Towards European Health Data Space

COUNTRY VISIT
Denmark

Country visit – Denmark

Objectives of the country visits

The objective of the TEHDAS country visits is to provide an overview of the status of national health data management in different European countries. This mapping exercise takes place in the form of country visits in which national stakeholders working with health data or exchanging health data are interviewed.

The Joint Action Towards the European Health Data Space (TEHDAS) supports EU member states and the European Commission in developing and promoting concepts for the secondary use of health data to benefit public health and health research and innovation in Europe.

Any questions?

Contact us at
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Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to Denmark took place virtually between **14 and 17 December 2021.**

Who was involved?

20 stakeholder organisations were interviewed: Aarhus University – Data Unit, Aarhus University Hospital – Chief Medical Officer, Central Denmark Region – Connect (Center for Clinical and Genomic Data), Central Denmark Region – IT Architecture and Design, Central Denmark Region – Legal Department, Copenhagen University – Centre for Protein Research, Copenhagen University – Law Faculty, Coordinating Body for Research (KOR), Danish Health Data Authority, Danish Medicines Agency, Danish National Biobank, Danish National Genome Centre, Danish Regions, Ministry of Health (written input), Ministry of Industry, Business and Financial Affairs, Novo Nordisk, Region of Southern Denmark – Regional Data Support Centre, RKKP, Roche, Statistics Denmark. Sundhed.dk.

Denmark in brief

The Danish health information system is a highly integrated system covering the whole life cycle, containing a large collection of databases and registries. The completeness of the data is rooted in legislation and the trust of the population. Data is generally seen as a common good, with widespread support for data sharing. The Central Person Register (CPR) number is a unique identifier, which has been available for the past 50 years, covering all registered citizens in the country and allowing individual linkage across data sources. The Danish healthcare system is fully digitalised. Health data can be analysed in a remote secure environment provided by the data holders.

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Data collections/sources

- Denmark has a long and rich history of registry data, of more than 350 national registries.
- The data is stored at three key agents: the Danish Health Data Authority, the Danish Clinical Quality Registries (RKKP), and Statistics Denmark.
- The biobanks and National Genome Center store biological material and genomic information.
- The Regions are responsible for storing electronic health record (EHR) data in regional data warehouses.
- Coverage of EHRs is complete, and healthcare providers are legally obliged to report to the regional data warehouses.
- The EHR system is decentralised, and there are two different EHR systems used across the country. Data is not exchanged between the two systems directly, however, healthcare professionals are able to view their patients' EHR via the E-Journal, including data from other regions.
- Denmark has a tax-based universal healthcare, all citizens have access to healthcare providing full coverage of the population.

Data quality

- Health data in Denmark is updated in a timely manner e.g., it takes about 24 hours for EHR data to be sent to the regional data warehouse. Other register data have an update frequency between 1 day and 6 months.
- Quality control mechanisms in place include: reporting guidelines, training at point of collection, mandatory fields at data input point, validation of data at point of reception and feedback loops.

Data infrastructure

- Currently, there is no centralised metadata catalogue that provides a general overview of health-related data collections and access procedures.
- A metadata catalogue is being developed by the initiative 'Research Health Data Gateway' (En Indgang til Sundhedsdata). The metadata model being used in the is based on DCAT and ISO/IEC11179 and DCAT-AP DK OPEN DL.
- Disease registries use international standards, such as SNOMED-CT, ICD-10 and HL7 FHIR.
- The main steps to access data are:
    1. Obtain necessary (ethical) approvals
    2. Describe the research project and the planned use of data in an application
    3. Apply to the data holders from which the largest proportion of data is needed
- The data holders provide access to the requested data and to the remote secure environment for analysis.
- Access is only possible if the researcher is affiliated to an approved Danish research institute.
- It takes on average 1-6 months to receive access to the data.
- The fee for accessing the data varies between data holders.
- In most cases, access is only provided to data that is pseudonymised.
- Data linkage is possible using the CPR number.

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Data governance

- The Danish Health Data Authority is the body responsible for conceptualising and implementing health data governance.
- A National Board for Health Data allows shared decision-making and strategy setting.
- The regulatory framework for accessing and sharing data depends on the purpose for which data is requested.
- The most important legal acts are: The Act on Research Ethics Review of Health Research Projects, The Health Act, and The Danish Data Protection Act.
- GDPR is perceived to be interpreted differently between lawyers at national, regional and hospital-level, sometimes causing challenges.
- The need for ethical approval depends on the type of research project. For certain complex projects (e.g., extensive genome examinations without consent or stem cell research) the National Ethics Committee provides approval. This is also the case for certain data-based projects, where there is a risk of secondary findings. For other research projects it is the regional ethical committees that provide approval.
- If a violation of data security is detected, the research institute is temporarily banned from accessing data for a certain amount of time.
- There is high willingness among citizens to share their health data. One of the reasons suggested for this is because data does not move out of the country.
- Citizens can access their own records through the national e-health portal.

Resources (human, technical, financial)

- Human resource capacities for maintaining and operating data collections vary across data sources.
- Qualified staff are needed, as well as better and faster training of existing staff. Developers are also needed to develop the genomic data infrastructure.
- Financial incentives are needed to attract and keep highly qualified and skilled staff.
- The status of the ICT infrastructure in Denmark appears advanced. Health data collections are digitalised. Every hospital has an ICT department that trains healthcare providers to use the electronic systems and software.
- The Ministry of Business is investing in big data and artificial intelligence. The Novo Nordisk foundation co-funds initiatives and research infrastructures.
- The secondary use of health data is financed by several actors: the government, the Coordinating Body for Register-based Research, the private sector and foundations, such as Novo Nordisk as well as the Independent Research Fund Denmark.

Capacity building

- All new healthcare providers and staff members receive training to ensure data input is done correctly in the EHR system.
- All regions have set up Regional Support Centres offering training and support to researchers for data access and analysis.
- The Danish National Biobank offers a yearly course for PhD students on how to secure accessibility permissions and use the biobank samples efficiently.
- The European Network Training Centre provides training on regulatory work.
- Some institutes are establishing curricula on statistics and data analysis.

- Some training and capacity needs were identified:
    - Competencies and training skills to work with citizen-generated data (e.g., from wearables)
    - More training specific for healthcare staff on statistics and data analysis.

Best practices

- In general, data is seen as a common good and citizens have high trust in the health information system.
- Due to its long history of integrated databases and collections, Denmark operates with the entire country as a cohort.
- The right constellation is in place for ultimate secondary use of health data: universal tax-based healthcare, extensive long-term record keeping, individual-level linkage, lifetime follow up.
- Various support methods provided to researchers, such as the Regional Data Support Centres that help researchers access the data they need.
- Focus on the use of synthetic data in the 'Vision for better use of Danish Health Data' project.
- Multiple public-private partnerships provide co-funding options for innovation.

European Health Data Space (EHDS)

- There is political interest in joining the EHDS. It was reported that the Danish Health Data Authority may potentially act as the Danish node (health data access body that would function as a single national contact point) for the EHDS.
- Cross-border sharing of health data is very important but challenging. Foreign researchers receive access to data only if they are affiliated or partnered with a Danish research institute.
- In general, the Danish Health Data does not leave the country due to privacy and security procedures, but under certain circumstances and approvals, data can be shared cross-border.
- There is high support for using a system of federated collection, storage and analysis of health data.
- The 'Vision for better use of Danish Health Data' and the 'Research Health Data Gateway' ('En Indgang til Sundhedsdata') initiative support the EHDS vision in developing a single point of entry to metadata, with guidance and a common process for requesting access to data.
- There is the expectation to have an overview of the current health data management systems in EU member states and of the national regulations in place regarding health data governance.

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