



Towards
European
Health
Data
Space

Deliverable 4.1

Country factsheets

Mapping health data management systems through country visits: development, needs and expectations of the EHDS

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1 Executive summary

TEHDAS work package 4 (WP4) aims to reach out and engage with national and international stakeholders, to reflect on their needs and expectations for the future European Health Data Space (EHDS). In particular, Task 4.1 carried out a mapping exercise among Member States (MS), to provide an overview of national health data management systems and their readiness to join the EHDS. This mapping exercise took place in the form of country visits, in which national stakeholders working with health data or exchanging health data were interviewed. Making use of the diversity in Europe, 12 countries were visited.

This document starts by presenting the methodology used to carry out the country visits. The first step was the development of the TEHDAS mapping tool (i.e., guiding questions to be asked during the interviews), based on existing tools and methodologies for health information system assessment. The countries to be mapped were selected through a call for expression of interest among TEHDAS partner countries. The country visits themselves followed a 5-step methodology: stakeholder selection, preparatory desk review, semi-structured interviews, multi-stakeholder meeting, and dissemination of results.

Thereafter, the results from the 12 country visits are presented in the form of factsheets. The factsheets summarise the key findings from each country, grouped under the themes of the TEHDAS mapping tool: data collections; data quality; data infrastructure (including storage, access procedures and interoperability); data governance; resources (human, financial and technical); and capacity building. Each factsheet then reflects on the country's preparedness to join the EHDS for secondary use, including the political will and needs and expectations.

Finally, this deliverable provides guidelines on how the methodology developed for the TEHDAS country visits should be further used. It is important to note that countries' health data management systems are rapidly changing, and an iterative process should be used to take account of relevant developments.

2 Acknowledgement

We would like to acknowledge and express our thanks to all those who supported the team in carrying out these country visits. Thank you to the TEHDAS partners who volunteered to be country contacts and helped identify and contact the relevant stakeholders, set up the interviews and attend all interviews with the team of interviewers. We thank all the stakeholders who have taken the time to talk to us to present the data management procedures in their country and explain the situation of sharing and accessing health data from their perspective. We thank the assessors from other institutes who joined the Sciensano team and supported the team in various country visits. Finally, we thank the World Health Organisation (WHO) Regional Office for Europe for making the tool and its modules available to adaptation, and Neville Calleja for the expert support throughout the country visits.

3 Introduction

The Joint Action Towards the European Health Data Space (TEHDAS), helps EU Member States (MS), Associated Countries (AC) and the European Commission (EC) to develop and promote concepts for the secondary use of health data to benefit public health and health research and innovation in Europe.

More specifically, work package 4 (WP4) aims to reach out and engage with national and international stakeholders, to reflect on their needs and expectations for the future European Health Data Space (EHDS) for secondary use (the HealthData@EU infrastructure, as named in the proposal for a regulation on the EHDS). This work underpinned the legislation on the EHDS.

WP4 engaged with stakeholders at different levels to ensure their opinions needs and expectations are considered in the development of the EHDS. One of the engagement activities was to carry out a mapping exercise among MS to provide an overview of their health data management systems. Countries are at different stages in digitalising their health system, and in setting up national health data hubs and legal frameworks for secondary use of health data. Making use of the diversity in Europe, a selection of countries in different stages of development and different health systems were visited. This mapping exercise took place in the form of country visits (virtual or face-to-face) in which national stakeholders working with health data or exchanging health data were interviewed.

The objective of the mapping exercise was threefold:

1. To map the state of play of the national health data management systems in relation to a future EHDS by gathering key information regarding the general health information system and providing an overview of health data management practices regarding, for example, data storage, data quality, data access, and data governance.
2. To reflect on the needs and expectations at national level and how the EHDS could respond to them.
3. To identify capacity needs and opportunities through mapping of available training courses that are already provided by other projects/initiatives, and remaining needs for expertise and capacities in the countries.

As a basis for the mapping exercises, a broad definition of health information system (HIS) was applied: “A health information system is the total of resources, stakeholders, activities and outputs enabling evidence-informed health policymaking. Health information system activities relate to all phases of population health monitoring. These are data collection, interpretation (analysis and synthesis), health reporting, and knowledge translation, i.e., stimulating and enhancing the uptake of health information into policy and practice. Health information system governance relates to the mechanisms and processes to coordinate and steer all elements of a health information system” ⁽¹⁾. The focus of the mapping exercise is on health data management systems, which is viewed as a component of the HIS, and refers to the procedures and practices in place regarding how health data is handled. This includes how health data is collected, stored,

accessed and shared, but also considers the technical interoperability and governance framework to enable the data management.

The following document presents the methodology used in detail and the main results of the country visit in the form of factsheets. The factsheets present a brief overview of the state of play of the health data management systems in twelve countries. Finally, the document suggests guidelines on how to use the methodology and mapping tool for benchmarking in the future, combined forming the 'TEHDAS country visit toolkit'.

4 Methodology

4.1 Development of the TEHDAS mapping tool

The TEHDAS mapping tool was developed based on existing tools and methodologies (see Table 1), adapted to the scope and objectives of TEHDAS WP4 in order to support the semi-structured interview process. The main tools used were the health information system assessment and strategy development tool developed by the World Health Organisation (WHO) Regional Office for Europe in the framework of the WHO European Health Information Initiative (EHII), and the version used within the InfAct Joint Action on Health Information.

Table 1: Tools and methodologies used to develop the TEHDAS mapping tool

Author	Tool
The WHO Regional Office for Europe ⁽²⁾	Support tool to strengthen health information systems: guidance for health information
InfAct ^(3,4)	An adjusted tools developed from the WHO support tool for peer review assessment
MEASURE Evaluation ⁽⁵⁾	Health Information System Stages of Continuous Improvement Toolkit
MEASURE Evaluation ⁽⁶⁾	Health Information Systems Interoperability Maturity Toolkit
The Global Partnership for Sustainable Development Data ⁽⁷⁾	Joined-Up Data Maturity Assessment Toolkit

The TEHDAS mapping tool was refined based on the experience during the country visits. The final tool, including overarching themes and guiding questions, is included in the Annex.

4.2 Launch of the call for expression of interest

A call for expression of interest in the country visits was launched in September 2021. TEHDAS partners had the opportunity to indicate their interest to have the mapping exercise carried out in their country. The launch of the call for expression of interest took place as a virtual meeting. In this meeting, the methodology and the TEHDAS mapping tool for the country visits were introduced. The expected role and tasks of the interested TEHDAS partners, the country contact persons and the assessors were explained. The target number of countries to be visited was 12 MS/AC. The call for expression of interest was open for three weeks and 12 countries had applied by the time of the deadline. Therefore, no selection process was needed.

4.3 Methodology for conducting the country visits

The methodology used for the country visits consisted of a 5-step process⁽⁸⁾, involving the assessors (the team interviewing the stakeholders), the country contact person (who supports the assessors in the organisation of the country visit) and the stakeholders that were interviewed.

1. *Stakeholder selection*

The relevant stakeholders to be interviewed were identified by the country contact person, with input from the assessors visiting the country. Depending on the country, the number of stakeholders being interviewed and the exact institutes they were from differed. The process of stakeholder selection was initiated during a training on the TEHDAS country visits provided by the Task 4.1 leads in October 2021.

2. *Preparatory desk review*

The preparatory desk review consisted of a review of relevant documents provided by the country contact person as well as results from previous surveys/reports (e.g., surveys conducted in other WPs of TEHDAS) or EU/international documents. The desk review served as a starting point for the mapping exercise, not as a comprehensive, detailed description of the state of play of the health data management system. It was used to provide the assessors with an overview of the situation in the country they would visit.

3. *Semi-structured interviews*

Semi-structured interviews were carried out with the identified stakeholders, guided by the TEHDAS mapping tool. It was emphasised in the interviews that the mapping exercise was explorative and qualitative in nature, i.e. the aim of the exercise was to have an overview of the state of play of the health data management system and the preparedness of the country to potentially join a future EHDS.

4. *Multi-stakeholder meeting*

The initial findings of the country visit were presented to all the stakeholders interviewed in a multi-stakeholder meeting, which generally took place in the days following the final interview. This was an opportunity for the stakeholders to provide clarifications or amendments on the initial findings, if required. The multi-stakeholder meeting was also a valuable opportunity for all the stakeholders involved in the country's health data management system to come together, providing networking opportunities.

5. *Dissemination of results*

The final stage of the country visit methodology consisted of writing a report and accompanying factsheet, which compiled the results of the above four stages. The report is disseminated only to the stakeholders of the country visited, the EC, and to the TEHDAS consortium members. The accompanying factsheet is disseminated more widely beyond the TEHDAS project and is published on the TEHDAS website⁽⁹⁾.

5 Results

The countries visited during the mapping exercise are presented in Table 2, along with the respective dates. Figure 1 demonstrates the geographical distribution of the countries visited.

Table 2: Countries that participated in the TEHDAS mapping exercise.

	Country name	Date of country visit
1	Belgium	31 January – 4 February 2022
2	Czech Republic	11 – 14 July 2022
3	Denmark	14 – 17 December 2021
4	Estonia	11 – 14 April 2022
5	Finland	8 – 10 June 2022
6	Germany	24 November – 12 December 2022
7	Hungary	14 – 17 February 2022
8	Ireland	3 – 6 May 2022
9	Netherlands	29 – 31 March 2022
10	Portugal	23 – 26 May 2022
10	Slovenia	20 – 23 September 2022
22	Sweden	24 – 28 October 2022

Figure 1: Distribution of countries that participated in the TEHDAS country visits



In general, the results from the country visits showed that health data management procedures vary between countries. The vast majority of countries have **rich health data landscapes**. In most countries, health data **management is scattered across various stakeholders**, whilst a minority have a centralised organisation. Not all countries have fully digitalised health data (for example, some countries still have paper based patient records) which is a key requirement for the EHDS. Similarly, not all countries use a unique personal identifier in health, making linkage between datasets more complex.

Different mechanisms to ensure **data quality** were reported. Stakeholders elaborated on the mechanisms of quality checks (both manual and automatic), validation, and feedback procedures in use for each of the data sources.

Data interoperability was assessed, for instance looking at how widespread the use of internationally recognised standards is. Standards that were discussed regarding metadata and data exchange were mainly DCAT-AP⁽¹⁰⁾, OMOP⁽¹¹⁾ and HL7 FHIR⁽¹²⁾. Semantic interoperability standards were noted to be widely used in many of the countries, including the use of ICD-10⁽¹³⁾, LOINC⁽¹⁴⁾ and SNOMED CT⁽¹⁵⁾. Several countries also mentioned the use and development of national standards, and potential implications these have on cross-border interoperability.

Access to different types of health data was one of the key things being mapped. This included gathering information on how and where data are stored, and whether there is a common metadata catalogue in place facilitating data discoverability. In most countries, health data was hosted in different organisations. Only few countries noted the existence or ongoing development of a **common metadata catalogue**. Others indicated that some data holders have their own metadata catalogue. In general, stakeholders reported that in many cases researchers and policy makers experience challenges in accessing data from different data holders. This is due to the diverse, and sometimes un-transparent, access procedures, as well as differences in the fees requested and expected time to access the data. In addition, pseudonymisation and anonymisation processes were discussed and whether the stakeholders make use of a trusted third party.

In terms of **governance**, the mapping exercise showed the impact of the legal framework for health data use and re-use in the different countries. Many countries reported that the main barriers to secondary use of health data were **legal barriers**. For instance, in many cases the different interpretations of GDPR in the national legislation was noted as a main barrier for data sharing within and between countries. Furthermore, in most countries there is no clear national legislation for secondary use of health data. The roles of the main governing bodies and key legal acts in place were mapped.

The importance of **citizens' involvement and trust** was another key aspect explored in the country visits. Different activities are implemented across countries to involve citizens. In addition, ethical procedures to ensure safe handling and protection of the health data of citizens were explored. Many of the countries require an ethical committee approval for implementing research and accessing health data. Some have set up national ethical committees. In other countries, the ethical committees are based in institutes, hospitals, or universities. This can add complexity when data users are unsure of which is the appropriate body for approval.

Next, needs and availability for human, technical and financial **resources** were discussed. Many of the stakeholders noted large needs in human resources, many of which included personnel with technical and legal expertise. Data stewards were also mentioned often, being the persons providing both technical management and contextual knowledge of the data. The need for additional financial resources was common across many stakeholders within all the countries, both to support human resources and to further develop the technical infrastructure for implementation of the EHDS.

To complete the country visits and evaluate countries' political will and technical preparedness to join a future EHDS, views on the legislative proposal were explored. All countries recognise the added value of the EHDS for secondary use of health data within and between countries.

Countries expect the EHDS to lead to better streamlined data sharing and increased joint research for better health in Europe. However, many needs and concerns still remain. With the ambition of the EHDS, it was important for the stakeholders that differences in preparedness of the health information systems in general, and health data management systems in particular, between countries are considered. Ensuring equal benefit for all countries was also emphasised. Among others, stakeholders called for legal, organisational and semantic interoperability across Europe, and guidelines for secure sharing of data. Stakeholders highlighted that transparency, protecting citizen's privacy and trust should be guaranteed.

Finally, MS/AC are currently at different preparedness levels for joining the EHDS. To facilitate better learning across countries, available training courses and best practices were identified. Remaining needs for expertise and capacities in the countries were also listed.

The next sections present the factsheets for each county visited, elaborating on the above-mentioned aspects.



Country visit – Belgium

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.

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Any questions?

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

When did it take place?

The visit to Belgium took place virtually between **31 January and 4 February 2022**.

Who was involved?

14 stakeholder organisations were interviewed: Belgian Cancer Registry (BCR), Belgian Data Protection Authority, Belgian Health Care Knowledge Centre (KCE), Cabinet of Minister of Health and Social Affairs Vandenbroucke, Common Sickness Funds Agency (IMA-AIM), Consultants for the Health Data Authority, Crossroads Bank for Social Security (CBSS) and e-Health platform, Federal Agency for Medicines and Health Products (FAMHP), FPS Public Health, Food Chain Safety and Environment, Healthdata.be, INTEGEO, National Institute for Health and Disability Insurance (NIHDI), Sciensano, Statbel – Belgian Statistical Office.

Belgium in brief

The Belgian Health Information System has rich health data of high quality. However, the data landscape remains fragmented across multiple data holders, on different federal and regional layers. In Belgium, the health system is primarily funded through social security contributions and taxation. All registered citizens have a social security number making linkage possible, however not across all sources due to legal and organisational difficulties. Linkage is often allowed only in ad hoc project based manner. An important initiative is Belgium's national initiative towards establishing the Belgian Health Data Authority was highlighted as the next steps to facilitate the use of health data for secondary use.

Data collections/sources

- Primary health care providers use multiple electronic health records (EHR) systems. The EHRs are mostly digitalised using a unique national identifier that is also used by general practitioners (GP).
- Secure exchange of EHRs between health care providers and patients is possible through the national eHealth platform.
- Citizens can access most of their data through the online platform www.mijngezondheid.be/ www.masante.belgique.be.
- Belgium has over 150 clinical registries containing health data.
- The Belgian Cancer Registry (BCR), a national, population-based registry collecting data on cancer incidence since 2004.
- The Belgian institute for health (Sciensano) manages surveillance systems, part of the clinical registries (e.g. Central Rare Disease Registry), and health surveys (e.g. the Health Interview Survey).
- The Belgian statistical office (Statbel) mainly collects sociodemographic data.
- The Common Sickness Funds Agency (AIM-IMA) collects data on reimbursed healthcare services and prescription medication from the 7 Belgian sickness funds.
- The INTEGO project is based on an automated data collection of EHRs of patients from Flemish GP practices.

Data quality

- In general, data updates are infrequent and not in real time, which can hinder policy making.
- For the purposes of healthcare delivery, the patient information is updated weekly on the online platform.
- Data from the sickness funds is updated regularly.
- There are various quality control mechanisms in place, including: cross checks with feedback loops, data validation, and verification at data source level.

Data infrastructure

- In Belgium, there is no central storage of patient data.
- The platform healthdata.be includes copies of data sets from different data sources including hospital data, patient data, pharmaceutical data, and research labs data.
- A common metadata catalogue is under development.
- There is a general agreement about aligning all health data sources (laboratories and GP practices) to use CDA/HL7-FHIR, as the data exchange standard.
- Stakeholders aim for full standardisation using SNOMED-CT for semantic interoperability by 2027.
- The national e-Health platform for primary use uses SNOMED-CT and ICD-10 standards.
- There is no common access procedure to the different data sources.
- Access to individual level data generally requires Information Security Committee (ISC) approval.
- Linkage among datasets is potentially possible through the social security number, however, difficulties were reported due to legal barriers.
- Pseudonymisation is done by a trusted third party, such as the eHealth platform.
- The fees to access data differ and vary between being free of charge to stakeholders that request a fee for service.
- The time to access data depends on the complexity of the request, but is often reported to be long (6 to 18 months).

Data governance

- Belgium is characterised by decentralised management procedures, spread across the different federal and regional governments.
- There is a need for more transparency on roles of the data holders and access procedures to health data for secondary use.
- Belgium is setting up a Health Data Authority (HDA), an infrastructure to improve findability of data collections by establishing a metadata catalogue and streamline and harmonise data access procedures and governance.
- Multiple national acts are under revision in preparation for the HDA and EHDS: Patients' Rights Act, The Health Care Quality of Practice Act, and The Belgian Privacy Act.
- Research projects that require access to data generally need ethical approval, and approval from the Information Security Committee.

Resources (human, technical, financial)

- Human resource:
 - For maintenance and operating of data collections.
 - More data analysts and data scientists, which was reported as a highly solicited and rare profession.
 - For administrative and scientific support with application processes (including for health data access) for researchers.
 - More experts for the development of ICT solutions.
 - More experts in the use of artificial intelligence.
- Financial resources are needed across all stakeholders. It was reported that to facilitate this, Belgium is using multiple EU funds towards the setup of a new legislative framework for data sharing and operational agreements between communities and regions.

Capacity building

- Training and skills development needs:
 - Data literacy of healthcare providers.
 - Training and knowledge exchange among registries on novel techniques, to promote common advancements among registries.
 - Training on all aspects of data privacy.
 - Training in statistical tools for data analysis
 - Training on the use of standards, such as SNOMED-CT and HL7-FHIR.
- Available training opportunities:
 - Some data holders are investing in dedicated user access support services and provide data management software and privacy training

Best practices

- In Belgium there is an initiative called DPO Connect that brings together national data protection officers to discuss challenges and exchange experiences.
- The common sickness funds agency (IMA-AIM) has a permanent sample of socially insured people that includes individual level pseudonymised data and is readily accessible to governmental agencies for the purpose of policymaking.
- Belgium has multiple open data platforms, for example the HISIA platform for survey data in Sciensano, and the IMA-AIM Atlas for indicators on socio-demographic characteristics and the use of health care. These platforms provide interactive tools that enable the analysis of publicly available, anonymised datasets.

European Health Data Space (EHDS)

- There is a national ambition in setting up a Health Data Authority (HDA) which is aligned with the EHDS. A proposed legislation was published in July 2022.
- There is high involvement in international collaborations. Belgium coordinates or takes part in multiple health data related international projects (TEHDAS, PHIRI, B1MG, HealthyCloud, EHDS2 pilot, ELIXIR, BBMRI and many more).
- It has not been decided who the EHDS national contact will be yet, however, preparatory work is ongoing through the development of the Belgian HDA. There is potential for it to be the national contact point for secondary use of health data.
- Some of the reported expectations for the EHDS:
 - It is seen as an opportunity for international comparisons and research exchange.
 - It should provide academic incentives for training of data analysts.
 - It should improve transparency in access decisions (by publishing evaluations) and transparency towards citizens.
 - It could potentially develop a European level platform for Data Protection Officers discussion.



Country visit – Czech Republic

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 TEHDAS.sciensano@sciensano.be
Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to the Czech Republic took place virtually between **11 and 14 July 2022**.

Who was involved?

14 stakeholder organisations were interviewed:

General Health Insurance Company (VZP); Institute of Health Information and Statistics (UZIS); Masaryk Memorial Cancer Institute; Masaryk University; Masaryk University – Computer Centre; Ministry of Education, Youth and Sports; National Institute of Mental Health (NUDZ); OAKS Consulting; Olomouc University Hospital (FNOL); Representative of EHDS Rapporteur (Chamber of Deputies, Parliament of the Czech Republic); State Institute of Drug Control (SUKL); St. Anne's University Hospital Brno (FNUSA); Czech Technical University in Prague (CVUT CIIRC); University Hospital Hradec Králové (FNHK). The selection of interviewers, support and contextual information was provided by the Ministry of Health of the Czech Republic.

Czech Republic in brief

The Czech Republic is in the process of digitalisation of the healthcare system. Digitalisation is one of the key specific objectives of the Strategic Framework for the development of healthcare until 2030 (Health 2030). The provision of healthcare services in the Czech health system is financed through mandatory health insurance, provided by seven health insurances. The main health insurance provider is the General Health Insurance Company of the Czech Republic (VZP), covering around 6 million people. The birth number is currently used as the unique personal identifier in healthcare. However, there are plans to move towards sector-specific unique identifiers (e.g., for healthcare, employment) due to the sensitivity of the birth number. This may affect the future ability to perform cross-sectoral linkage. It is currently not possible to link health data with data from other sectors because the linkage needs to be defined in law.

Data collections/sources

- Some health data are digitalised. Electronic information systems are used by healthcare providers (HCPs) on all levels. However, most medical records are also paper-based due to a legal barrier to e-signature of health documentation. The Act on Health Services requires special e-identity of HCPs for e-signature of health documentation, but no law has been enacted yet to create this e-identity.
- Hospitals have different software for processing, storing and archiving health data, produced by at least five suppliers. Several hospitals were updating their information systems in 2022. There is no central data repository; an infrastructure for exchange of health data is currently being built. Currently, patients' health data is generally not shared electronically between HCPs. No centralised electronic health record (EHR) exists. A concept of a national EHR is under examination.
- The Institute of Health Information and Statistics (UZIS) maintains the National Health Information System (NHIS), including national registries (system oriented and medical). Reporting from HCPs is mandatory. UZIS is responsible for health surveys in cooperation with the Czech Statistical Office.
- Health insurance data is mainly digitalised and centralised in the Registry of Reimbursed Services.
- There is no national biobank; biobanks are decentralised at the healthcare providers.
- The National Institute of Mental Health (NUDZ) generates data on mental health.
- Some disease-specific registries have been set up by private sector players through voluntary agreements with HCPs, to overcome barriers to linking individual-level data with national registries.

Data quality

- In general, data quality was noted as an important area for development.
- The national registries have basic built-in automatic controls. Manual checks are also performed.
- At the hospital level, quality departments regularly perform audits and accreditations, and generally manual quality checks are performed.
- Administrative quality checks are performed on health insurance data (e.g., for coding errors).
- NUDZ performs manual quality checks.

Data infrastructure

- Data storage in healthcare is generally decentralised. Medical records and biobanks are stored within individual healthcare providers. Registry data is stored centrally in the NHIS.
- There is no national metadata catalogue. There is an initiative to develop a national 'directory' for research data. A catalogue for biobank data is also under development, using different vocabularies.
- For data access, no distinction is made between national/foreign, or private/public researchers.
- There is no centralised infrastructure for access to data; data users apply to each data holder. Access is generally provided by sending data files electronically or physically. There is a secure processing environment (SPE) for academic research at the Czech Technical University in Prague (CVUT CIIRC), however its use appears limited with respect to health data.
- For the national registries, the Act on Health Services (2011) states that external users cannot access identifiable data. In practice, researchers receive pseudonymised data.
- Hospital data can be accessed by applying to the individual hospitals. Access to medical records for research requires consent from patients, a barrier to retrospective studies in particular.
- Access to biobank data is coordinated through the Czech node of BBMRI (BBMRI.cz).
- Timelines for access to data vary. Reimbursement of costs for the effort associated with data preparation can be requested, but is usually not requested in practice.
- Hospital information systems are not interoperable. It is generally not possible to link health data with data from other sectors.
- The Ministry of Health is responsible for developing national standards. The DASTA national standard describes healthcare related information. It is used for data transfer between information systems of healthcare facilities. It is also used for data exchange between hospitals since the first version in 1994. Challenges were noted to achieve interoperability with other European countries.
- ICD-10 is generally used, as well as other national and international standards (e.g., ATC for drug classification). ICD-11 is in the pre-implementation phase.

Data governance

- There is currently no clear and sufficient legal framework for secondary use of health data.
- There are strict laws on privacy in data sharing and processing. A strong emphasis is placed on checking compliance with data handling rules, with systematic supervision by the National Cyber and Information Security Agency (NÚKIB).
- Some experts consider that prior to making legislative changes in the Czech Republic, a final legislative text on the EHDS adopted at EU level is needed.
- Stakeholders report that there is legal uncertainty on electronic signatures (the nature and level of security of electronic signatures and applications).
- Stakeholders highlight the urgent need for clear legal definitions on data processing and secondary use of data in Czech law, and for a code of conduct for health data exchange.
- The main laws governing health data use and re-use of certain data (NHIS) include: Act on Health Services (2011); Czech Personal Data Processing Act (2019); Act on Cybersecurity (2014). A new eHealth Act, valid from January 2022, includes the establishment of an infrastructure for eHealth and health data exchange using certain central electronic healthcare services.
- The Czech Strategic Framework for Health 2030 identifies digitalisation of healthcare as one of the key objectives.
- The birth number is currently used as a unique personal identifier in health. There are plans to move towards sector-specific identifiers (e.g., for health, employment), which may affect cross-sectoral linkage.
- Ethical committee approval is legally required for interventional research only. For research on medical records, it is at the discretion of the data holder whether to request it.
- Access to medical records for research requires consent from patients.
- There is no citizen portal providing access to their health documentation. If citizens want to access their health documentation (as is their right); they must apply to the hospitals directly and receive a physical copy. Some hospitals are implementing digital patient portals for access to certain data.

Resources (human, technical, financial)

- Human resource needs:
 - IT personnel
 - Data analysts and biostatisticians in hospitals, data stewards
 - Lawyers
 - Trained staff for the implementation of standards
 - Specialised human resources for cybersecurity in hospitals
 - Multidisciplinary experts (IT, security, medical, system-oriented aspects)
- Technical resource needs: development of the IT infrastructure in hospitals
- Financial resource needs:
 - UZIS will require more resources to meet increases in requests with the EHDS
 - Financial investment in national infrastructures and research infrastructures are needed
 - Financial resources are required to attract skilled personnel

Capacity building

- Training needs:
 - Education on standards, interoperability and how to input data in a structured format
 - Training on cyber-security and data protection
 - Training on ethical aspects and legal requirements
- Training opportunities:
 - Several data holders provide services to researchers (e.g., in writing research proposals)
 - Education to biobanks and IT staff on use of HL7 FHIR and added value of using standards
 - Training to students to become data stewards
 - Training on using hospital information system, GDPR, data protection

Best practices

- The OAKS consultancy aims to provide an example of a private sector company supporting public health. They have overcome the barrier to accessing registry data for research by gaining access to medical records through agreements with healthcare providers.
- There is high involvement in EU projects and Research Infrastructures in the Czech Republic (e.g., TEHDAS, JADECARE, X-eHealth, ECRIN, PHIRI, BBMRI, B1MG and others). A national introductory project dedicated to secondary use of health data is under preparation in the EU Recovery and Resilience Facility framework for the Czech Republic.
- The collection and processing of data (NHIS) in UZIS is based on the law and public interest.
- In general, access to certain data in the Czech Republic appears to occur in a timely manner. For UZIS, internal timelines to access are defined in law as 15 days, or 30-60 days for analyses. For biobanks, it generally takes 2-3 months to receive the sample.

European Health Data Space (EHDS)

- In general, there is a positive attitude towards the EHDS and the EHDS legislative proposal from the European Commission, and a recognition of the potential benefits.
- At the time of the country visit, it was not yet clear what entity would take on the role of national contact point or health data access body/bodies for the EHDS for secondary use.
- A hybrid funding model is generally preferred for implementation of the EHDS. Stakeholders expressed concern that fee policies could be a barrier to research.
- Many stakeholders welcome an opt-out mechanism for secondary use of health data.
- The DASTA national data exchange standard may prove to be a challenge regarding interoperability.
- Needs to join the EHDS:
 - Structured EHR data
 - Clear legislative framework for secondary use of data and the legal basis for data sharing
 - Funding for healthcare providers to make their data available
 - Harmonised rules on how to anonymise and pseudonymise data
- Expectations for the EHDS:
 - Guidelines for safe sharing and accessing health data
 - Clear definitions of responsibility and liability in the EHDS
 - Federated analysis should be introduced, as well as the use of synthetic data
 - Harmonisation of data, interoperability and setting standards for structured data storage
 - Reduce administrative burden on healthcare providers by creating an interoperable system that avoids duplication of reporting
 - Provide a legal framework for sharing and linking data between health and non-health institutes (e.g., research)
 - Incentives for data holders to share their data for research: e.g., financial, citations
 - Clear definitions of terms (e.g., pseudonymisation, anonymisation)
 - Clarity on the use of consent
 - Inclusion of data from everyday life of patients to predict and develop decision-support systems
 - The EHDS should take account of differences in countries' health information systems as well as citizens' values



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 TEHDAS.sciensano@sciensano.be
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.

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.

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.



Country visit – Estonia

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 TEHDAS.sciensano@sciensano.be
Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to Estonia took place virtually between **11 and 14 April 2022**.

Who was involved?

15 stakeholder organisations were interviewed:

Biobank, Connected Health Cluster, Data Protection Inspectorate, Estonian Health Insurance Fund (EHIF, written input), Estonian State Agency for Medicines, Health Board, Health and Welfare Information Systems Centre (TEHIK), Ministry of Social Affairs (MoSA), National Institute for Health Development (NIHD), North Estonia Medical Centre, Roche, Statistics Estonia, TalTech, Tartu University Hospital, University of Tartu.

Estonia in brief

The Estonian health information system has been digitalised since 2009. The Estonian X-road allows data sharing on all administrative levels in a secure way. The Estonian healthcare is mainly funded by the Estonian Health Insurance Fund (EHIF). All registered citizens have a national ID number making linkage possible. A Next Generation HIS is in progress to rethink all aspects of Estonian health information, including the type documents and data exchange standards used, new governance and funding models.

Data collections/sources

- The national electronic health information system is a fully digitalised e-health system that centralises patient data from all healthcare providers.
- This data is accessible for both healthcare providers and the patients through the national eHealth Portal. All transactions are logged and visible to the patient.
- The Estonian Health Insurance Fund (EHIF) database contains claims data from Estonian healthcare providers with whom they have contracts.
- The National Institute for Health Development (NIHD) holds 6 medical registries, fully digitalised and include individual level data, and health statistics.
- The Health Board is the competent authority for surveillance, prevention and control of communicable diseases. It has several information systems, including the Communicable Diseases Register.
- Statistics Estonia collects socio-demographic data. It owns the national census.
- The Estonian State Agency for Medicines owns data regarding Medicinal products, and pharmacovigilance data.
- The Estonian Biobank is a population-based biobank of the Estonian Genome Center at the University of Tartu and collects genetic information about 20% of the adult Estonian population.

Data quality

- The national HIS data is logged, and quality checks are implemented both manually and automatic.
- The claims data of EHIF implement automatic control checks for mistakes.
- Data in the NIHD have both automatic and manual checks.
- Data at the Health Board is checked and sent back to disease register in case errors are detected.
- The Biobank implements data cleaning and quality checks by a quality control team.

Data infrastructure

- The national HIS has a centralised storage for a part of the EHR data from all healthcare providers.
- The data in the EHIF is stored in one central data warehouse that pools together data from different operational systems.
- In addition to the biological samples, the Estonian Biobank stores descriptive phenotype data and genetic data.
- No common metadata catalogue. There is a register of registers (RIHA) that is a non-standardised catalogue of state-based data and 1200 registries.
- NIHD, Statistics Estonia and EHIF have individual available metadata catalogues.
- There is no trusted third party (TTP) that deals with the pseudonymisation of the data, each source has in-house anonymization and/or pseudonymisation, and linkage processes.
- Access is mostly given to pseudonymised data. If identifiable data is needed, an ethical approval specifying it, is required.
- Mostly, there is no fee for access. Some stakeholders charge a fee for the working time to prepare the datasets.
- Time to access data varies, can reach up to 6 months for complex requests.
- The same process applies for national and EU researchers, and for industry. Data is not shared with third countries where GDPR does not apply.
- The Biobank and Statistics Estonia each have a secure processing environment.
- All e-Government data is exchanged through the x-road system using blockchain technology.
- TEHIK, the health and welfare information systems center promotes and provides guidance on the implementation of standards: LOINC and ICD-10.
- The health information system is using CDA and HL7 V3 standards for data exchange and aims to integrate SNOMED and HL7 FHIR standards.

Data governance

- Data protection is primarily governed by the GDPR, but interpretations differ.
- There is a Data Protection Act that allows to use personal data for scientific research and policy. This act is supervised by the Data Protection Inspectorate (DPI).
- Secondary use of data does not require patient’s consent. Except for the Biobanks.
- The NIHD collects data for the registries and for health statistics based on EU and state legislation and other public interest.
- A new consent management tool is under development which will be launched by the Ministry of Economic Affairs and Communication

Resources (human, technical, financial)

- Due to its small size, Estonia has limited resources.
- Human resources needed across stakeholders:
 - Legal specialists
 - IT specialists
 - Statisticians
 - Data analysts
 - Data stewards
- Financial resources are mainly needed to fund and hire more personnel
- For hospitals, more funding is needed for IT services

Capacity building

- Several trainings are currently provided by the different stakeholders, such as:
 - Statistics Estonia provides courses on statistical programmes (e.g. R, STATA).
 - Tallinn University provides training for physicians on data privacy and security.
 - The Ministry of Economics Affairs and Communications provides a 2-day course on data stewardship and data quality control.
- Some training needs that were reported were for improving data literacy, and on data analysis tools.
- Stakeholders also reported that there is more need to share best practices at an EU level to learn from the different skills and experience across EU countries.

Best practices

- A big strength in Estonia is its X-road software-based solution that allows Estonia's e-Government services information to be shared and linked across administrations.
- Another aspect to be considered, is that even though there is no common metadata yet, there are individual user-friendly metadata catalogues (NIHD, and Statistics Estonia) that are also available in English.
- In general, the health sector provides a lot of open data for research and policy making (e.g., the COVID data portal).
- Citizens have a high level of control over the access to their data through the eHealth Portal.
- Researchers receive a lot of support, such as implementing data quality checks and providing advice on the use of data from the different data holders, the preparation of data proposals, analysis, and secure processing environments.

European Health Data Space (EHDS)

- Estonia has reported high interest in cross-border sharing of health data for research, and a positive approach towards the EHDS.
- At this moment, the national competent body roles and structure related to the EHDS are still to be decided upon. There is a possibility that a new body would be set up for this purpose.
- Estonia participates in different EU networks and initiatives dealing with health data such as BBMRI, BiMG (for biobanks), TEHDAS, X-eHealth.
- Needs for EHDS:
 - There should be EU financial resources to join the EHDS.
 - There is a need for common guidelines on the interpretations of GDPR.
 - There should be training provided and sharing of best practices at EU level, for example sharing of open-source software components as building blocks for health research.
- Expectations from the EHDS:
 - Easier exchange and better pan-European analysis of data, specifically useful in the area of rare diseases.
 - EU wide standardisation and harmonisation of data which will bring great benefits for research.
 - Harmonised copy rights agreements on the results of data analyses and publications.
 - Speed up common taxonomy or standards of data collection.



Country visit – Finland

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.

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Any questions?

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

When did it take place?

The visit to Finland took place face to face in Helsinki between **6 and 10 June 2022**.

Who was involved?

23 stakeholder organisations were interviewed:

Finnish Institute for Health and Welfare (THL); Kela; Helsinki University Hospital (HUS); Findata; IT Centre for Science (CSC); Technical Research Institute of Finland (VTT); University of Helsinki; Turku University Hospital; University of Oulu; Sitra; Ministry of Social Affairs and Health (STM); Eksote; Biobank of Eastern Finland; Helsinki Biobank; FinBB; Pharma Industry Finland; Healthtech Finland; Business Finland; Roche; Medaffcon; Esior; Veil.ai; BC Platforms.

Finland in brief

Finland has a tax funded healthcare system. It is characterised by a fully digitalised and rich health data landscape. All residents have a social security number, which is used as personal unique identifier for linking individual-level health data. Finland is the first European country to set up a specific legal act on the secondary use of health and social data in 2019. Its recently established data permit authority, Findata, facilitates the access to health data for research and policy making. The Finnish Institute for Health and Welfare (THL) and the Social Insurance Institution of Finland (Kela) are the main data holders for most of the national registries. Finland has almost all elements in place for joining the EHDS. However, resources will be needed in expand the capacity of the national infrastructure to answer to the increased demand for data sharing as a result of the EHDS.

Data collections/sources

- The Finnish national eHealth infrastructure Kanta is a centralised patient data repository for health, wellbeing and social welfare information. Kanta is maintained by the Social Insurance Institution of Finland (Kela). Kela also holds drug reimbursement, prescriptions data, and social benefits data.
- Cross-border ePrescription service has been running through the Kanta platform since 2019. Work for developing the digital patient summary exchange system with other MS is ongoing.
- Districts have their own data lakes where data is available for secondary use, located at university hospitals. HUS is the largest healthcare provider in Finland and operates a data lake for the Helsinki region containing decades of clinical information.
- The Finnish Institute of Health and Welfare (THL) has comprehensive datasets in the social welfare and healthcare sector. It contains population monitoring data in the form of national registers, population surveys and biobanks. THL has 16 social and healthcare registers.
- Biobanks are distributed across 11 hospital biobanks, six of which are hospital biobanks linked to the hospital data lakes.
- The Finnish Biobank Cooperative FinBB was established to provide a centralised access to collections and services of the Finnish biobanks through their [Fingenious gateway](#) service.

Data quality

- In general, there is ongoing work on data quality and structuring of data across Finland. Stakeholders noted a need for incentives for healthcare providers to improve data quality at the hospital level.
- Registry data at THL are validated and checked through basic automated checks, manual checks, comparison to previous years and feedback loops. More automated checks are being developed.
- Hospital data lakes implement data quality standards.

Data infrastructure

- A copy of patient health data is stored centrally in the Kanta Data Platform. The original data remains at the data holders: the separate registers of health and social care service providers, and data lakes.
- Findata only temporarily stores data during the permit request process. Ready-made datasets are under development.
- Biobanks have no centralised storage.
- The Fingenious gateway offers a metadata catalogue presenting all available samples in biobanks, and streamlines access to these samples.
- The [Aineistokatalogi](#) is a common metadata catalogue, and currently includes structured information on data from more than 35 data holders. It is established on a national standard based on DDI lifecycle and GSIM.
- Access to data is mainly requested via Findata (e.g. to Kanta and THL data). When data is needed from only one data holder and linkage is not required, access to data may be requested and provided from the individual data holders directly.
- The IT Centre for Science (CSC) provides the secure processing environment (SPE) and additional technical support to Findata. At the time of country visit, Finland has 7 audited SPEs (three of which are hosted by CSC). More are under development.
- Time to access data through Findata has decreased from 2019 to 2022. Previous waiting times for Findata were reported to be up to 14 months. Applications are now checked within one week, with an average time until decision of 3-4 months. Access from single data holders takes about 2-3 months.
- Access fees vary and are split between data holders (~87%) and Findata (~13%). Findata charges a fixed fee for the permit process and an hourly fee for data management. Data holders charge for data extraction and delivery.
- In general, national and international researchers have the same rights to data access.
- All individual-level data is shared/provided in a pseudonymised way.
- THL updates and publishes international and national classifications and terminologies for eHealth.
- Hospitals and biobanks use ICD10 and HL7 versions for data exchange. In general, the OMOP common data model is widely used, and an increase use of SNOMED-CT was reported for semantic interoperability.

Data governance

- Long-standing national strategies and legislation support the use of IT for health and social services in Finland. The eHealth strategy in 2013 defined the task to create new legislation on the secondary use of health data. The Isaacus project in 2016 laid the foundations for the establishment of Findata.
- THL is the main institute that informs policy makers and implements evidence-based studies to support decision making.
- A multi-member sanction board is set up to control data privacy breaches. This includes the data protection ombudsman and its deputies.
- The main laws governing health data use include: The Medical Research Act (updated in 2021); Statistics Act (2004); Act on the Finnish Institute of Health and Welfare (THL) (2008); Biobank Act (2013); Act on Secondary Use of Health and Social Data (2019); Client Data Act (2021).
- Currently, a Health and Social Services Reform will become effective at the start of 2023, aiming to improve the availability and quality of basic public services by combining multiple municipalities into 21 self-governing wellbeing counties.
- The Toivo Programme is reported to be the structural implementation for this reform. It focuses on developing the knowledge-based management capacity of the counties.
- Ethical approval is required only when there is an intervention involved in the research project, such as in clinical trials and in surveys.
- Surveys are based on informed consent for data collection as well as for further linkage with registry data. Using and accessing register data does not require ethical approval nor consent.
- On citizen engagement, citizens have access to their Kanta data through ‘My Kanta Pages’ where they can provide or withdraw consent for sharing their data as needed, to provide them health and social care services. They can also upload their wellbeing wearables data.

Resources (human, technical, financial)

- The overall need for skilled human resources in the public sector reported includes data analysts and IT professionals.
- Most of the resource needs relate to Findata becoming the national contact point for the EHDS and the resources needed to improve time for receiving access to the data.
- Stakeholders expressed the need to improve technical capabilities and human resources for registry owners.
- Financial needs were reported for the transition from ICD10 to ICD11 in hospitals.

Capacity building

- Findata offers the following opportunities:
 - Data access application clinics to researchers to help them with their data access procedure
 - Free courses for data holders on using data description tools (in cooperation with THL)
 - Free half-day courses to the data holders several times a year, to help them get started with metadata descriptions to the Aineistokatalogi
 - Helpdesk: one national contact point to ask about availability of the data, quality, etc.
 - Universities and university hospitals provide training on tools for health data analysis
 - Biobank course on data and sample handling to healthcare providers
- Needs:
 - Training on data literacy for healthcare providers, to demonstrate the value of good quality data input for research

Best practices

- Finland established streamlined access procedures to data through Findata for health and social data, and Fingenious gateway for biobanks.
- The work towards the Act on Secondary Use of Health and Social Data provides the legal foundation for the EHDS. The development was reported to be based on transparency and trust in the government and the public authorities.
- Biobanks allow for enrichment of their data sets from external research projects that used biobanks data. The enriched data is then used to improve healthcare, such as screening projects.
- In general, there is strong interest in AI for health, for example using AI applications to improve healthcare, and the use of high quality, row-level anonymised and synthetic data for many secondary use cases by university hospitals and global pharma companies

European Health Data Space (EHDS)

- Finland is prepared to join the EHDS, and there is strong political will and agreements with the overall legislative proposal for the EHDS. Similarities are noted with the Act for Secondary Use.
- Most elements are already in place and it is likely that Findata would be the national contact point for secondary use and one of the health data access bodies.
- In general, there is willingness for Finnish data to be sent to and shared with other countries, but under the condition that the SPEs would have to meet the same requirements in accordance to the Regulation on secure operating environments.
- Needs for joining the EHDS:
 - Stakeholders report that resources will be needed to expand the national infrastructure and Findata specifically, including funding, staff and skills
- Expectations from the EHDS:
 - Finnish researchers will have access to more data across Europe.
 - An established network, peer to peer support between Findata and the other health data access bodies.
 - Clear concept of mutual recognition in case of a multi-country application procedure
 - Better interaction with relevant research infrastructures, and co-creation.
 - Private sector involvement, for dynamic technical solutions.
 - Create standard procedures on how to handle personal data across borders.
 - EHDS and EU should define requirements for trusted research environments, and clear legislation for federated analysis.



Country visit – Germany

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
TEHDAS.sciensano@sciensano.be
Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to Germany took place virtually between **24 November and 12 December 2022**.

Who was involved?

15 stakeholder organisations were interviewed: Federal Commissioner for Data Protection and Freedom of Information; Federal Ministry of Health, Division 511; Federal Ministry of Education and Research; Federal Statistical Office; gematik GmbH (National Digital Health Agency); German Biobank Node; German Human Genome-Phenome Archive (GHGA); German National Research Data Infrastructure for Personal Health Data (NFDI4Health consortium); Health Data Lab at the Federal Institute for Drugs and Medical Devices (BfArM); Institute for Quality Assurance and Transparency in Health Care (IQTIG); Integrating genomics into healthcare (genomDE); Medical Informatics Initiative (MII); National Cohort Study (NAKO); Network of University Medicine (NUM); Robert Koch Institute (RKI).

Germany in brief

The Federal Republic of Germany consists of 16 states (Länder), with a high degree of autonomy. Germany has a highly decentralised and complex health data management system. The health and care system is mainly financed through the statutory health insurance provided by approximately 100 insurance funds, covering about 90% of the population. Currently, health records are not fully digitalised. The digitalisation process is ongoing. There is no personal unique identifier used in health or across sectors. There is a health insurance number for the residents covered by statutory health insurance but this is not generally linked to clinical data or used to link individual level datasets. However, there are several projects and initiatives ongoing that aim to facilitate the findability and accessibility of health-related data for secondary use.

Data collections/sources

- Germany has a fragmented landscape of data collections, with hundreds of collections across levels (local, Länder, national). Several recent initiatives aim to improve harmonisation and accessibility.
- gematik GmbH has set up the telematics infrastructure (TI) and electronic patient records (ePA). Currently, using the ePA based on an opt-in system but will become opt-out to increase coverage.
- The Health Data Lab is being built at BfArM, including health claims data from statutory health insurances. There are plans to integrate data from the ePA in the future.
- The MII aims to facilitate the use of health care data from university hospitals. It is a decentralised infrastructure: data remains in the hospitals' data integration centres.
- The NUM is a network of university hospitals, formed in light of the COVID-19 pandemic to facilitate research. Different studies collect and link clinical, biosample and imaging data.
- There is a long history of cohorts to study population health in Germany. NFDI4Health built a platform to make these studies centrally discoverable and accessible. The largest population-based cohort study (NAKO) directly links their data to health insurance data.
- The RKI carries out surveys (e.g., Health Interview Survey) and maintains some registries. The German Centre for Cancer Registry Data (ZfKD) at RKI receives a core dataset from state-level cancer registries to produce national statistics on cancer epidemiology.
- Destatis maintains several health-related statistics.
- The German Biobank Alliance is an umbrella organisation for most biobanks in university hospitals.
- genomDE, in close cooperation with the GHGA, facilitates access to whole genome sequencing, with genome computing centers.

Data quality

- Multiple validation checks are used by different stakeholders, as well as standardised methodologies.
- Claims data at the Health Data Lab is of high quality and completeness as it relies on reimbursement data and the use of standards. The Health Data Lab reported quality checks are in place.
- Surveys have different quality checks implemented (e.g., plausibility checks). There is a strong focus on training interviewers to ensure high quality of data collection.
- NFDI4Health uses data quality analysis pipelines. Further quality metrics are under development.

Data infrastructure

- In general, data storage is highly decentralised in Germany.
- Access to data is generally requested separately to each institute.
- If approval from the data protection authority is required, this must be sought from the authority in each state from which data is requested.
- There is a complex landscape of initiatives to facilitate access and re-use of health data.
- The MII, together with the NUM, is developing the German Portal for Medical Research Data (FDPG) as a one-stop shop to facilitate access to routine health data from university hospitals.
- NFDI4Health is building a domain-specific health research data infrastructure. It includes data from clinical trials, epidemiological and public health studies.
- In general, data is pseudonymised. There are several trusted third parties (TTPs).
- Fees and times to access data differ. In general, foreign researchers have similar processes to access data as national researchers. Some stakeholders reported different access rights and fees for industry.
- There is no national metadata catalogue. Some institutions have their own (e.g., RKI, FDPG of the MII).
- There are multiple secure processing environments across institutes (e.g., NUM, NAKO). Some are developing SPEs (e.g., HDL, ZfKD), and others use distributed analysis platforms (e.g., NFDI4Health).
- With the support of gematik GmbH as coordination office, the Interop Council has developed a National Interoperability Roadmap for 2023-2024, which aims to provide terminology services, as well as develop guidelines and recommendations for harmonising different standards.
- Semantic standards used include ICD-10 and SNOMED CT. There is broad use of FHIR for data exchange.

Data governance

- There has been increased strategic focus on digitalisation in Germany in recent years.
- The Federal Ministry of Health is responsible for organising the national health data ecosystem.
- The Federal Ministry of Education and Research is funding initiatives, projects, and data infrastructure for secondary use of health data (e.g., MII, NUM, NAKO, NFDI, DZG).
- There are several institutes that guide evidence-based policy making (e.g., RKI, BfArM).
- The main laws governing the use and re-use of health data in Germany include: GDPR, Federal Data Protection Law, Social codebooks 5 and 10, Data Transparency Regulation, state-level data protection laws and Federal Cancer Registry Data Act.
- A new legislation for the secondary use of health data is being drafted, in preparation for the EHDS.
- Currently there are 18 Data Protection Authorities across the 16 states and at the Federal level. In terms of data protection, there is a focus on decentralisation of data and avoidance of data accumulation.
- Ethical committees in Germany are also decentralised at state-level.
- The legal basis for the secondary use of health data is mainly consent or federal and state law.
- Stakeholders note some challenges for researchers to perform research. The multiplication of ethical committees and data protection laws makes it difficult to identify which one is relevant in what case.
- Regarding citizens' involvement, it was reported that there is generally high willingness of patients to share clinical data for research. For example, a German study on cancer patients noted the willingness is mainly linked to the trust in the institution collecting that data, and in the consent model used.
- Citizens are able to access their ePA data and those using appropriate end devices can indicate who can have access to their ePA. Several activities to consult the citizens were described (e.g., stakeholder working groups in the setting up of the Health Data Lab).

Resources (human, technical, financial)

- Human resource needs identified by stakeholders mainly related to skilled staff e.g.:
 - IT specialists
 - Legal advisers
 - IT experts with knowledge on coding
 - Clinicians with knowledge and expertise in genomics. Possibly, an increase in genetics departments in hospitals
- Technical resource needs:
 - General need for development of the IT infrastructure for health data
 - Data hosting capacities (both software and hardware)
- Financial resource needs:
 - Funding to establish the infrastructure to become a part of the EHDS
 - Sustainable funding for the initiatives in place

Capacity building

- Stakeholders reported several training opportunities, such as:
 - Federal Commissioner for Data Protection and Freedom of Information offers a symposium on data protection in research
 - de.NBI/ELIXIR-DE provides training on health data management as part of ELIXIR, with 1500 to 2000 participants per year
 - MII has a task force dedicated to further research, a Master's programme and exchange between university hospitals and researchers. An MII project, starting in January 2023, is coordinating basic services for training and continuous education within the MII.
- Stakeholders noted that there is a need for sharing among Member States on best practices and guidance, for example from FHIR experts

Best practices

Some best practices were noted during the country visit to Germany, such as:

- The Data Saves Lives toolkit has been translated into German language and adapted to local circumstances. This toolkit aims to equip patient groups and health influencers with the information and materials they need to have a positive dialogue with their communities about health data.
- Every ministry is establishing a data laboratory for evidence-based decision making. Data scientists are employed in all ministries.
- The Joint Science Conference (GWK) brings together federal and state governments to set joint priorities for science and research. The Conference deals with questions of research funding, science and research policy strategies that jointly affect the Federal Government and the states.

European Health Data Space (EHDS)

- There is support for the EHDS at political level in Germany. It is viewed as a good opportunity to streamline the national situation.
- It was noted that the EHDS objectives align with the federal government's data policy to expand data infrastructures in an interoperable, energy and resource saving, and decentralised manner.
- At the time of the country visit (December 2022), it had not yet been decided how the infrastructure for the EHDS would be structured in Germany, for instance what institute would be the national contact point for secondary use. It was noted that there may be multiple HDABs, depending on the data type. A final legislative text is needed prior to such decisions being made.
- Stakeholders noted that there is a need to find a unified structure for the different German initiatives to be part of the EHDS.
- Some needs that were noted are:
 - Additional EU funding to achieve the necessary changes for implementation of the EHDS
 - Use cases clarifying the added value for secondary use and cross border health data sharing
 - A longer timeline for implementation (e.g., 10 years) as the current timeline is viewed as too tight for the decentralised German data ecosystem.
- Some of the expectations that were reported with regards to the EHDS are:
 - Recognise the difference in systems across member states, allowing flexibility in implementation of EHDS in different countries
 - Implement a robust framework in line with the provisions of the GDPR and data protection
 - Demonstrate clear benefit for citizens, for instance through monitoring and reporting to citizens on their data that was used
 - Reduce the burden for small data holders



Country visit – Hungary

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.

When did it take place?

The visit to Hungary took place virtually between **14 and 17 February 2022**.

Who was involved?

Seven stakeholder organisations were interviewed:

E-Group, Ministry of Human Capacities, Ministry of Interior, National Health Insurance Fund, Roche, Semmelweis University, State Secretary for Health.

Any questions?

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

Hungary in brief

The Hungarian health information system (HIS) has several rich sources of health data. The HIS appears to be mainly focused on healthcare and performance, rather than population health monitoring. The Hungarian healthcare system is funded through a single payer, the National Health Insurance Fund (NEAK). All registered citizens have a social security number, used for healthcare. There is strong political interest in digital health and an ambition for a data-driven health system and decision making. AI and big data analysis are supported and promoted through multiple innovative projects.

Data collections/sources

- The main health data sources in Hungary are:
 - National E-Health Infrastructure (EESZT): individual-level healthcare data from all healthcare providers
 - NEAK: public healthcare reimbursement data
 - National Public Health Centre: public health data
 - Hungarian Central Statistical Office: demographic data
- There are some patient registries with data on specific diseases (e.g., National Cancer Registry, National Registry of Congenital Disorders).
- Most health data from GPs and hospitals is digitalised. There are 3 to 4 providers of EHR softwares in the hospital sector. Data from all EHRs is collected centrally in the EESZT. Reporting to the EESZT is mandatory.
- National health insurance fund: universal coverage through the single payer of the public healthcare system. Almost all citizens have access to healthcare, providing a wide coverage of structured health insurance data across the population.
- The use of private healthcare is high and growing. Since 2020 private providers must also report to the EESZT, reducing the data gap on private healthcare use.

Data quality

- Stakeholders note a need for action on data quality.
- NEAK data is optimised for reimbursement purposes. Checks are performed in the context of financial consistency.
- The EESZT infrastructure has some quality assurance mechanisms in the software. Data is updated daily.
- Much of the health data is unstructured, but the proportion of structured data is increasing.

Data infrastructure

- Health data is stored centrally in two main data collections: the EESZT and the NEAK.
- National Infocommunications Services Company (NISZ) is a state-owned company for public sector ICT services and data storage, including health data.
- The pilot ‘data lake’ project aims to create a data lake of EHR data to improve access for researchers.
- There is currently no common metadata catalogue. The new National Data Asset Agency is tasked with developing a public data inventory, not limited to health data.
- Data for secondary use is mostly pseudonymised, and data sources do the pseudonymisation in-house.
- Data access procedures vary between data sources:
 - EESZT: reportedly time-consuming access for secondary use.
 - NEAK: clear access procedure on website. Access mainly to aggregated or anonymised data. Individual-level pseudonymised data only accessible on-site. Hourly fee to private sector users, no fees to academic researchers. Time to access is on average 60 days.
- International standards ICD-10 and ATC are used mainly in finance and administration. SNOMED-CT is planned to be introduced in clinical documentation. For data exchange, a national EHR reference model is under development. Ongoing projects use local standards, specific projects use HL7 V3 and FHIR.
- Data linkage is generally project-based.
- Health data can be transferred internationally with explicit consent from the individual.

Data governance

- A number of legal provisions govern the use of health data.
- There are legal challenges to linking individual level data and a need for clear legal framework on secondary use of health data.
- National Data Asset Agency was established in 2020, with the aim of facilitating access to public data. The planned tasks at its establishment include developing an open data portal, a public data inventory, and supporting analysis of data from public institutions.
- The EESZT has an opt-out mechanism: patients can state that their data should not be viewed by a specific healthcare professional, or can opt out of data use for research.
- Research projects using personal data require ethical approval. There are different levels of ethical committees, depending on the research project.
- A pilot ‘data lake’ project aims to establish a data board to evaluate research projects on the basis of data protection.
- Citizen empowerment is important: citizens have access to their health data and visibility on who accesses it via e-portal. Trust in data sharing and use increased during the pandemic.
- There is a reported willingness to increase the number of public-private partnerships to promote data sharing.

Resources (human, technical, financial)

- Human resource capacities for maintaining and operating data collections vary across data sources.
- The NEAK reported a difficulty meeting data requests due to human resource needs.
- There is a need for skilled human resources, particularly data scientists.
- It was reported that there is a need to align the mind-set between healthcare professionals and researchers/data users.
- Technological progress has been seen in Hungary, with an increasing determination for AI tools and data-driven decision-making. There is a reported need for technical and financial resources to support the secondary use of health data.

Capacity building

- Several trainings needs were identified by stakeholders:
 - Improving data literacy and technical knowledge of healthcare providers
 - Strengthening links between healthcare providers and researchers/data users
 - Strengthening AI capacity
 - Training on data security and data linkage
 - Education of data scientists
 - EU level input and training on semantic interoperability and structured datasets.

Best practices

- The EESZT connects all healthcare providers into one location and serves as a structural foundation that can be further used beyond primary use of health data.
- Citizens are empowered by having visibility on who accesses their patient files (eID), which contributes significantly to trust of citizens.
- The concept of research rooms where researchers can use already existing anonymised or pseudonymised data, providing more rapid access to data.

European Health Data Space (EHDS)

- Hungary is active in cross-border research and data sharing initiatives.
- Overall, there is strong political will to become part of a future EHDS. There is a call that the EHDS should provide equal benefit to all countries, and this benefit should be clearly communicated.
- It is currently unclear which entity could play the role of national contact point in Hungary. There could be a potential for the newly established National Data Asset Agency to take on this role. However, the Agency's formal tasks are under development, and it is important to note that its remit is not limited to health.
- There are promising developments in health data use in Hungary. Strategic investments are being made in data-driven tools and artificial intelligence (AI), as well as innovative pilot projects building the technical infrastructure for federated analysis.
- There was a call for a separate infrastructure for the secondary use of health data, so as not to interfere with the primary use.
- The EU data spaces are recognised as a valuable next step for cross-border collaboration and service provision. There was a call for attention to be paid to data protection and privacy concerns.
- Some stakeholders report a preference that access to health data should be conditional and not free, with transparent business models.
- It was noted that the EHDS should focus on cybersecurity, trust, and citizen empowerment.



Country visit – Ireland

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.

When did it take place?

The visit to Ireland took place virtually between **3 and 6 May 2022**.

Who was involved?

Eight stakeholder organisations were interviewed:

Central Statistics Office (CSO), Department of Health (DoH), Economic and Social Research Institute (ESRI), Health Information and Quality Authority (HIQA), Health Research Board (HRB), Health Service Executive (HSE), Private Hospitals Association, National Office of Clinical Audit (NOCA).

Any questions?

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

Ireland in brief

The Irish Health Information System (HIS) has some valuable data sources, but many are fragmented and siloed. The health system is not fully digitalised, with both paper and digital records. The public healthcare system is tax-financed. The Health Service Executive (HSE) is responsible for provision of public health and care services. There is high uptake of private health insurance. A large proportion of health services are provided by the private system. A unique identifier for health (Individual Health Identifier) was introduced in 2014, however it has not been fully deployed and its usage for linking data is currently limited. There is significant work ongoing to develop the technical infrastructure and governance framework for the HIS.

Data collections/sources

- The national metadata catalogue includes over 120 data collections and collated sources of information.
- There is no national electronic health record (EHRs). Hospitals use different systems which are only interoperable to a degree, mainly through the national messaging broker. There is currently no integrated patient management system in the community. The eHealth Ireland programme aims towards coordinated health information systems across the HSE.
- HSE collects community and hospital level data. Community data tends to be operational and aggregated.
- Data from public hospitals is collected in the Hospital Inpatient Enquiry (HIPE). Hospital-specific medical record numbers are used, tracking episodes of care rather than patients. There is limited reporting from private providers.
- The Department of Health is responsible for the Healthy Ireland survey. The Central Statistics Office (CSO) hosts the Irish Health Interview Survey.
- Health Research Board (HRB) hosts 4 national data collections. Many other data sources exist, including disease-specific registries (e.g., National Cancer Registry).

Data quality

- HIQA is the independent authority for improving health information and quality (remit for public providers).
- HIQA develops recommendations to support decision-making. It drives improvements in data quality by developing national standards/guidance and assessing compliance. It also develops learning resources to assist health and social care providers improve the quality of their data and information.
- Quality control mechanisms appear to be mainly manual, with some automated controls, e.g.:
- HIPE data undergoes rigorous checks/audits.
- NOCA has a tool to ensure that data matches the standards implemented, and a validation process.

Data infrastructure

- Data storage is decentralised. A national metadata catalogue of national data collections is hosted by the HIQA. An update is ongoing.
- The Irish Social Science Data Archive (ISSDA) has a catalogue of surveys and social science data. Some individual data holders have their own metadata catalogue (e.g., CSO, NOCA, HRB).
- Access procedures vary. There is limited infrastructure to connect research queries to data holders. Some links between research bodies and data holders facilitate access (e.g., ESRI and HSE). DASSL project is a technical proof-of-concept on data access, storage, sharing and linkage, due to be concluded in 2022.
- Generally no fees for data access, and national and foreign researchers have the same process.
- Pseudonymisation practices vary, usually in-house.
- There is no health-specific secure processing environment (SPE). The CSO has a SPE, but this is limited in health.
- The lack of a unique identifier implemented consistently across the health system is a barrier to data linkage across different sources. The Health Information Bill will promote the use of the social services number (PPSN) in health, improving the potential for linkage of individual level data.
- A few standards for data exchange are currently in use (e.g., HL7 V2.4, HL7-FHIR, NIMIS for imaging data).
- Semantic interoperability standards in use: ICD-10, aim to transfer to ICD-11. Ireland is a member of SNOMED-CT; a SNOMED-CT Governance Board provides oversight of its implementation.
- HIQA is developing recommendations on a Model for Health Information Standards.

Data governance

- There is currently no health data governance framework, however significant work is ongoing.
- Stakeholders report a need for a body with strategic oversight for primary and secondary use of data.
- A Health Information Bill is being drafted by the Department of Health, aiming to address current challenges and set the policy direction over the next ten years. The objectives include to:
 - Provide legal framework for primary and secondary use of health data
 - Address legal gaps regarding sensitive data
 - Establish a National Health Information Centre
 - Establish a national health information guardian
- HIQA published recommendations on the need for reform of the Irish HIS.
- Consent is needed for research when using health data. The Health Research Consent Declaration Committee (HRCDC) can allow research in the public interest.
- National Office of Research Ethics Committees centralises ethical approval for some research types.
- The CSO's role in health increased during the pandemic, (e.g., COVID-19 Data Research Hub). Difficulties integrating some data types under a Statistics Act.

Resources (human, technical, financial)

- The cyber-attack on the HSE in 2021 means that many financial, technical and human resources are being funnelled into cyber-security.
- There has been increased investment in the ICT infrastructure for health data in recent years.
- Human resource needs:
 - Data analysts/engineers
 - Statisticians
 - Cyber-security experts
 - Software developers
 - Business analysts
 - Information governance knowledge and expertise at national and local level
- Technical resource needs:
 - Development of a secure processing environment for health, and an infrastructure to connect access requests to data holders.

Capacity building

- Examples of training needs:
 - Improved data literacy of healthcare professionals to improve data quality at source
 - Training on robust data governance
- There were several examples of training opportunities across different institutions, such as:
 - Data protection training
 - Training in standards (e.g., ICD-10)
 - Methodological training to researchers on how to use datasets
 - Data quality modules
 - Support to researchers for ethical submissions

Best practices

- The Health Research Consent Declaration Committee (HRCDC) was established in 2018 under the Health Research Regulations. The committee can provide a ‘consent declaration’, allowing a research project to be carried out without the need for consent, when it is deemed to be in the public interest, facilitating research.
- The Health Information Bill proposes the establishment of a national data guardian, to act as an ombudsman to citizens, representing their views on health data use and re-use.
- The National Office of Research Ethics Committees was established in 2020, and includes the formation of national-level ethics committees for specific types of research. This facilitates research by streamlining the ethics approval process for collaborative studies.
- HIQA developed ‘Guidance on a data quality framework’, to support organisations to systematically assess, document and improve data quality. The guidance is accompanied by an online learning course to assist its implementation and explain the importance of data quality.

European Health Data Space (EHDS)

- There is strong political will to join the EHDS and a strong recognition of the benefits it can bring. However, stakeholders note that data sharing is currently difficult in Ireland and there are technical and legal issues to be addressed first at national level.
- The national contact point for the secondary use of health data will be a new entity. The upcoming Health Information Bill proposes the formation of the National Health Information Centre, with the aim that it could take on this role.
- Needs for the EHDS:
 - Clear governance of the national HIS, including a data governance framework (e.g., to ensure implementation of data and quality standards)
 - Universal implementation of a unique identifier for health, and ability to link individual level data
 - Harmonised definitions and indicators, structured data, and adoption of standards across private and public providers
 - Legal mandate for data reporting from private providers
- Expectations from the EHDS:
 - EU and local level incentives and enablers for digitalisation
 - EHDS must be relevant for citizens and healthcare providers, demonstrating clear and tangible benefits.



Country visit – Netherlands

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 TEHDAS.sciensano@sciensano.be
Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to the Netherlands took place face to face in the Hague between **29 and 31 March 2022**.

Who was involved?

16 stakeholder organisations were interviewed: CBS-NL – Central Statistics Office; CIBG – National Contact Point for eHealth NL (NCPeH-NL); Erasmus MC; Health Insurance Company Cooperation; Health-RI; HL7 Netherlands; Ministry of Health Welfare and Sport (VWS) – Directorate of Information Policy / Cluster (Interoperability & Information Security), Directorate of Innovation and Healthcare Renewal, Directorate of Public Health, Division of Medical Ethics; Netherlands Comprehensive Cancer Organisation (IKNL); NEN (Dutch Normalisation Institute); Nictiz; Nivel; Ondernemers in de Zorg (Dutch ICT providers in the Netherlands); PALGA (Dutch Nationwide Pathology Databank); RIVM (Public Health Institute); VNO-NCW (Dutch Association of employers and entrepreneurs); Zorginstituut NL (Healthcare Institute).

Netherlands in brief

The Dutch Health Information System is rich and digitalised but fragmented, with decentralised management. In general, health data is stored in a structured manner. There are multiple initiatives aiming to standardise data and ensure quality. In the near future, citizens will be able to access their health data through the Personal Health Environment (PHE); a nation-wide program to implement this, is currently running. The burgerservicenummer (BSN) is the citizen number used as a unique personal identifier for health, covering all registered citizens and allowing individual level data linkage across data sources. In the Netherlands there is a distinction between secondary use of health data for scientific research and the use for innovation. Scientific research refers to studies conducted for the public good, whilst innovation refers to studies for commercial purposes.

Data collections/sources

- Electronic health records (EHRs) are digitalised but decentralised. There are two main providers.
- Upcoming PHEs allow patients to access a copy of their data from all their healthcare providers.
- Dutch Hospital Data (DHD) is a central collection of hospital data. Nivel and the Integrated Primary Care Information (ICPI) database have primary care data.
- Obligatory insurance provided by private not-for-profit companies. Central pool of health insurance data (Vektis).
- Statistics Netherlands (CBS) has several health-related registries, with mandatory reporting. CBS also carries out the Health Interview Survey.
- National Institute for Public Health and the Environment (RIVM) collects, stores, receives and re-uses data for research and policymaking. RIVM has its own datasets, and hosts screening programme data.
- >100 national quality registries. Dutch Cancer Registry has 2.3 million patients.
- Biobanks are decentralised in hospitals and other organisations. There is no plan to create a central biobank. PALGA is the national pathology register, with data from all pathology laboratories.

Data quality

- Quality control mechanisms in place: most registries in the Netherlands have quality validation processes and long feedback loops to healthcare providers to fix input errors and ensure proper registration at the source (e.g., validity checks on the data by quality departments and medical professionals).
- Health-RI: defines quality standards for research. In the future, possibility to have a data quality train checking consistency of data.
- Pathology data in PALGA are updated nightly.

Data infrastructure

- Decentralised storage of mostly digitalised and structured health data.
- Currently, there is no centralised metadata catalogue providing a general overview of health-related data collections and access procedures. RIVM and the Health-RI have developed metadata catalogues that could be combined to create the common metadata catalogue for the Netherlands. DCAT-AP standard is used by Health-RI.
- Pseudonymisation is done by CBS and the Zorg Trusted Third Party (based on BSN, name, date of birth, and postcode).
- The nationally developed Zibs common data model is the most used standard. Nictiz and HL7-NL promote the use of SNOMED-CT and HL7 FHIR, respectively. Some data collections (Nivel and Erasmus MC) are transferring their data to the OMOP common data model.
- Data access procedure:
 1. Obtain necessary (ethical) approvals
 2. Describe the research project protocol
 3. Apply to the different data holders separately
- Time and fees for accessing data vary between data holders. Same access procedure and fees apply for foreign researchers.
- Data linkage is possible but not always using the BSN number.
- CBS have a secure processing environment where they give access to data for analysis. Most university medical centres are also implementing such an environment.
- Personal Health Train (PHT) proof of concept for federated analysis by the Health-RI.

Data governance

- Wegiz legislative proposal drafted in 2021 to improve interoperability for primary use and normalisation of EHRs. In parliament for adoption (at time of writing).
- Ministry of Health, Welfare and Sport developing a roadmap for secondary use of health data.
- RIVM and CBS access aggregated data and perform studies to inform policy makers.
- The legal basis for use of health data for research and innovation is fragmented and on certain points unclear (Executive Act of the GDPR, UAVG).
- Consent is the common legal basis to use personal health data. Lexis specialis mentions that under certain conditions, when consent is not possible, opt-out mechanisms can be used. Due to differing interpretations of the legislation, continuous discussions and different procedures exist.
- Citizens use a two-factor authentication log-in, Mijn DigiD, to access a copy of their health data through the PHE, or directly from their healthcare provider. Medmij manages a set of data exchange standards ensuring that health data is transferred securely.
- There are some pilot initiatives where citizens can also input data from wearables into their PHE.
- Discussion to implement an opt-in and opt-out system for citizens through their Personal Health Environment.

Resources (human, technical, financial)

- Human resources needs:
 - Maintenance and operation of health data collections.
 - Data analysts, scientists etc.
 - ICT experts
 - Legal experts
 - Data stewards (new job profile)
- Technical resources needs:
 - Transformation of health data into the OMOP common data model, or other standardised data models.
- Financial resources needs and status quo:
 - General need for financial incentives to maintain skilled staff, such as data analysts, data stewards and ICT experts.
 - Ministry of Health, Welfare and Sports finances the PHE, PALGA and the IKNL. Healthcare providers and hospitals in general are financed by health insurances.
 - Ministry of Economy provides a Growth Fund that financed the Health-RI and the Dutch Artificial Intelligence Coalition.

Capacity building

- Training needs:
 - Need for training on how to input data in a structured manner and data literacy to healthcare providers.
- Training opportunities:
 - Nictiz provides communication, trainings and podcasts on terminology and how to use standards. It also provides the AMIGO tool, amongst other tools, for assistance to implement standards.
 - HL7 NL has launched an eLearning course for the HL7-FHIR starter code. Potential to become a European course. HL7 NL also provides training in collaboration with Firely.
 - RIVM provide services to researchers internally, on statistical modelling and general support to access and analyse health data.
 - RIVM occasionally also provides external trainings on high performance computing, R, machine learning and data management procedures.
 - Dutch Techcentre for Lifesciences (DTL) in collaboration with Health-RI already provides training for data stewards.

Best practices

- The PHT, the implementation of use cases piloting the federated analysis technology to create a proof of concept.
- Projects applying Privacy Preserving Technologies in order to perform federated analysis while ensuring patient privacy.
- Investment in the development of technical and procedural standards, including the involvement of healthcare professionals in the creation and deployment of these standards.
- The support and expertise provided by HL7-NL in the translation and transfer of health data from a local, national, standard to the HL7-FHIR model.

European Health Data Space (EHDS)

- General will to participate in the EHDS for secondary use but not yet decided who would take the role of the national contact point. Ongoing work on setting up the roadmap for the legislation on the secondary use of health data in the so called data reuse obstacle removal trajectory initiated by the Ministry of Health, Economic Affairs, Education and Health-RI.
- Cross-border sharing of health data is very important and is happening, as foreign researchers have the same access rights to health data as Dutch researchers.
- There is support for a system of federated collection, storage and analysis of health data, in particular through the regional health data nodes coordinated by Health-RI. Ongoing pilots on federated analysis through the PHT at Health-RI.
- The Netherlands is part of multiple international initiatives, such as BBMRI, ELIXIR, EATRIS, B1-MG, TEHDAS, EHDEN, DARWIN, ODISSEI, HL7 Netherlands, and many others.
- Needs to join the EHDS:
 - Need to have a harmonised network of hospitals and general practitioners, standardised electronic patient summary exchange and EHRs.
 - Need to have a common descriptive metadata catalogue for the Netherlands.
 - Need to transfer health data from nationally developed standards to internationally recognized common data models.
 - Need to have an integrated sectoral legal framework for healthcare data usage.
- Stakeholders highlighted the importance of introducing health and lifestyle data (e.g., from wearables, behavioural data) for research and innovation.
- Stakeholders highlighted the need for clarifications of certain definitions and the GDPR. Proposal to create a platform within the EHDS where healthcare providers, citizens, patients, data protection officers and legal officers can interact and share best practices.



Country visit – Portugal

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
TEHDAS.sciensano@sciensano.be
Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to Portugal took place face to face in Lisbon between **23 and 26 May 2022**.

Who was involved?

11 stakeholder organisations were interviewed: SPMS International Projects and Affairs Unit; SPMS Advanced Analytics and Intelligence Unit; SPMS Planning, Architecture, Compliance and Engineering Unit; SPMS Data Protection and Cybersecurity Unit; Directorate-General for Health (DGS) Department for Quality in Health and the Information and Analysis Service; Hospital Professor Doutor Fernando Fonseca; Statistics Portugal (INE); Central Administration of the Health System (ACSS); National Institute of Health Doctor Ricardo Jorge (INSA); Center Regional Health Administration

Portugal in brief

The Portuguese Health Information System is rich and digitalised with a centralised management of the EHRs. The Ministry of Health is composed of a direct administration comprising the Public Health Agencies, an indirect administration composed of laboratories and national institutes, and a public business sector composed of public enterprises, national hospitals and shared services (SPMS). SPMS is the ICT provider of the National Health Service (NHS). The NHS is financed through taxation, covering all citizens. Most health data is stored in a structured manner at the source. Citizens have access to their health data through a web portal and can opt-out from the use of their data for primary use but not for secondary use. All citizens have a unique health identification number that is given to them at birth allowing individual level data linkage across data sources. Currently, there is no common metadata catalogue available. SPMS guides researchers where to find the data and there is a national template on how to request access to the data. Remote secure processing environments are in discussion but not in place currently. Although the infrastructure for use and re-use of health data is already established, there is a lack of governance and of the legal framework to be ready to join the EHDS for secondary use.

Data collections/sources

- Electronic health records (EHRs) are digitalised and centralised in the SClínico National Clinical Registry. A copy of structured data from all public hospitals that use the SPMS EHR software and fragmented data from public hospitals using a different EHR software.
- The National Health Service (NHS) is financed through taxation, covering all citizens. Private healthcare activity exists and around 20% of the population opts for it.
- Web portal is available allowing citizens to access a copy of their data from all their healthcare providers, ability to see who uses their data and to opt-out from the use of their health data.
- Transparency portal with at least 150 structured, open data from anonymised datasets, aggregated data and data received from different sources (e.g., INSA, ACSS, DGS). Possibility for the user to create graphs in an interactive dashboard .
- Private hospitals do not have the legal obligation to share their data with the NHS.
- In Portugal apart from the SClínico there are around 80 data registries, or systems, as they are called.
- The National Institute of Statistics (INE) performs the SILC survey on income and living conditions, the European health interview survey and health examination survey. INE also receives administrative data from private hospitals and do the health reporting to Eurostat, the OECD and the WHO.
- The Central Administration of the Health System (ACSS) collects data on hospital mortality, financial data from every hospital and primary healthcare contracting data of every hospital and healthcare provider.
- The National Institute of Health Doctor Ricardo Jorge (INSA) is the national institute of health and the national laboratory of health. It has the only population-based sample biobank.

Data quality

- Quality assessment scheme in place. Several quality checks are implemented with automated tools. At the DGS there is a manual analysis as well as business intelligence tools used to identify duplicates and missing values.
- For every information system/registry there is a quality check locally at the collection and storage point. Then for the analysis step there is also a quality check. Institutes also perform quality checks before they store and share the data.
- The Transparency Portal has a feedback mechanism to maintain its quality by providing an area where users can give feedback about missing indicators of interest to them.

Data infrastructure

- Centralised storage of a copy of digitalised and structured health data at SPMS.
- Currently, no centralised metadata catalogue providing a general overview of health-related data collections and access procedures. The Transparency Portal has a metadata catalogue based on the DCAT-AP standard but only for the open data it gives access to.
- For patient summaries and semantic interoperability ICD-10 is mostly used in hospitals. Portuguese catalogues for laboratory analysis use LOINC and SNOMED CT. For health data exchange they use HL7 V2.5 and will move to HL7 FHIR.
- Data access procedure:
 - Obtain necessary (ethical) approvals from the hosting institution
 - Completion of the SPMS common access request form/template including the approved project protocol
 - Researcher must be part of a recognised institution
 - SPMS performs the legal and feasibility analysis → provides a joint statement
 - DPO of SPMS contacts data controllers of the data sets and they decide on the access terms
- Time to access data is 3-4 months and there are no fees for accessing data.
- Same access procedure and fees apply for foreign researchers.
- Pseudonymisation and linkage of individual level data is done mostly by SPMS using the unique health identification number.
- No remote secure processing environment in place, only physical at the Statistical office.

Data governance

- Legislative framework for primary use of health data is more defined but there is no legislation yet on the secondary use of health data.
- SPMS already has a legal governance in place.
- Some scattered laws on genomics and clinical research exist but the regulation on the EHDS will drive the development of a national legislation for the secondary use of health data.
- Privacy control and safeguards to avoid data privacy breaches, each data requestor needs to sign a data confidentiality and data processing agreement.
- The roles and coordinating bodies are being currently defined by the roadmap for secondary use by the Ministry of Health. SPMS and ACSS inform policy makers through the DGS.
- SPMS also supervises compliance with the GDPR, receives complaints from citizens in case of data breaches and gives guidance to data controllers on the interpretation of the GDPR.
- Citizens have access to their health data using the Web portal where they can access their e-prescriptions, vaccination card, allergies, previous consultations, telemedicine services and can perform administrative actions. They can opt out from the use of their data and can see who is accessing their data. However, they cannot opt-out for the secondary use of their data.
- 24 hours phone contact (NHS24/SNS 24 Balcão) providing support to citizens on the use of the platform, the application and how to schedule a consultation.

Resources (human, technical, financial)

- Human resources needs:
 - Data analysts, scientists etc.
 - ICT experts
 - Legal personnel at the hospitals
 - Difficulty responding to all data access requests due to a lack of human resources was reported
 - Difficulty retaining skilled data analysts in the public sector due to lack of financial incentives
- Technical resources needs:
 - Need to develop the IT infrastructure at ACSS.
 - In INSA there is a need for more technical resources, for instance a virtual machine, an upgraded IT infrastructure and resources to maintain it.
- Financial resources needs and status quo:
 - Need for financial resources at several institutes, such as INSA, to support with the fees for the services provided by their technical provider, SPMS.
 - The recovery and resilience fund has helped the developments but there is a need for more funding.

Capacity building

- Training needs:
 - Need for more training on data literacy, programming and big data analysis.
- Training opportunities:
 - Hospitals provide training to new staff on how to use the local EHR software.
 - SPMS offers public training sessions on SNOMED-CT and other standards. These training sessions are followed by healthcare providers among others. They also provide implementation guidelines for the HL7 FHIR data exchange standard.
 - The Transparency Portal provides special courses on the GDPR for implementers in the Public Administration and more courses.
 - INSA offers training on epidemiology.
 - The central regional health administration there is already an ongoing programme on data protection issues at the level of the healthcare providers. They also provide training to university students in statistics and big data analysis.

Best practices

- It is important to highlight the well-developed infrastructure, the fact that most health data is digitalised and that citizens have control over their health data (e.g., web portal).
- The short time to access data and the fact that there are no fees requested is a best practice. This likely results from the fact that health data is centralised in Portugal within SPMS.
- The pilot study conducted by INSA on linking individual level data and doing a multi-country assessment for the COVID-19 vaccine effectiveness, financed by the ECDC.

European Health Data Space (EHDS)

- General will to participate in the EHDS for secondary use. Ongoing work on setting up the roadmap for the legislation on the secondary use of health data and building the National Health Data Space.
- The National Health Data Space might be under the responsibility of SPMS.
- It is likely that the Portuguese health data access body and national contact point within the EHDS network will be one of the existing entities rather than creating a new one. SPMS has been working on the EHDS so it is possible it will take on this role. The national decision had not been made at the time of the country visit.
- Cross-border sharing of health data is very important and is happening, EHDS is expected to scale it up.
- Portugal is participating in multiple European projects and research infrastructures, such as ELIXIR and TEHDAS.
- Portugal participates actively in MyHealth@EU and they are the coordinators of the X-eHealth project (designing the business specification of MyHealth@EU).
- Needs to join the EHDS:
 - Need for a governance and legal framework to establish the roles of every stakeholder in the HIS.
 - Strong need for resources at the hospitals. Currently they have to outsource the digitalisation and structuring of health data, which is very costly.
 - Need to have a common descriptive metadata catalogue for Portugal.
- Stakeholders stressed the importance to ensure coherence between the EHDS and Eurostat. The EHDS should align with the standards already in use and requested by Eurostat.
- Stakeholders noted that the European Commission could work on providing a European cloud solution.
- Stakeholders highlighted the need to have a reference document at EU level, giving an overview of the methodology used in different EU member states when it comes to indicators for public health monitoring for example.



Country visit – Slovenia

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.

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When did it take place?

The visit to Slovenia took place face to face in Ljubljana between **20 and 23 September 2022**.

Who was involved?

9 stakeholder organisations were interviewed: Health Insurance Institute (ZZZS), Information Commissioner, Institute of Oncology Ljubljana, Ministry of Health, National Institute of Public Health (NIJZ), Primorska University, Statistical Office of the Republic of Slovenia (SURs), University of Ljubljana, University of Maribor.

Any questions?

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

Slovenia in brief

Slovenia was an early adopter of e-health, and has a well-developed health information system with a strong technical infrastructure. Almost all health data is digitalised, with wide implementation of EHRs connected to central services, for instance for EHR exchange. Health data management in Slovenia is highly centralised and the health information system is register-oriented. The Slovenian healthcare system is financed through statutory health insurance. The single compulsory public health insurance, the Health Insurance Institute of Slovenia (ZZZS), provides almost universal coverage for necessary services. Whilst several personal identifiers are used in health, the personal identification number is used for linkage of data across data sources. Some challenges were noted by stakeholders in terms of the legal framework surrounding the secondary use of health data.

Data collections/sources

- The National Institute of Public Health (NIJZ) is responsible for population health registers, health service databases, and many surveys. Registries are defined in the Healthcare Databases Act and surveys are defined in Annual Programme of Statistical Surveys.
- The Slovenian Cancer Registry is maintained by the Institute of Oncology Ljubljana. It is the fourth population based cancer registry worldwide. Reporting is mandatory.
- The ‘eHealth’ system for digital health has been in place since 2015. Healthcare providers (HCPs) can choose EHR systems as long as they comply with central specifications. There are 35 EHR software providers. Seven participate to the eHealth infrastructure, covering 90% of the market.
- The Central Registry of Patient Data (CRPD) is a transient data repository of EHRs, with the main aim of facilitating national EHR exchange. HCPs’ information systems are connected via APIs.
- The Health Insurance Institute of Slovenia (ZZZS) has data on health service reimbursements, cash benefits, medicines and medical devices. It has a register on insured persons, employers and HCPs.
- The Statistical Office of Slovenia (SURS) has some health-related data collections: National Health Accounts, EU-SILC (collaboration with NIJZ within EU-SILC on the following domains: Health status and disability; Health care; Health determinants); database on vital statistics.

Data quality

- Most health data in Slovenia is digitalised and some is structured.
- Data comes into NIJZ via the e-transfer portal ePrenosi, with automated data checks in the software. Errors are automatically fed back to HCPs for correction.
- eHealth has some automated quality control mechanisms but these are limited as the data is processed in real time. Stakeholders reported a need for a specific quality department.
- The Cancer Registry has strict coding rules. Trained nurses review information, perform coding and input data in a structured manner. Quality checks are applied at several points.
- ZZZS has rules for data input and checks are performed at the source.

Data infrastructure

- Data storage is centralised. Registries are stored at NIJZ with few exceptions (e.g., Cancer Registry).
- EHRs are centrally stored in the CRPD but archived information is at individual HCPs. The CRPD is a transient repository. It currently has capacity for storage of 5-10 years of electronic health data.
- eHealth data is kept in the territory of Slovenia using a national cloud with sufficient capacity.
- There is currently no national metadata catalogue. Registries are strictly defined in the Annex of the Healthcare Databases Act, including specific variables collected. NIJZ also has an online [catalogue](#), with information on each database. It currently does not use international standards. Work is planned to implement international standards in the NIJZ catalogue.
- For data access, there is no national centralised procedure. Users apply to individual data holders.
- There is usually no difference made between national and international researchers.
- Generally, access is provided to anonymised data, or pseudonymised data when required.
- There is one secure processing environment (SPE) at SURS. NIJZ has a contract to use it. Data is sometimes sent directly to researchers after data protection committee approval, or they get access to the data in secure room.
- Generally, fees are only requested if the data holders performs the analysis and provides aggregated data or when microdata are prepared for research purposes. Fees are not charged to use the SPE.
- Linking individual level data is possible but it needs to be allowed in the law.
- The national [Open Data Portal of Slovenia](#) contains data from the public sector. Different institutes also have their own open data portals (e.g., [NIJZ](#), [Cancer Registry](#), [SURS – SiStat Database](#)).
- On data interoperability, NIJZ is responsible for classifications. Internationally recognised standards used include ICD-10 Australian Modification, ATC codes for medications, and ACHI for medical procedures. SNOMED CT is used in specific cases but not widely implemented. For data exchange, the CRPD uses openEHR. In the future HL7 FHIR will also be implemented.

Data governance

- There is currently no specific legal framework for the secondary use of health data.
- The Slovenian constitution states that all personal data processing must be provided for in the law.
- The main legislation governing health data use is the Healthcare Databases Act. It defines all registries, as well as specific eligible users and purposes for each database. Data linkage is only allowed if explicitly stipulated per database.
- The other main laws relevant to the use of health data in Slovenia include: GDPR, Personal Data Protection Act, National Statistics Act, Health Care and Health Insurance Act, Act on Patients' Rights, Act on Communicable Diseases.
- Stakeholders noted that the main challenges for secondary use of health data are legal. For instance, the lack of systematic data linkage prevents research focusing on wider health determinants.
- There is a strong strategic focus on the eHealth infrastructure, with significant digitalisation of the health sector. The new eHealth strategy, "Slovenia – eHealth for a healthier society", has been developed with support from the European Commission's Structural Reform and Support Programme.
- There is a plan to move the management of the eHealth infrastructure from NIJZ to the Ministry of Health, possibly establishing a separate body for IT services for the eHealth infrastructure.
- On citizen engagement, citizens have access to their data through the [zVEM](#) patient portal and mobile app. Patients can opt out from specific institutions using their patient summary, or consent to a specific doctor to access their records through the patient portal.
- The Information Commissioner is the national agency with the primary role of monitoring whether personal data is lawfully handled and protected, in compliance with the GDPR. There is a strong focus on data privacy in the Slovenian population, giving the Information Commissioner a central role in policymaking.

Resources (human, technical, financial)

- Human resource needs identified by different stakeholders:
 - Cybersecurity experts
 - Data analysts
 - Semantic experts
 - Additional human resources to deal with increased requests with the EHDS
- Financial resources:
 - The technical infrastructure is generally well-developed and well-resourced but stakeholders note that additional financial resources would be needed to further develop it (e.g., creation of new SPEs)

Capacity building

- Examples of training opportunities identified:
 - Training on data protection
 - Training for young doctors with short courses on eHealth and health information
 - Data analytics training
 - School of Public Health by the NIJZ
 - SURS annual conference with researchers where they present outputs and receive feedback
- Examples of training needs identified:
 - Training to healthcare providers on how to input data in a structured manner

Best practices

- Several best practices were identified during the country visit in Slovenia.
- The best municipality awards reward the municipality that has most improved indicators and invested in health, providing incentives to improve their data collection for the registries.
- The Slovenian Cancer Registry has specially educated nurses who register cancer cases in a structured manner and follow international cancer registry courses. The nurses are educated for one year before they can work independently. The Cancer Registry reported that every cancer case is reviewed manually by professional coders, allowing careful determination of all rare cancer entities, which could otherwise slip through processing massive information.
- The architecture of Slovenian eHealth infrastructure enables it to harness the full potential of digital records in a timely manner. For instance, data inputted once is transferred to different relevant databases (e.g., vaccination data).

European Health Data Space (EHDS)

- In general, Slovenian stakeholders recognise the potential benefits of the EHDS.
- However, stakeholders note that more clarity is needed on certain aspects. For instance:
 - It is important to ensure the comparability and quality of data
 - The option for patients to remove or restrict access to certain parts of their EHR may have implications on data integrity, consistency and usability for secondary use
 - The exemption of micro-enterprises as data holders may incur data gaps, especially in a country where a large proportion of healthcare is provided by micro-enterprises
- The technical infrastructure is well-developed in Slovenia to support implementation of the EHDS, but will require enlargement. Slovenia is not yet part of MyHealth@EU due to lack of staff to set up the national contact point for primary use at NIJZ. Operation is planned for 2023.
- NIJZ is currently the competent authority for the direct grants supporting the establishment of a Health Data Access Body (HDAB) for the EHDS. It is being decided if NIJZ or a new institution would become the HDAB and/or national contact point (NCP) for secondary use.
- There are some legal challenges that need to be addressed at national level. Stakeholders note that a final agreed legislative text on the EHDS is required before legislative changes are made at national level.
- Needs for the EHDS:
 - Guidance on how to implement the EHDS, with a clear roadmap of what to do when
 - Assistance to understand differences in reporting between Member States despite harmonised methodologies
 - Strengthening of human resources and financial support for implementation
 - Need for a clearer legislative text and clear definition of responsibilities and terminologies
- Expectations of the EHDS:
 - Understanding that Member States are not at the same starting point
 - The European Commission should consider and clarify the short-, mid- and long-term goals for EHDS implementation
 - Harmonisation of guidelines from the EU (e.g., set of standards to be used)
 - Ensuring quality assurance (e.g., ensuring quality of data inputted by patients into Personal Health Records, training for proper coding at the source)
 - Take stock of good work and European cooperation already done in other areas, such as cancer registries



Country visit – Sweden

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.

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Any questions?

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

When did it take place?

The visit to Sweden took place face to face in Stockholm between **24 and 28 October 2022**.

Who was involved?

26 stakeholder organisations were interviewed: Analytic Imaging Diagnostics Arena (AIDA); Astra Zeneca; Biobank Sweden; Dental and Pharmaceutical Benefits Agency (TLV); Genomic Medicine Sweden (GMS); Karolinska University Hospital; Medtech4Health; Ministry of Health and Social Affairs; National Board of Health and Welfare (NBHW); National Life Sciences Coordinator; Public Health Agency of Sweden; Regional Cancer Centres (RCC); Research-based Pharmaceutical Industry (Lif); Roche; Statistics Sweden; SciLifelab; Stockholm Center for Health Data; Swedish Association of Local Authorities and Regions (SALAR); Swedish Authority for Privacy Protection (IMY); Swedish e-Health Agency; Swedish Ethical Review Authority; Swedish Medical Products Agency; Swedish MedTech; Swedish Research Council; Swelife.

Sweden in brief

Sweden has a tax funded healthcare system. It has fully digitalised health care systems, with complete coverage of the population. It is characterised by a rich health data landscape with a long tradition of national registries, and quality registries. However, data sources are currently existing in silos, limiting full use of the richness of data. All residents have a personal identification number, which is used for linking individual level health data. Healthcare and health data management in Sweden is decentralised due to the division into several responsible agencies, 21 regions and 290 municipalities with high level of autonomy. eHealth has long been a priority in Sweden. With a newly elected government at the time of the country visit, there were still some uncertainties regarding preparations for a future implementation of EHDS. However, development of a common infrastructure for the Swedish health care sector has been indicated as a priority.

Data collections/sources

- EHR systems are fragmented across the regions. Each region can choose the EHR system to be used.
- The National Board of Health and Welfare (NBHW) maintains six national health registries with individual level health data.
- There are about 100 national quality registries (NQRs), which contain individual level data on different diseases, medical interventions, and treatment outcomes. The NQRs are under the responsibility of the regions, and is coordinated by the Swedish Association Of Local Authorities And Regions (SALAR).
- The Public Health Agency of Sweden (PHAS) collects and analyses data for public health monitoring and surveillance for health threats and communicable diseases, performs microbiological analysis, carries out several national health surveys and maintains national health register for vaccinations.
- Information Network Cancer (INCA) is a registry platform owned by Regional Cancer Centres (RCC) organisations, and brings together all cancer related quality registries.
- Statistics Sweden is the main source of sociodemographic data.
- The eHealth Agency collects data on prescription drugs and medical products.
- The Medical Products Agency has data on manufacturing and sale of pharmaceuticals.
- There are about 200 biobanks across six regional biobank centres. The national infrastructure Biobanks Sweden is set up to allow easier collaboration among the different biobanks.
- There are multiple genomic data collections fragmented across Sweden. There is a national genomics platform (NGP) which is being set up by Genomics Medicines Sweden (GMS).

Data quality

- Quality controls are generally implemented at point of data collection. Errors are fed back to HCPs.
- The Swedish eHealth Agency ensures quality of their data by producing statistics based on the international standard “Generic Statistical Business Process Model” (GSBPM).
- The PHAS uses automated quality checks, quality protocol for the national registry, and mandatory reporting of a specific set of variables.
- The NBHW uses various quality protocols for each registry.
- The NQRs are certified based on the quality of the register. However, stakeholders noted that the quality of data in the different quality registries varies greatly.
- The cancer registries at INCA use integrations and set forms for data validation. The RCCs follow up with the clinics regarding missing cancer cases.

Data infrastructure

- There is no centralised national repository for EHRs. They are stored at regional and municipal levels.
- Similarly, biobanks and genomic data are currently not stored centrally.
- Data for monitoring and secondary use are collected into national registries by different data holders.
- The [Register Utiliser Tool \(RUT\)](#) provides metadata from national registers, biobank sample collections, and other major research databases.
- NBHW also provides some metadata for the national health registries they maintain
- In general, both national and international researchers can get access to aggregated data.
- Access to individual-level health data for the purpose of research requires approval from Swedish Ethical Review Authority.
- Access application forms are available from the stakeholders: [NBHW](#), [NQRs](#), [eHealth Agency](#). A digital application for PHAS is under development.
- Most data holders request an hourly fee to cover the processing and delivery of the data, which depends on the size and complexity of the data set. Time to access varies.
- The main SPE in use is [MONA \(Microdata Online Access\)](#) owned by Statistics Sweden. Researchers may upload data they have been granted access to for further analysis.
- ICD-10-SE is widely used ensuring statistical comparability. Additionally, there is a general aim to also promote SNOMED CT for semantic interoperability in relevant use cases.
- The agency for digital governance (DIGG) is leading the work, together with several other agencies, to establish a joint administrative digital infrastructure called [ENA](#).

Data governance

- eHealth is a priority. Multiple strategies for eHealth and innovation in life science have been published since 2005. A common joint vision for eHealth was developed by the government and SALAR focusing on legislation, standards, semantics.
- The Life Science Strategy for innovation and life sciences includes a focus on secondary use of data and unlocking the potential of data (e.g., through interoperability).
- In 2021, the government launched the national data strategy to promote the use of data and strengthen the digital competence and innovation capacity in Sweden.
- There is a plan for implementing a national strategy for information and cyber security in the society in 2023.
- A new government was elected in October 2022. It was reported that priority would be given to the development of a common infrastructure for the Swedish health care sector.
- The legal framework for data use and re-use is based on five main principles: proportionality, transparency, trust, rights of natural persons, and protection.
- The main laws governing health data use include: Act on Official Statistics (2001); Ethics Review Act (2003); Data Protection Act (2008); Patient Data Act (2008); Regulation for National Registries on Health; and the updated Biobanks Act (2022).
- Ethical approval is required for accessing almost all types of health data according to Article 9.1 GDPR in Sweden, submitted to the Swedish Ethical Review Authority.
- The central application for ethical approval costs 5000SEK per project or 16,000SEK for multi-center project.
- Citizens can in some cases read some of their health data through the 1177.se portal, and are able to access a free transcript on all their information at NBHW once per year, and from the national health register for vaccinations at PHAS.
- In genomics, citizens are involved through activities with patient organisations.

Resources (human, technical, financial)

- Overall, there is a need for skilled staff such as experts on the interplay between health and technology, data stewards, informatics specialists, and lawyers.
- Most stakeholders indicated need for additional funding to further develop the infrastructure for secondary use of health data. A co-funding model (national and international) was suggested to invest in digital health and genomics.
- Stakeholders expressed the need for more hardware for data analysis and cybersecurity.
- Some examples were provided on AI projects in healthcare (for example in medical imaging).

Capacity building

- Swedish organisations offer many training opportunities. Some examples are:
 - NBHW: provides training on application procedure for students, researchers and analysts
 - NQRs: offer technical support and statistical help
 - eHealth Agency: organises workshops to business intelligence system users and researchers
 - Swedish Authority for Privacy Protection: offers guidance on all aspects surrounding ethical application
 - Statistics Sweden: offers training on how to use MONA and statistical analysis
 - SciLifeLab: training on bioinformatics, data management courses, AI courses

Best practices

- Sweden has set up a National Life Sciences Coordinator, an inter-ministerial office, to bring together views of multiple ministries in all aspects regarding health and life science. This office consists of several officials from the Ministry of Enterprise and Innovation, the Ministry of Education and Research, and the Ministry of Health and Social Affairs.
- The Swedish government launches public inquiries and commissions its agencies with governmental assignments that normally include assessments and piloting of any upcoming issues.

European Health Data Space (EHDS)

- There is strong political will and agreement in Sweden with the overall legislation on the EHDS.
- There is a positive view on the ambition to increase use of health data for primary and secondary use.
- The EHDS was reported to be an important part of the Swedish Presidency of the Council of the EU, starting January 2023.
- Work is already ongoing for implementing future federated analysis. The Medical Products Agency published a report describing the foundation for federated analysis.
- Sweden already implemented a mapping of the RUT metadata catalogue and registry descriptions to DCAT-AP metadata standards.
- The eHealth Agency is the national contact point for the primary use of health data (MyHealth@EU). For secondary use it is not decided yet who will take on the role. Currently, the eHealth Agency is acting as the competent authority for the direct grants to MSs.
- No political decision has been made with regards to the Health Data Access Bodies (HDABs).
- Some stakeholders suggested considering regional HDABs as moving the processing and management of data requests and permits away from the actual holder of data registries and expertise to a central HDAB may be problematic.
- Some needs and concerns were expressed regarding the future EHDS.
- With the current proposed structure of EHDS, Sweden might need to re-assess the national legal framework and governance structures.
- Some stakeholders expressed the need for clearer definitions within the current EHDS proposal, and noted that they perceive some legal uncertainties in parts of the current proposal.
- Expectations from the EHDS:
 - Ensure data protection, patient safety, cybersecurity
 - Provide clarification of the involvement of private companies in the EHDS
 - Improve interoperability and the use of internationally recognised standards
 - Define clear standards that should be set and approved by the EU (e.g., openEHR)
 - Avoid increasing existing workload
 - Ensure adequate privacy protection (avoidance of re-identification)
 - Provide clearer distinction between EHDS and GDPR
 - Maintain the public trust that has been built nationally through strong security and privacy protection processes
 - Define minimum set of datasets that need to be structured
 - Avoid duplication with existing data collection and sharing system at EU level, such as Eurostat and ECDC
 - Provide clearer definitions (e.g. data holder)
 - Ensure balanced administrative burden on Member States

6 Guidelines for using the ‘TEHDAS country visit toolkit’

This section provides guidelines on how the ‘TEHDAS country visit toolkit’ could be used in the future for benchmarking¹ of the preparedness of MS to join the EHDS. However, it is important to highlight that the mapping exercise performed by the TEHDAS Task 4.1 team, and the results presented above, were not a benchmarking exercise. The methodology was qualitative in nature, with the objective of obtaining an overview of the current situation of the health data management systems in the different MS and their preparedness to join the EHDS.

To achieve the objectives set out for the TEHDAS mapping exercise, the developed tool and the methodology described above have proven useful for their purpose. The country visits provided a good overview of the current state of play of the health data management systems in the MS/AC, and their preparedness to join the future EHDS. It should be noted that countries’ development and preparedness are rapidly and continuously changing. Therefore, we believe that this approach should be used to continue the mapping exercise, in an iterative manner. Furthermore, this methodology could also be used for benchmarking, comparing countries’ situations against the standard defined in the proposed EHDS regulation. For this purpose, the mapping tool may need to be altered, some questions changed or added, given that the concept of the EHDS is constantly maturing.

For this reason, based on the TEHDAS country visit experience we developed the ‘**TEHDAS country visit toolkit**’. More specifically, the ‘TEHDAS country visit toolkit’ is composed of:

- The 5-step country visit methodology (as described in Section 4.3)
- The TEHDAS mapping tool (see Annex 1)
- Guidelines and best practices (presented below)

Guidelines and best practices

Based on the TEHDAS experience, the following guidelines and best practices are proposed on how to use the ‘TEHDAS country visit toolkit’ for benchmarking and mapping the preparedness of MS to join the EHDS for secondary use of data and more specifically the HealthData@EU infrastructure:

1. Use the ‘TEHDAS country visit toolkit’ as described in this document.
2. Conduct this mapping exercise using this toolkit in **an iterative way** to keep an overview of the situation within the different MS/AC at different stages: during the EHDS preparation, once the regulation and implementing acts have been approved and during the implementation of the EHDS within MS/AC.

¹ As defined as “the act of measuring the quality of something by comparing it with something else of an accepted standard”. Cambridge Dictionary. Available at: <https://dictionary.cambridge.org/dictionary/english/benchmarking>

3. Based on the TEHDAS experience, to ensure good operation of the 'TEHDAS country visit toolkit', consistency and validity of the methods, we recommend paying particular attention to the following:
 - Consider external developments (e.g., specificities in the finalised EHDS legislation and implementing acts) and add additional questions if needed.
 - Ensure the correct profiles within the interviewing team, in order to cover the scope of the mapping tool (e.g., legal expertise, technical knowledge). It is recommended to have a team of 2-4 interviewers to carry out the country visits, with the relevant experience.
 - Identify the appropriate country contact person who is correctly placed to identify and ensure engagement from stakeholders. Ensure good collaboration with the country contact person through regular bilateral preparatory meetings.
 - Engage and interview a broad spectrum of stakeholders, covering the entire landscape of the health information system and health data management landscape. This includes (but is not limited to): policymakers from all relevant ministries, research institutes, data protection authorities, technical stakeholders, industry, health insurance funds, healthcare providers and hospitals, ethical committees, and legal experts.
 - Carry out face-to-face meetings where possible. Whilst the TEHDAS experience demonstrated that the results were of the same quality, face-to-face meetings allowed easier interaction with stakeholders, facilitating the process and considering cultural sensitivities.

7 Conclusion

In conclusion, this document presents the findings of the TEHDAS country visits implemented between December 2021 and December 2022. The results provide an overview of the state of play of national health data management systems and countries' readiness to join the EHDS. It is important to note that these results provide a snapshot of the situation at the time of the visit. The spectrum of countries visited covers a variety of systems from across Europe.

The mapping exercise had benefits for both the participating countries and the EC. Firstly, the mapping helps provide an overview of the state of play of health data management systems across Europe. This overview is crucial in building a sustainable and pragmatic EHDS. The mapping exercise allowed for reflection on needs, expectations, and level of development at national level, and on how TEHDAS and the EHDS could respond to them. MS/AC authorities and stakeholders were mobilised and encouraged to be involved in the process. Country visits also investigated the human and financial resources needed for various European countries to potentially join and link to a future EHDS and become national nodes. It also provided an opportunity to familiarise various stakeholders with TEHDAS and its activities.

A further benefit for the MS/AC being mapped was that the country visit provided an opportunity to bring together stakeholders involved in the HIS, and to have an overview of the current situation in their country regarding health data management and the regulations supporting health data exchange for secondary use. A subtask of the exercise entailed the identification of capacity building and training needs. These findings can be built upon in future exercises to build capacity for the implementation of the EHDS.

Finally, the methodology described above can also be used for benchmarking activities, comparing national situations against the final EHDS regulation. Suggested guidelines on how to use the 'TEHDAS country visit' toolkit for benchmarking have been presented in this document. The benefits of continued use of this methodology include monitoring, continuous improvement, and enhanced planning of implementation towards the EHDS at both national and EU level.

References

- (1) Verschuuren M, van Oers H. Population Health Monitoring: Climbing the Information Pyramid. Switzerland; Springer; 2019. Available from: <https://be1lib.org/book/3661052/728e4e?id=3661052&secret=728e4e>
- (2) World Health Organisation Regional office for Europe. Support tool to strengthen health information systems: guidance for health information system assessment and strategy development. World Health Organization; Regional Office for Europe; 2021. Available from: <https://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/publications/2021/support-tool-to-strengthen-health-information-systems-guidance-for-health-information-system-assessment-and-strategy-development-2021>
- (3) Joint Action on Health Information, Verschuuren M, Calleja N, Bogaert P. WP5 Task 1: Health Information System Assessment Manual Objectives, process & guidelines, and roles & tasks. Brussels: Sciensano; 2018. Available from: http://www.inf-act.eu/sites/inf-act.eu/files/2020-01/UPDATED_%20InfAct%20assessment%20manual_1.0_Final.pdf
- (4) Bogaert P, Verschuuren M, Van Oyen H, van Oers H. Identifying common enablers and barriers in European health information systems. Health Policy, 125(12); 2021. Available from: <https://doi.org/10.1016/j.healthpol.2021.09.006>
- (5) MEASURE Evaluation. Health Information Systems Interoperability Maturity Toolkit: Assessment Tool. North Carolina; Carolina Population Center; 2017. Available from: <https://www.measureevaluation.org/resources/publications/tl-17-03b.html>
- (6) MEASURE Evaluation. Health Information System Stages of Continuous Improvement Toolkit: Workbook. North Carolina; Carolina Population Center; 2019. Available from: <https://www.measureevaluation.org/resources/publications/tl-18-09.html>
- (7) Orrell, T. The Joined-Up Data Maturity Assessment. Global partnership for Sustainable Development Data; United States of America; 2020. Available from: https://www.data4sdgs.org/sites/default/files/file_uploads/Joined_Up_Data_Maturity_Assessment_draft5.pdf
- (8) Bogaert P, Verschuuren M, Van Oyen H, van Oers H. Capacity building in European health information systems: the InfAct peer assessment methodology. European Journal of Public Health, 32(3); June 2022. Available from: <https://doi.org/10.1093/eurpub/ckac014>
- (9) TEHDAS country visits. Available from: <https://tehdas.eu/packages/package-4-outreach-engagement-and-sustainability/tehdas-country-visits/>
- (10) Data Catalog Vocabulary (DCAT) - Version 2. Available from: <https://www.w3.org/TR/vocab-dcat-2/>

- (11) Standardized Data: The OMOP Common Data Model. Available from: <https://www.ohdsi.org/data-standardization/>
- (12) FHIR Specification (v4.3.0: R4B - STU). Available from: <https://hl7.org/fhir/>
- (13) International Statistical Classification of Diseases ICD-10 Version:2019. Available from: <https://icd.who.int/browse10/2019/en>
- (14) LOINC, The international standard for identifying health measurements, observations, and documents. Available from: <https://loinc.org/>
- (15) SNOMED International. Available from: <https://www.snomed.org/>

Annex 1

The following table presents the TEHDAS mapping tool, which includes the guiding questions that were used during the country visits.

Table 3: The TEHDAS mapping tool

Item ID	Question	
Data collection/sources		
1_EHR/EMR	What is the status of Electronic Health Records (EHRs) shared between various healthcare providers in your country?	a) Do you have centralised EHRs? b) What is the coverage of information in the EHR? c) Are international classifications used?
2_Health insurance data		
What is the status of health insurance data? What is the coverage?		
3_Population monitoring data		
Which disease registries are operating? By whom?		
What type of regular health surveys are carried out? By whom?		
Do you have a registry on vital statistics? What is the coverage?		
4_Other health data (e.g., public health related, epidemiology, -omics)		
What kind of health data do you collect? How are biobanks and genomic data organised?		
Are the different data sources and health information system digitalised?		
Are there different open data available for each of the data collections?		
Data quality		
What quality control mechanisms are applied?		
What kind of automated control mechanisms are built into the different data/information systems? Are manual quality control mechanisms applied? If so, what kind?		

How is the quality of health data collected assured?
Are audits performed to check the completeness and correctness of data?
Data infrastructure
1_Data storage
Is there a (central) data warehouse/data lake/data hub in place? Or are data collections decentralised? Who maintains it?
Is there a common metadata catalogue available?
Is a unique personal identification number (UPIN) in use? Is this number used for health and across sectors? Is it available for all residents?
Is the data stored in anonymised or pseudonymised way? Is the pseudonymisation done by a trusted third party?
2_Data access
How can data be accessed and used for secondary purposes?
What are the procedures for data access for the different data collections?
Are the procedures/forms for requesting access available (on a platform/website)?
Is data accessible for foreign researchers in the same way/process as it is for national researchers?
Is there a set fee to request access to data for research or for policy making? Does the fee differ for the private or for the public sector?
What is the average timeframe from requesting access to data and receiving the data?
Are there secure processing environments in the country (SPEs)? How many? In what institutes?
How is data provided to researchers (e.g., sent via email, provided in a secure processing environment)?
3_Interoperability
Are there interoperability standards and guidelines defined and used?
Which metadata standards and data exchange standards are in use (e.g., OMOP, HL7 FHIR, DICOM)?

Which standards for semantic interoperability are in use (e.g., ICD-10, SNOMED CT...)?
Is there an entity that is responsible to publish and monitor the use of national and international data exchange and semantic standards?
What is the status of ICT infrastructure for data sharing? Is there a widely adopted model for organising health data (example EHR) in a common format (e.g., XML) so that systems that are not directly linked to one another can share information with others using the same model?
Is individual-level data linkage possible for primary use? If so, is it done on a regular basis between data repositories?
Is individual-level data linkage possible for secondary use? If so, is it done on a regular basis between data repositories (either for research or for policy making)?
Which entities are responsible for linking the data?
Data governance
1_Strategy and legal framework
What are the most recent strategies for eHealth/digitalisation/secondary use of health data in place?
Which ministry or other public body is responsible for planning, conceptualising and implementing health data strategy?
Is there a structured process in place for the identification of the national health data governance priorities?
Is there a multi-stakeholder coordination mechanism for the development and implementation of a health data governance strategy in place, or is the topic assigned to a specific institution or body?
Is there a legal framework in place for secondary use of personal health data, for example, use of health data for research purposes or statistics? This is particularly relevant for personal health data from the medical setting (hospitals, polyclinics, general practice, etc.) for public health purposes and research.
What are the main legal acts in place that impact the collection, access and sharing of health data?
What are the legal bases in place for data collection and access for the different data sources? Are there specific guardrails for the legal basis for the processing of personal data for (public) health purposes? Is such processing primarily based on the legal mandate of the institutions, the consent of the data subject or a public interest?

2_Data privacy, ethical requirements and data protection
Is there a (central) data permit authority? Which authority/authorities take(s) on this role? Is it shared among more than one authority?
Is there a national/regional data protection authority? Are there institutional data protection officers or data protection committees in each entity (hospital/university/institute)?
Are there agreements in the country among stakeholders and regions for sharing data? And with other countries and international organisations?
What are the procedures to request privacy or legal approval for data exchange?
Are there procedures to request ethical approval for data exchange?
Are there national or regional ethical committees in place?
3_Citizens' engagement
How are citizens and patients informed about health data?
Do citizens and/or patients have access and control of their own data in the health information system?
Are there different activities in place to include citizens opinions on health data related topics (e.g., public consultations)? Are patients included in working groups and discussions?
Resources
1_Human, technical and financial resources
Do stakeholders have sufficient human resources for maintaining/operating data collections? If not, what are the typical profiles/expertise still needed?
Do stakeholders have adequate (IT and technical) resources to analyse health data, to respond to data access requests, and to produce regular health reports?
Do stakeholders have sufficient and sustainable financial resources to collect health data, maintain and facilitate access to health data?
Is the country investing in Big Data and AI research and development? What programs for AI are currently ongoing?
Capacity building
1_Training availability and needs

What are the different trainings provided by the stakeholders? Are they available to external participants? In English?
Are there any organised trainings relevant for (continuous) health information skills development?
What trainings and expertise building are needed to facilitate secondary use of data?
EHDS
1_Expectations and needs
What are the views regarding cross-country/EU wide use of health data?
Is there political will/discussions ongoing regarding the future EHDS? Are there national preparations taking place?
Is it feasible, if not already done, to put in place a national contact point and health data access body/bodies (HDAB)?
What are the different expectations from the EHDS? What is the perceived added value of setting up an EHDS?
What are the needs for being able to join the future EHDS?
What concerns remain to prepare for joining the EHDS?
What services would you expect at EU level from the EHDS?