Towards the European Health Data Space (EHDS)
A focus on secondary use of data for cancer registries

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BACKGROUND

The European Health Data Space (EHDS) is a cornerstone of the European Health Union and the first common EU data space dedicated to a specific sector as part of the European strategy for data.

The main components of the EHDS are:

- Primary use of data for healthcare delivery
- Requirements for electronic health record (EHR) systems
- Secondary use of data for research and public interest purposes

Significant opportunities exist to strengthen the Nordic countries' position as leaders in cancer data utilisation, particularly in the light of the forthcoming EHDS, which defines several roles relevant to cancer registries and researchers:

- Health Data Holders, and Trusted Data Holders (TDHs)
- Health Data Users
- Health Data Access Body (HDAB)
- Secure Processing Environments (SPEs)

Note: TDHs often host their own SPEs and national HDABs may delegate some responsibilities to TDHs.

EUROPEAN HEALTH DATA SPACE IN A NUTSHELL

LEGISLATIVE PROCESS

The EHDS regulation (26 March 2025) aims to establish a common framework for the use and exchange of electronic health data across the EU. It builds on GDPR, Data Governance Act, Data Act, and Network and Information Systems Directive. Provisions will be implemented in stages during 2027–2034. Most obligations will only apply 4 years after a regulation has entered into force.

IMPLEMENTATION

The TEHDAS2 project prepares the ground for the harmonised implementation of the secondary use of health data in the European Health Data Space.

The project is divided into eight work packages (WP). WP 1–3 are linked to the execution of the project and WP 4–8 are linked to secondary use of health data.

SECURE PROCESSING ENVIRONMENTS (SPE)

Secure Processing Environments (SPE) are secure digital workspaces where authorised users can process electronic health data in a highly controlled manner.

SPEs are a cornerstone of the EHDS infrastructure and adhere to criteria including:

- **Data security**: Prevent unauthorised access, maintain confidentiality, ensure data integrity
- **Restricted access**: Allow users to process only those data covered by a valid data permit, and only within the permitted scope
- **Controlled outputs**: Ensure that only non-personal data—that is, aggregated and anonymised results—can be exported, and only after authorisation by the competent HDAB.

SPE may be used by data users, or a Health Data Access Body (HDAB).

CHALLENGES

- Actual funding versus expectations
- Costs and bureaucracy including user adaptation to rules and practices, application processes and use of SPE
- SPE has low stakeholder engagement
- Large variation between countries in technical maturity and resources
- Potentially conflicting EU versus national legislation
- High expectations for HDAB role
- Insufficient focus on federated analysis and use of synthetic data
- True data sovereignty

CANCER REGISTRY OF NORWAY PARTICIPATION

The Cancer Registry of Norway (CRN), part of Norwegian Institute of Public Health (NIPH), contributes to various Eu4health and EHDS projects.

SPUHIN (Secure Provision and Use of Health data In Norway)

SPUHIN aims to secure the provision and use of health data in Norway. The director of CRN, Giske Ursin, is a member of the SPUHIN project board.

CRN has participated in workshops and consultations, and contributes to:

- WP 5: Requirements for SPE (lead Jan F Nygård)
- WP 6: Verification of SPE (member Jan F Nygård)
- WP 7: Secure data transport to SPE (member Petter Topp)
- WP 8: Architecture (member Petter Topp)
- WP 9: Reporting available metadata (Siri Larønningen, Gintaras Pikelis)

A GAP analysis related to SPEs (WP5 and WP6) has been published. This involved the NORTRE group: TSD (University of Oslo), HUNT Cloud (NTNU) and SAFE (University of Bergen). It covered information security management systems, Access management, Data export and import, Functional requirements.

An open consultation on SPUHIN SPE will close on October 18, 2025.

QUANTUM

The QUANTUM project (2024–2026) aims to create a common quality label system and tool to assess the quality and utility of secondary use datasets, and the maturity of the data holder responsible for each dataset. These labels will be presented as metadata at HealthData@EU to enable data users (e.g. researchers, policymakers, healthcare professionals) to identify suitable data sources.

The CRN contributes to WP 1–4 (Siri Larønningen) and WP3 (Gintaras Pikelis):

- WP 1: Specification of the data quality and utility, and maturity label
- WP 2: Design, development and testing of the label
- WP 3: Mid-scale implementation of the label
- WP 4: Capacity building, community engagement and scale up

Challenges in QUANTUM include:

- The self-assessment of quality labels
- No detailed quality descriptions for individual variables, only general quality measures

Joint Action CancerWatch: timely data access to ECIS (JRC)

CancerWatch is coordinated by the CRN and will guide cancer registries to meet requirements of the emerging EHDS, particularly related to:

- Preparing metadata catalogues (HealthDCAT-AP)
- Designing access to European Cancer Registry data via the HDAB structure
- Creating data quality labels for the cancer registries
- Analysing and expanding mechanisms for linkages with European cancer registries via EHDS mechanisms

OTHER INITIATIVES

EU Data Access and Coordination Office (DACO), Value for Nordic Health Data (VALO), ELIXIR, UnCan European Federated Cancer Research data hub, European Cancer Patient Digital Centre (ECPDC).

Cancer Registry of Norway

NIPH Norwegian Institute of Public Health

For more information