy making and regulatory activities** to support public sector bodies or Union institutions, agencies and bodies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
- **Statistics**, such as national, multi-national and Union level official statistics defined in Regulation (EU) No 223/2009 related to health or care sectors;

Reserved for public sector bodies and Union institutions, offices, and agencies carrying out tasks under Union or national law, including third-party data processing on their behalf

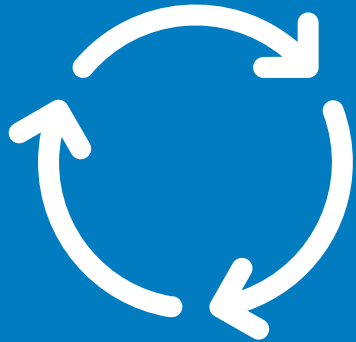
- Vocational or higher **education or teaching activities** in health or care sectors;
- **Scientific research** related to health or care sectors, contributing to public health or health technology assessment or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices with the aim of benefitting the end users including: development and innovation activities for products or services; training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic medical devices, AI systems and digital health applications;
- **Improving delivery of care, treatment optimization and providing healthcare**, based on the electronic health data of other natural persons



- Taking decisions **detrimental to individuals or groups** based on electronic health data, qualifying as decisions if they have legal, social or economic impacts.
- Making **employment-related decisions** or offering less favorable terms in goods or services based on health data, including discriminatory decisions affecting insurance, credit or loans
- Conducting **advertising or marketing** activities
- Developing products or devices that could **harm individuals**, public health or society, including illegal drugs, alcohol, weaponry, or addictive products.
- Engaging in activities that **conflict with ethical standards** set by national law

“Health data holders shall make the following categories of electronic health data available for secondary use”

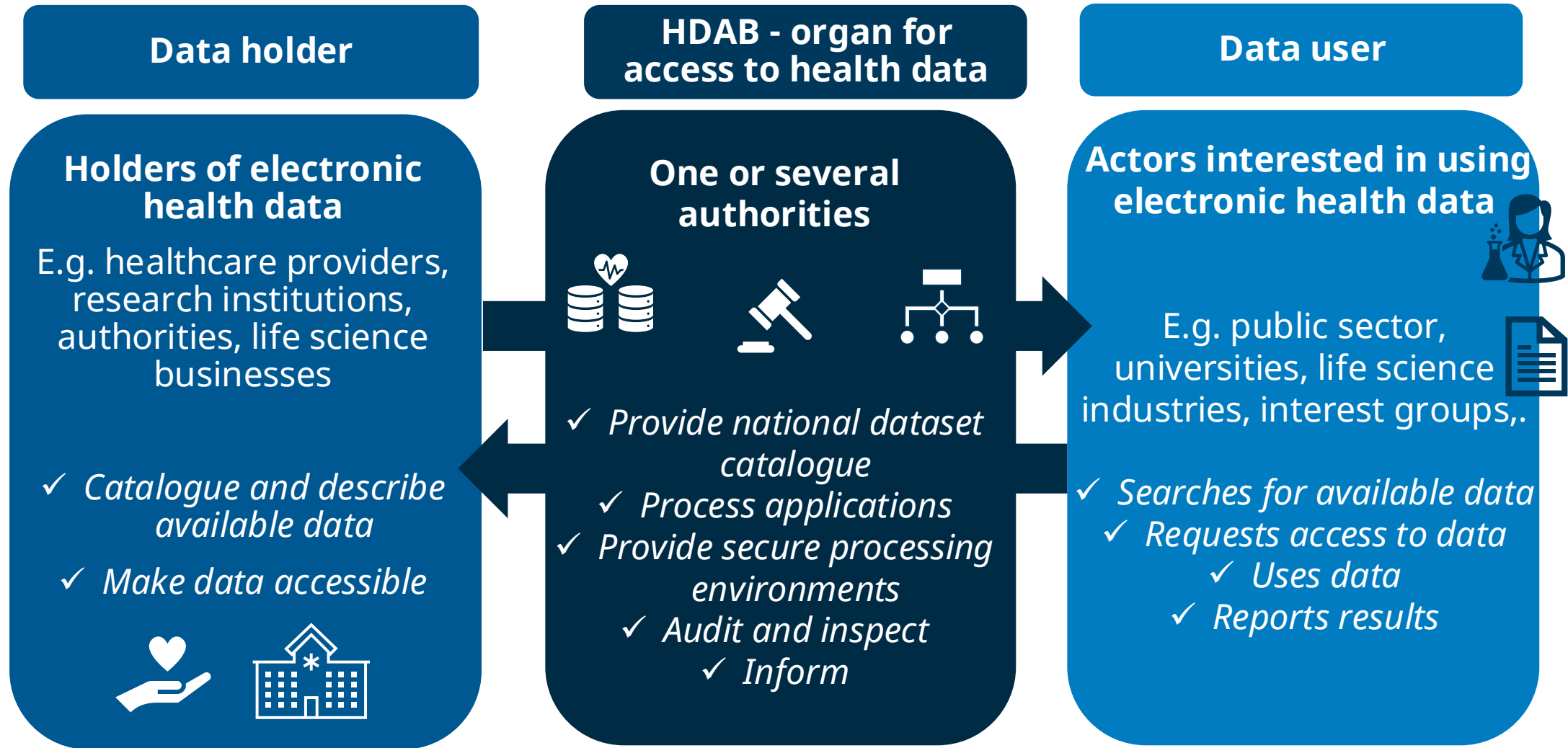
- (a) electronic health data from EHRs;
- (b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;
- (c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- (d) data on pathogens that impact human health;
- (e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;
- (f) human genetic, epigenomic and genomic data;
- (g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
- (h) personal electronic health data automatically generated through medical devices;
- (i) data from wellness applications;
- (j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
- (k) data from population-based health data registries such as public health registries;
- (l) data from medical registries and mortality registries;
- (m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
- (n) other health data from medical devices;
- (o) data from registries for medicinal products and medical devices;
- (p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
- (q) health data from biobanks and associated databases.



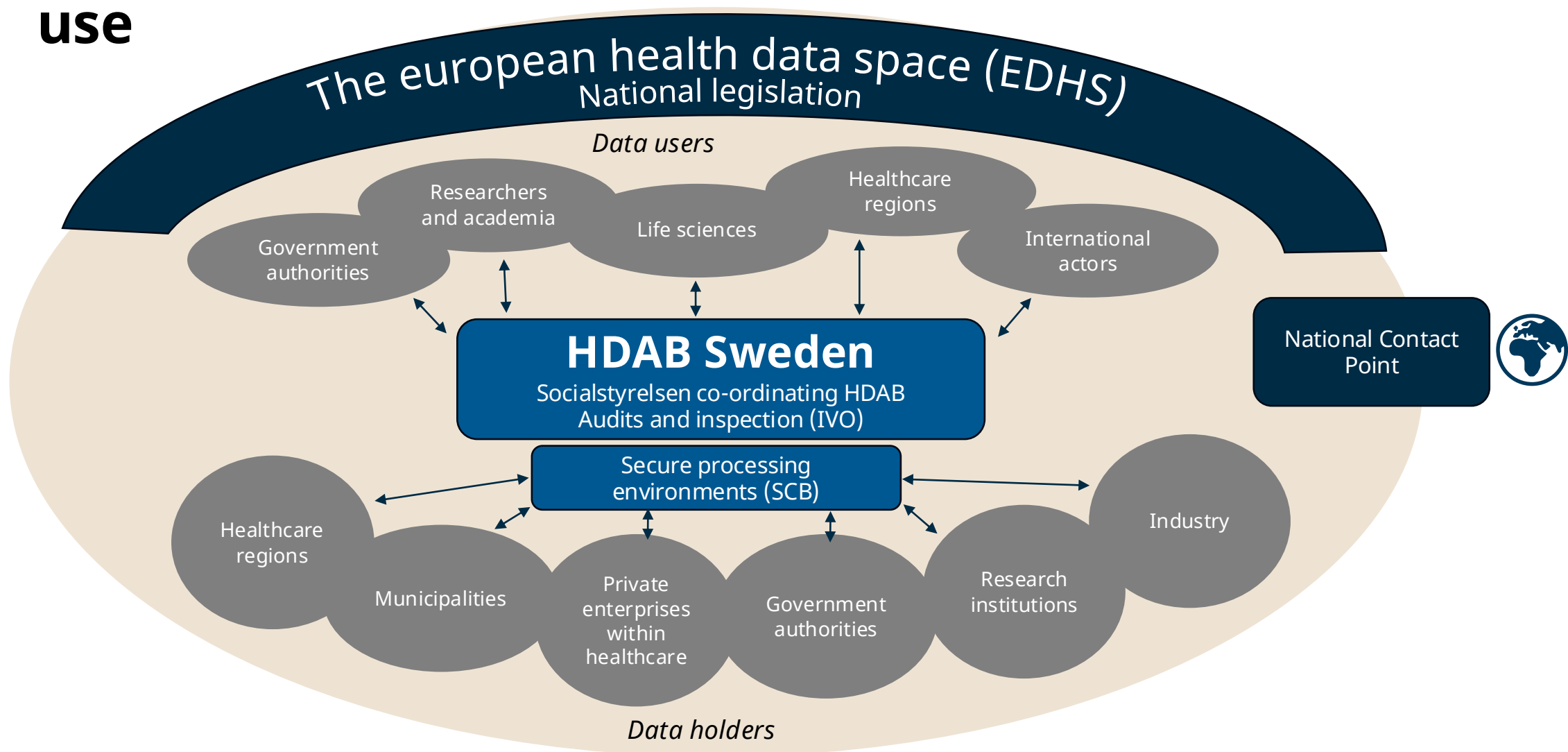
EHDS secondary use of data and HDAB

- Every member state must assign a **Health Data Access Body – HDAB**
- HDAB is responsible for administrating, assessing, granting and providing the access to health data for secondary use

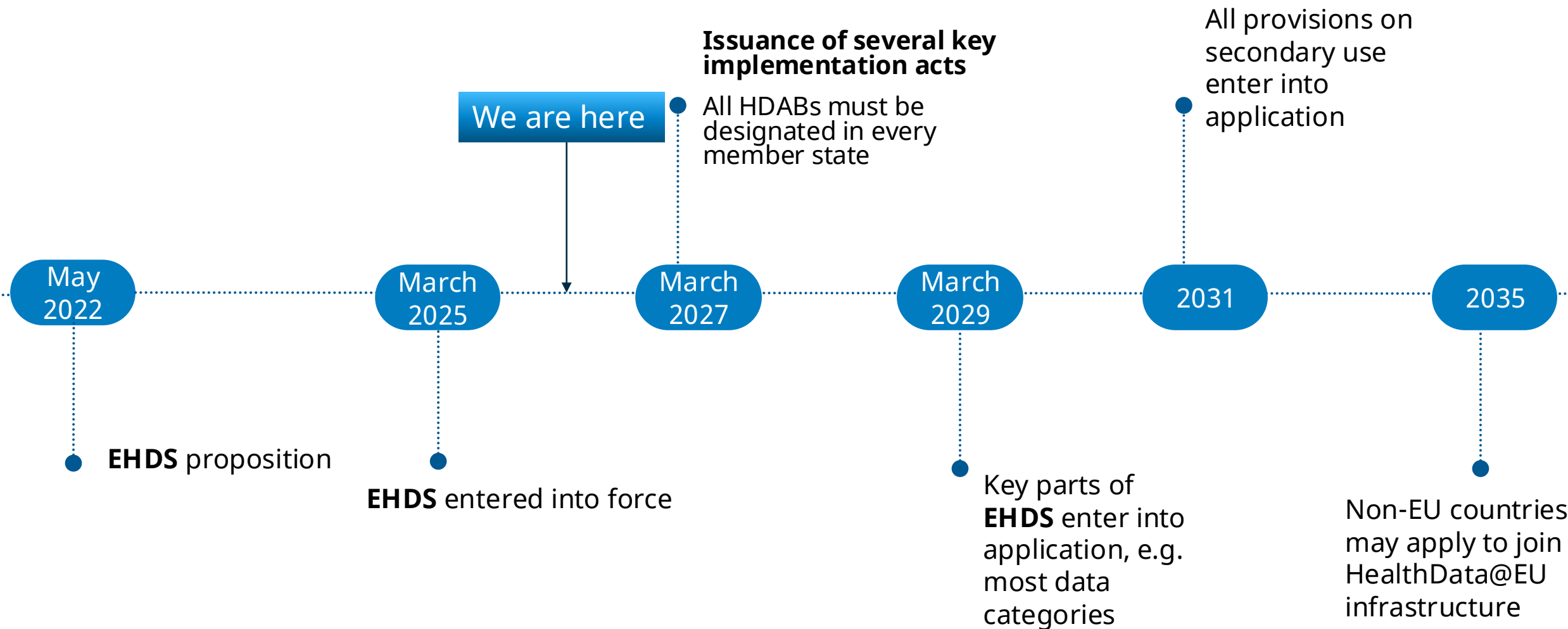
Roles within EHDS secondary use user journey



The system with stakeholders in the EHDS secondary use



High-level timeline for implementation



In preparation for EHDS in Sweden – HDAB

National Board of Health and Welfare

Three government mandates preparing for the role as HDAB, and one ongoing government inquiry

National board of health and welfare (NBHW/SOS) is commissioned to prepare to become health data access body HDAB

Health and Social Care Inspectorate (IVO) is commissioned to prepare for the role of auditing and inspecting compliance with the EHDS

Statistics Sweden SCB is commissioned to investigate how a system of secure processing environments for EHDS should be organised and implemented in a Swedish EHDS context

All to be reported by June 15 2026

S 2024: A Government inquiry

Ministry of Health and Social Affairs in preparation for adjustment of national law, also reporting in June 2026

The HDAB commission for the National Board of Health and Welfare

- **Investigation and analysis of the prerequisites for taking on the assignment of all* HDAB tasks, including**
 - The National entry point for applications for access to health data, including application management, assessment and decisions on data permits
 - Request and prepare data from dataholders, provide data access for data users,
 - Maintain a nationell catalog of available datasets for secondary use,
 - To coordinate the HDAB tasks on national level and in relation to EU, and take on the responsibilities in reporting
- *except those potentially assigned to other agencies

The HDAB commission for the National Board of Health and Welfare

- **Investigate the prerequisites for taking on the role of National Contact Point for secondary use in the Healthdata@eu infrastructure**
- Analyze potential conflicts of interest and propose an organizational model
- Estimate the costs before and after the implementation of EHDS
- Participate in preparations for EHDS on the national and EU level.
- Collaborate with other relevant Agencies and assist the ongoing government inquiry on the national digital infrastructure if needed.
- Interact with other government agencies, regional and local authorities, private caregivers, research communities as well as data holders, data users and others.

*except those potentially assigned to other agencies

The three roles of NBHW regarding EHDS

	HDAB	Data holder	Data user
Health data	<ul style="list-style-type: none"> • Issues data permits • Receives data from data holders • Makes data accessible in SPEs 	Shall be able to deliver data to HDAB	Can order data from other data users
Metadata	<ul style="list-style-type: none"> • Host the national data catalogue • Support data holders in adhering to the standard 	<ul style="list-style-type: none"> • Describe datasets according to metadata standard • Supply metadata about datasets to the catalogue 	Discover datasets across all data holders within EHDS through the catalogue
National contact point (X-border infrastructure for applying for and using health data in EHDS)	<ul style="list-style-type: none"> • Responsible for infrastructure • Support the onboarding to the infrastructure 	Must be able to send and receive messagings through the system	Gets their requested data delivered through the system

The HDAB commission of Statistics Sweden (SCB)

Investigate how a system of secure processing environments according to EHDS can be organized and developed in Sweden

Analysis includes

- If Statistics Sweden or other agency in the health and welfare sector can provide one or more SPEs
- Investigate if and how existing infrastructure can be used
- If Statistics Sweden could provide an SPE based on the current system (MONA) or if new development is needed

The HDAB commission of The Health and Social Care Inspectorate (IVO)

- **Prepare for the HDAB role with the responsibility to monitor and supervise compliance among data holders and data users according to EHDS**
- Investigate and describe the tasks and how they may be executed in the most efficient manner.



**Government inquiry (S 2024:A)
Ministry of Health and Social Affairs in
preparation for adjustment of national law**

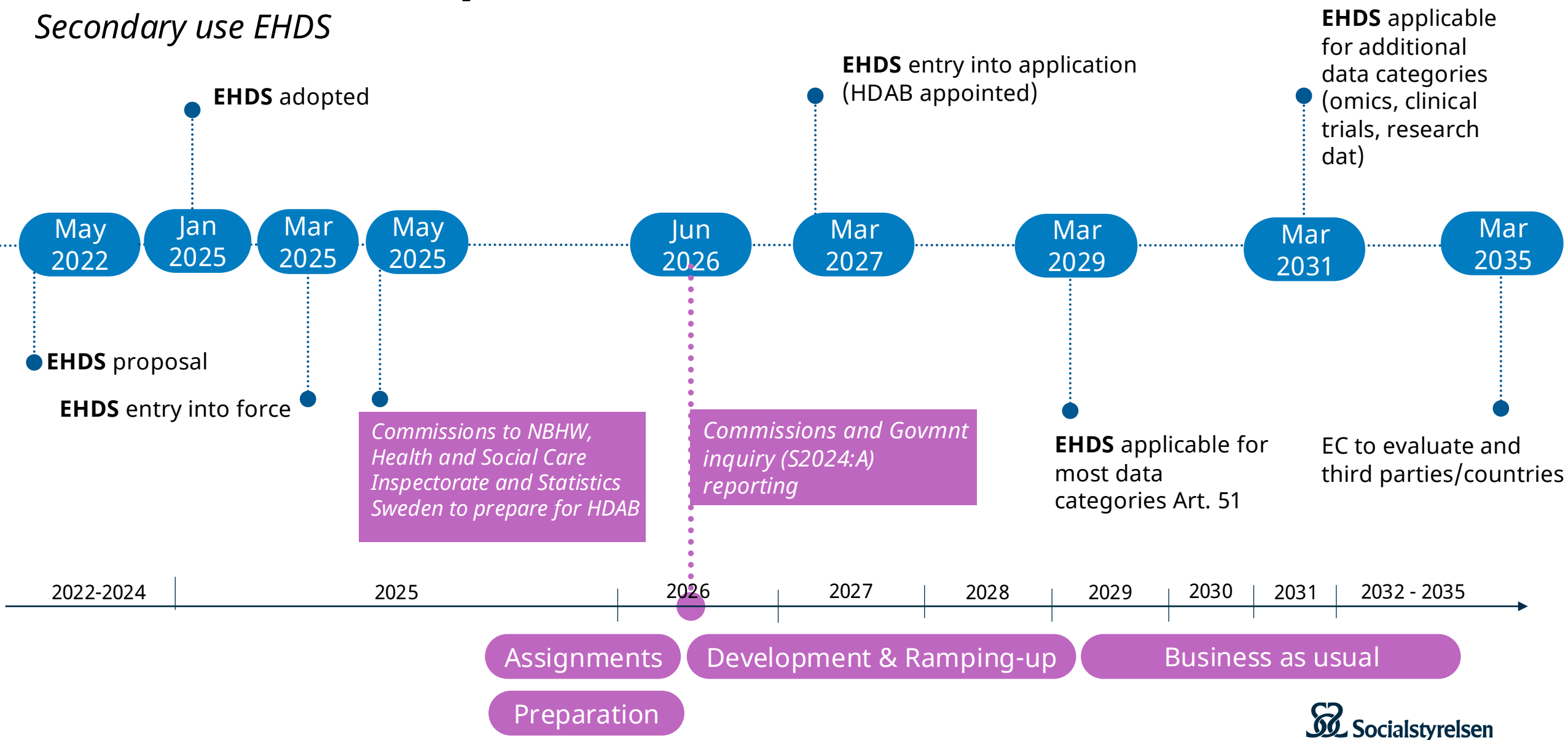
EHDS and secondary use (Oct 2025-June 2026)

- Fee structure for access to health data for secondary use
- Sanction fees for non-compliance among dataholders and data users (eg. time limits)
- Analysis of EHDS regulation regarding data permits in relation to national regulations concerning e.g ethical assessment of research studies
- Trusted data holders - pre-assessment and management of applications for data permits
- Intermediation entities for access to health data for secondary use (on behalf of data holders)



Timelines for implementation

Secondary use EHDS



**For more information, see FAQ at the european
commission or the legislation itself**

[Frequently Asked Questions on the
European Health Data Space - Public
Health](#)

[Regulation - EU - 2025/327 - EN - EUR-
Lex](#)

Thank you!

