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EDAH

EUROPEAN DATA SPACE IN HEALTH

Interconnecting Innovation Ecosystems for Common European Data Space in Health

Funded by the European Union

D2.3 CASE STUDY: SWEDEN

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Contents

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History of Versions

Version	Date	Status	Page (if applicable)
V0	8-2-23	Draft circulated among partners	
V1	20-2-23	Advanced version for final revision	
V2	27-2-23	Fully revised version	
V3	28-2-23	Final version	

Disclaimer

Executive Summary

The present Deliverable 2.3 "Case Study Sweden" has been developed within the framework of WP2 "Analysis of ecosystems and innovation agendas" of **EDAH**.

EDAH (Interconnecting innovation ecosystems for common European data space in Health) is a 2-year preparatory action funded by Horizon Europe that aims to contribute to the development of the European Health Data Space. The 4-partners-consortium seeks to establish close collaborations with the EU presidencies during the project's lifetime, to help prioritise EHDA in their successive agendas. EDAH also seeks to engage a wide range of quadruple helix stakeholders from diverse innovation ecosystems across Europe in identifying barriers and enablers to EHDS, channelling the different Member States' inputs into EU policy processes. By bridging the current digital health divide in Europe, EDAH contributes to the New European Innovation Agenda with more inclusive, dynamic, diverse and interconnected European innovation ecosystems.

EDAH aims to unlock the power of health data for innovative medicines and future healthcare by helping develop the European Health Data Space.

The project's key milestones are:

1. Set an open dialogue to facilitate the agreement among Member States, Associated Countries and EU Regions about key aspects related to EHDS.
2. Advancing towards common legal, governance, data quality and interoperability framework to facilitate the advancement of EHDS.
3. Scaling up good practices and addressing important gaps in the regional and national innovation ecosystems, through a better understanding of the digital health innovation landscape.

The following report is the third of a series of 7 case studies envisaged in this project (namely Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria). The studies are connected to the EU presidencies happening during the timespan of this preparatory action, from September 2022 to August 2024, corresponding to the end of Czech Republic's, Swedish, Spanish, Belgian and the initial weeks of Hungarian Presidency.

Sweden holds the Presidency of the Council of the European Union from January 1st to June 30th, 2023. On January 19th it was announced that for this period, Sweden already started working on the proposal for a Regulation on a European Health Data Space (EUROPE B12944A11, EUROPE B13078A23).

Healthcare in Sweden is decentralised, due to the division into 21 regions and 290 municipalities with high level of autonomy. The health system performs well in general, life expectancy in the country is high and the health among the population is good.[1]

Sweden has a tax-funded healthcare system with complete coverage of the population. Regarding digitalization level, the system is characterized by a rich health data landscape with a long tradition of national registries. All residents have a personal identification number linked to individual health data.

Sweden introduced the world's first electronic prescription for outpatients and is still one of the leading countries, with more than 99% of all prescriptions being electronic[2] ; e-prescribing in Sweden is a complex, sociotechnical system integrated with other systems, such as Electronic Medical Records (EMR) and

[1] https://sweden.se/life/society/healthcare-in-sweden
[2] https://journals.sagepub.com/doi/10.1177/20552076221131139

dispensing systems at pharmacies. eHealth is an integrated part of the healthcare sector in Sweden. The regions invest around €1.15 billion annually in healthcare IT.

This report reviews some key aspects of the life sciences ecosystem and the health system in general, focussing on digital health enablers and barriers and the legislative framework of the use of health data, providing examples of good practices that can facilitate or act as references for the EHDS implementation.

In the following pages the authors gather information from primary sources about the healthcare innovation agenda of the country, the level of digitalisation, and the main legislation providing legal framework to this field.

This report has been elaborated by CEBR - Council of European Bio Regions (EDAH consortium partner, WP2 leader) and Biocat (coordinator). The public sources used are listed as footnotes. This report has been submitted to revision by local players with relevant roles in the Swedish digital health ecosystem. We thank them for their critical revision and useful comments.

The EDAH consortium intends to present the main conclusions of this report in a public event during the Swedish Presidency of the Council.

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Introduction to this report

Specific objectives of EDAH

The partnership implementing EDAH has five specific objectives:

- O1 – Ensuring a coherent overview of the (ongoing) strategic developments related to the European Health Data Space (EU level policy processes, important initiatives and projects) and developing a deeper understanding of seven important EU ecosystems (innovation agendas and ecosystem stakeholders) represented by clusters/networks from Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria.
- O2 – Setting up a coordination mechanism to connect important stakeholders from innovation ecosystems all around Europe and engage them in focused dialogue around key challenges and opportunities related to advancing the EHDS.
- O3 – Scaling up the dialogue at the EU level via developing further collaboration pathways with EU presidencies.
- O4 – All of the above will be used for, step-by-step, developing, validating and finalising the Joint Action Plan (JAP) for synergetic work in the interconnected ecosystems of EU health-related clusters/ networks (facilitated by the dialogue mechanisms and collaboration frameworks developed in this project) to jointly advance the development of the EHDS.

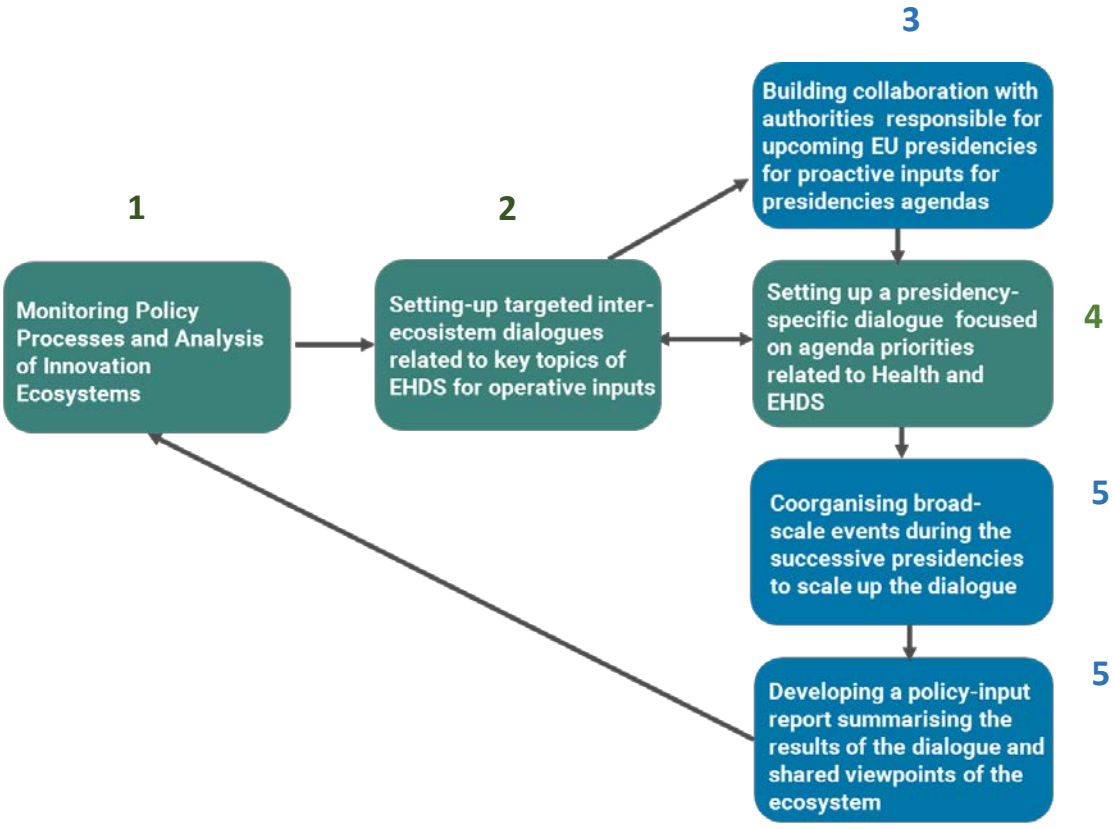


Figure 1: Workflow of the EDAH project: step 1 is the analysis of Innovation Ecosystems

List of consortium partners and beneficiary numbers

Beneficiary #	Name	Acronym	Country
1	BIOCAT LA FUNDACIO BIOREGIO DE CATALUNYA	Biocat	ES
2	HEALTH CLUSTER PORTUGAL	HCP	PT
3	SCANBALT	ScanBalt	EE
4	COUNCIL OF EUROPEAN BIOREGIONS	CEBR	BE

Work Package 2 – Analysis of ecosystems and innovation agendas

Objectives

- Monitoring and analysing strategic EU-level processes related to the development of the European Health Data Space;
- Getting in-depth understanding of seven key innovation ecosystems, namely in Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria;
- Based on the above, identifying good practices, potential for synergies and complementarities in innovation agendas and with ongoing initiatives/processes to advance the development of EHDS as a joint effort of EU interconnected innovation ecosystems.

Task 2.1 Scanning strategic developments regarding European Health Data Space

The consortium will continuously track advancements in various important EU-level policy processes, monitor progress related to initiatives such as TEHDAS and GAIA-X (e.g., key milestones achieved), relevant new studies and analyses, etc. This information will be processed and analysed to identify potential synergies, needs for action and inputs by EDAH to support important developments in line with the idea of more dynamic, inclusive, gender diverse, and connected innovation ecosystems for the joint development of the European Health Data Space, fostering innovation in industry and the public sector.

The work under this task will materialise into monthly Strategic Progress Updates (SPUs) prepared for the monthly EDAH Coordination Working Group meetings. The SPUs will cover the key developments as well as suggestions for related response and actions in the context of the EDAH project.

Task 2.2 Carrying out case studies

Case studies on seven key EU clusters/networks/ecosystems will be carried out in order to 1) facilitate learning from various good practices of strong EU clusters/networks in advancing digital health and related innovation in their regions/ countries as well as good practices related to quadruple helix collaboration; 2) reach a better understanding of the ecosystems and innovation agendas of these clusters/networks; 3) five case studies will additionally focus on the possibilities of advancing specific topics related to the EHDS in the context of the upcoming EU presidency in the clusters´/networks´ country of origin. The clusters/networks selected for case studies represent Portugal, Czech Republic, Sweden, Spain, Hungary, Belgium (the five upcoming EU presidency countries), and Bulgaria (as an example of current Modest Innovator region, to get insights about key needs for development in terms of digital health and related ecosystem in such context).

1 – Swedish Ecosystem Overview

1.1 Country overview

Sweden is a large country in Northern Europe, fifth in geographical area among European countries, located on the Scandinavian peninsula. It has over 10.2 million inhabitants and is divided into 21 counties (NUTS3, 2021), usually grouped into 3 regions: Norrland, the mountain and forest region in the north; Svealand, the lowland and highland region in the center; and Götaland, the southern region with the Småland highlands and Skåne plains. The capital is Stockholm, largest city of Sweden and largest urban area in Scandinavia: approximately 2.4 million people live in its metropolitan area.

Sweden is a constitutional monarchy with a parliamentary democracy and a stable political and social environment. It ranks highly for democracy, political and civil rights, and freedom of expression and is the top European performer in research and innovation. According to the 2022 European Innovation scoreboard[3], the Swedish innovation system ranks n.1 in Europe and since 2015 it occupies one of the top 2 positions. This is largely due to the performances of Stockholm region: ranked #3 European Regional Innovation scoreboard in 2015 and 2017, it reached #2 in 2019 and is now ranked #1 since 2021.

According to the International Monetary Fund (2022)[4], it is the 25th richest country in the world in terms of nominal GDP, with a high standard of living (17th in the world by GDP per capita).

Due to the size of the internal market, Sweden is an export-oriented economy, relying on traditional resources such as timber, hydropower, and iron ore, and with a strong engineering sector, telecommunications, automotive industry, and pharmaceutical industries.

Life sciences are rapidly growing, with a high degree of innovation, with pharmaceutical exports which have seen an increase of 60% in 10 years, becoming the second largest exported item, valued at 100 billion SEK (€8.8 billion) and a positive trade net of 47 billion SEK (€4.16 billion), according to Statistics Sweden. The government considers the life science sector important for Sweden's development and has made it a priority since 2014.

1.2 - Health system

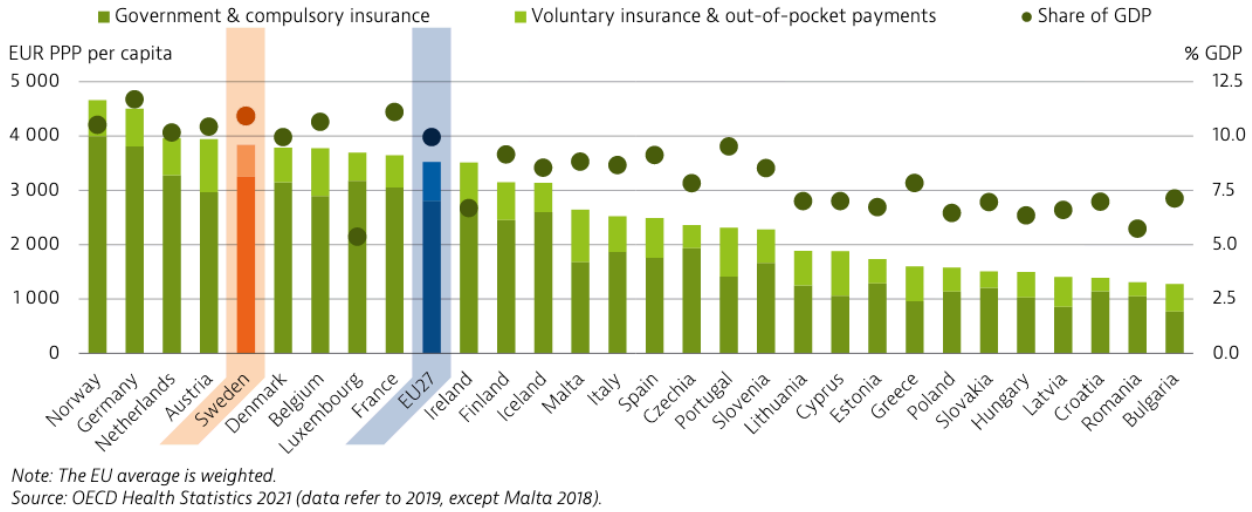
According to the OECD Sweden Country Health Profile 2021[5], Sweden's life expectancy is one of the highest in the EU but decreased by nearly a year in 2020 due to the COVID-19 pandemic. Although the health care system provides good access to quality care, there are still some challenges in achieving equal access across regions, timely care, improved coordination for those with chronic diseases, and better long-term care.

The Swedish health system is decentralized, covering all residents, and while the national government is responsible for regulation and supervision, the 21 counties are responsible for financing (through local taxation), purchasing and providing health services, in particular primary, specialist, and psychiatric care. In parallel, the 290 municipalities handle care for the disabled, rehabilitation, home care, social care for children and adults, elderly care, and school health care. On top of this, the national government is funding specific programmes e.g., for creating incentives for improving healthcare availability.

[3] https://ec.europa.eu/research-and-innovation/en/statistics/performance-indicators/european-innovation-scoreboard/eis
[4] https://www.imf.org/en/Countries/SWE
[5] https://www.oecd-ilibrary.org/social-issues-migration-health/sweden-country-health-profile-2021_b9027e42-en

Private healthcare can be reimbursed by the county (as for primary care) or it can be handled through a 'private-to-private' relationship, i.e., fully paid by the patient, directly or through an additional voluntary private insurance.

The same OECD report states that in 2019 Sweden's health and social care expenditure was 10.9% of GDP, which was the third highest among EU countries, and well above the EU average of 9.9%. With an adjusted spending of €3,837 per person in 2019, Sweden ranked fourth in EU health spending per capita. 85% of total health spending is publicly funded, higher than the EU average of 80%, while the remaining 14% is paid by households and only 1% is through voluntary health insurance. Despite this, the number of people with private insurance coverage has increased over the past 20 years as it provides quicker access to private medical care.



Note: The EU average is weighted.
Source: OECD Health Statistics 2021 (data refer to 2019, except Malta 2018).

Figure 2 – Health spending in the EU27 and the position of Sweden. Source: OECD/European Observatory on Health Systems and Policies (2021), Sweden: Country Health Profile 2021, State of Health in the EU, OECD Publishing, Paris, https://doi.org/10.1787/b9027e42-en.

1.3 - Life sciences ecosystem

Sweden's life sciences industry employs over 40,000 individuals in more than 1,000 firms, according to Business Sweden (2022) and one in five researchers in the country is working in this field.

Companies are mainly concentrated in clusters located in Stockholm/Uppsala, Gothenburg, the Skåne region, Umeå, and Karlskoga-Örebro. Several well-known companies with Swedish origins, such as AstraZeneca, Elekta, Getinge, and Sobi, are prominent examples. Besides these, several international players, including Pfizer, Philips, Johnson & Johnson, and GE Healthcare, have also joined the efforts to enhance healthcare delivery and patient care in Sweden and around the world.

A dynamic ecosystem of scientists, experienced entrepreneurs, and business investors fuels the emergence of new life sciences start-ups each year. Sweden's success as a leader in the life sciences is driven by collaboration, with a long history of successful partnerships between healthcare providers, businesses, academia, and researchers. This results in a direct advantage from cross-disciplinary cooperation, with a smaller gap between research and practical applications. Collaboration takes various forms, including at national research centers, science parks, start-ups, and large corporations. Living labs, where the public partners with other innovation stakeholders, is another example, creating a "quadruple helix" system that includes government, industry, academia, and civil society. A critical aspect of Sweden's research strategy

is the Strategic Innovation Programs (SIPs), which bring together both public and private R&D initiatives. Additionally, the presence of high-quality healthcare data is another essential factor that contributes to creating a conducive research environment.

In addition to excelling in basic and applied research (neuroscience, oncology, metabolic and inflammatory diseases, as well as proteomics, genomics, and diagnostics being the most prominent areas), Sweden has emerged as a global leader in the digitalization, automation, and sustainability of both R&D and production processes. Sweden's unparalleled expertise extends to drug development, biotech tools, diagnostics, MedTech, and digital healthcare solutions. The country also leads the way in biomaterials, orthopaedic implants, regenerative medicine, medical imaging, and visualization.

Universities

Swedish Universities are engaged in cutting-edge research and innovation in various fields, as well as investing in partnerships and centers to address societal challenges and advance scientific knowledge. Here is a selection of those particularly active in the fields of interest for this report:

Karolinska Institutet in Stockholm is ranked as one of Europe's, and in some subject categories, the world's leading medical universities. Research at Karolinska Institutet spans the entire medical field, from basic experimental research to patient-oriented and nursing research. It represents Sweden's single largest centre of medical academic research and offers the country's widest range of medical courses and programmes. It is co-located with several other institutions, such as Karolinska University Hospital, Danderyd Hospital, Stockholm South General (Söder) Hospital, the Public Health Agency of Sweden, parts of the Royal Institute of Technology (KTH) and the shared research infrastructure of SciLifeLab (Science for Life Laboratory). It is also responsible for selecting the annual Nobel laureates in physiology or medicine through its members in the Nobel Assembly.

Lund University, founded in 1666, is ranked among the world's top 100 universities. It has 42,000 students and over 7,000 staff and is also known for its world leading research facilities, such as MAX IV and ESS. MAX IV was launched in June 2016 and holds the top spot as the leading synchrotron radiation facility worldwide. ESS, which stands for European Spallation Source, is expected to become the world's most potent neutron source once it opens in 2023. The region's research, innovation, and entrepreneurship are closely interwoven with Lund University through Ideon Science Park, Medicon Village, and Science Village Scandinavia.

Uppsala University is another renowned institution, the oldest still active University in Sweden. It is connected with the Uppsala Academic Hospital, which functions as a teaching hospital for the Faculty of Medicine and the Nursing School. Life sciences have a rich history of research in Uppsala: for example, the Science for Life Laboratory (SciLifeLab) provides advanced technical resources to map human and animal genomes and investigate the underlying causes of diseases. The University is also strong in the development of future antibiotics. Its over 52,000 students are supported by over 4.000 academic and over 2,000 administrative staff.

Umeå University, located in northern Sweden, is renowned for its strong tradition in genetics, molecular biology, and neurology, as well as in global health, infection biology, aging research, diabetes cure, and prostate cancer. It hosts over 36,000 students and can count on more than 4,000 staff. The University hospital hosts one of the seven schools for medicine and dental medicine in Sweden.

Linköping University is the base for the Wallenberg AI, Autonomous Systems and Software Program, a major national initiative focused on AI and autonomous systems, aimed at creating intelligent systems-of-systems

that can act in collaboration with humans and adapt to their environment through sensors, knowledge, and information.

Sahlgrenska Academy, the University of Gothenburg's faculty of education and research in health sciences, operates in connection with the University hospital; is known for its activity in cancer treatment and its cutting-edge research, including the world's first successful uterus transplant.

Faculty of Medicine and Health – Örebro university, operating in close connection with the Örebro University Hospital became the 7th medical school in Sweden in 2010. Nowadays the faculty has two schools, the School of Medical Sciences and the School of Health Sciences, covering a broad range of disciplines in medicine, healthcare, sport science and disability science.

FUHS (University Holdings in Sweden) was founded in 2005 and has all 18 Swedish university holding companies as members. The holding companies, with innovation offices, incubators, and science parks, play an important role in commercializing university research, leveraging innovation, and providing early-stage funding as institutional investors. FUHS is a non-profit association based in Solna.

Other Research facilities and infrastructures

Sweden boasts top-notch universities in medical research and is actively enhancing its clinical study infrastructure through collaboration among healthcare providers, researchers, and businesses, with the patient's best interest in mind.

Clinical Studies Sweden is a partnership between the Swedish Research Council and the country's healthcare regions, which aims to establish a national research infrastructure to improve conditions for conducting clinical studies. This coordination allows for more efficient studies, with patients being able to participate from any location in the country.

SciLifeLab – Science for Life Laboratories, is a national center for molecular biosciences with a focus on health and the environment. As a joint effort between Karolinska Institutet, KTH Royal Institute of Technology, Stockholm University and Uppsala University, it is affiliated with over 150 research groups and provides nationwide access to advanced technologies and information. SciLifeLab collaborates with health and medical services, authorities, and businesses to apply research results in society, resulting in new clinical methodologies, drugs, and a better environment.

The Human Protein Atlas (HPA) project aims to map all human proteins in cells, tissue, and organs using advanced biomolecular methods. In 2014, the first full version of the protein atlas database was launched, containing information from analyses of over 25,000 antibodies that can identify around 17,000 human proteins. This data is freely accessible to all researchers, both from academia and industry, and serves as a crucial tool for research and healthcare advancement. In addition, large-scale projects under the umbrella of Personalized Medicine are underway, aimed at diagnosing, treating, and curing patients based on their unique conditions.

Genomic Medicine Sweden (GMS) uses advanced sequencing technology to analyze genomes in clinical practice for diagnosing rare hereditary diseases and cancer. GMS aims to make these diagnostic tools widely accessible by establishing regional centers, in collaboration with universities and university hospitals across the country.

Innovation hubs

The increase in start-ups is largely due to global companies opening up their innovation processes to collaboration with smaller firms, academia, and healthcare sector to benefit from the digitalization of

health and life sciences. This is facilitated by a growing number of innovation hubs where information is shared, complementing traditional incubators that focus on commercializing research. These hubs provide a favourable environment for creating businesses, from developing ideas to establishing a knowledge-intensive company. They usually offer office spaces, access to customers and investors, and partnerships with support service providers. Innovation hubs are more business-oriented compared to incubators, which are typically associated with universities and research institutes. These collaborative environments provide an opportunity for researchers or entrepreneurs to turn their findings or technologies into marketable innovations. There are over 65 innovation hubs in Sweden, with some specifically focused on life sciences.

The Swedish industry association for incubators and science parks, SISP, has 65 members nationwide, representing over 5,000 companies and 70,000 employees. Here is a list of the members and their geographical localisation.

Alfred Nobel Science Park
Arctic Business Incubator
Atrinova Affärsutveckling
Bizmaker
Blekinge Business Incubator
Blue Science Park
Boden Business Park
Borås Inkubator
Brewhouse
Chalmers Ventures
Create Business Incubator
Dalarna Science Park
DigitalWell Ventures
eXpression Umeå
Faxe Park
Flemingsberg Science
Founders Loft
Företagsfabriken i Kronoberg
GU Ventures
Gävle INNOVATION HUB
HighFive
Ideon Innovation
Ideon Science Park
Inkubera
Innovation Skåne
Innovatum Science Park
Johanneberg Science Park
Kalmar Science Park
Karlstad Innovation Park
KI Innovations AB
KI Science Park
Kista Science City
Krinova Incubator and Science Park
LEAD
Lindholmen Science Park
Linköping Science Park
LTU Business
Luleå Science Park
Medeon Science Park
Medicon Village
MINC
Movexum
Netport Science Park
Norrköping Science Park
Peak Region Science Park
Piteå Science Park
Sahlgrenska Science Park
Sandbacka Science Park
Science Park Borås
Science Park Gotland
Science Park Jönköping
Science Park Skövde
Skellefteå Science City
SSE Business Lab
Södertälje Science Park
Sting
Sting Bioeconomy
SU Inkubator
Things
Umeå Biotech Incubator
Umeå Science Park
Uminova Innovation
Uppsala Innovation Centre
Växjö Linnæus Science Park

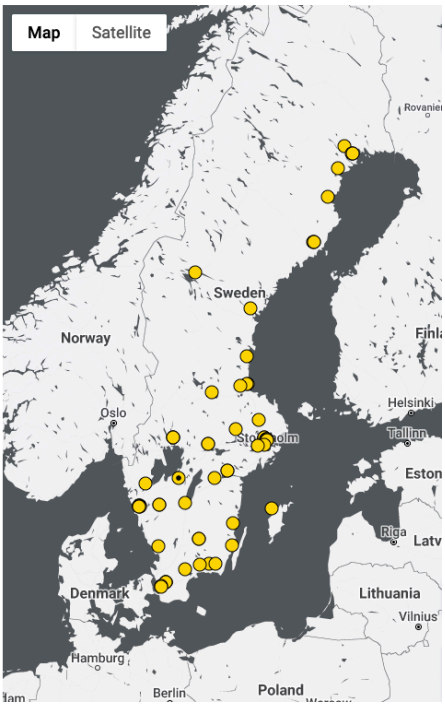


Figure 3 – List of SISP members and their distribution across the country (source: SISP official website)

Medicon Village in Lund is a life sciences research village that houses private enterprises, supportive innovation, and academic research, primarily Lund University's cancer unit. It brings together researchers, innovators, business people, and other experts to collaborate and exchange ideas. The village encompasses all aspects of the healthcare industry, from prevention to diagnostics, treatment, and care, creating a value chain that takes ideas to finished products or services.

The Stockholm–Uppsala region is Sweden's largest life science cluster. It includes half the business community in life sciences, five universities and health and medical care for almost three million people. Particularly in Uppsala, life science has become the Uppsala region's largest growth industry.

STUNS Life Science, in Uppsala (Foundation for collaboration between the universities, business and society), focuses on the development of talent, digital skills and sustainable growth of the ecosystem.

Testa Center is a private-public initiative between the Swedish government and Cytiva to secure the life science industry's growth and manufacturing capabilities. Supported, among others, by Vinnova (Swedish Innovation Agency), STUNS Life Sciences ERDF funds, this initiative is a testbed for biological production, offering infrastructure for the verification and validation of large-scale production processes. Testa Center is operated as a non-profit company and is fully owned by Cytiva (formerly GE Healthcare Life Sciences).

Sahlgrenska Science Park in Gothenburg brings together life sciences participants and a large network within the business sector to deliver expert knowledge and experience based on commercial viability. The idea is to use collaboration between companies, the healthcare sector, the University of Gothenburg and Chalmers University of Technology to strengthen the competitiveness of life sciences and to develop start-ups.

BioVentureHub offers infrastructure for medical and biotech companies and academic research groups to work in proximity and collaborate on different projects. It gives ambitious young companies the opportunity to take advantage of expertise and infrastructure previously only available to established companies. BioVentureHub, located in the heart of Astra Zeneca's research facility outside Gothenburg, acts as a nursery for research companies within the pharmaceuticals and medical technology sectors. Companies gain access to research resources, expertise and an international research environment.

Health data and biological samples

Swedish personal registration system: every Swede has a unique ID number since 1947 that links their data across archives and records. The ID is used for communication with authorities and healthcare documentation. The registries serve as hubs for healthcare knowledge to aid development, follow-up, and research. The registries allow the government to monitor, analyse, and report on health and social conditions and provide researchers with access to data. The National Board of Health and Welfare manages several national health data registries based on mandatory regulations. In addition, there are high-quality databases based on voluntary participation at the regional and county level. The personal identification system streamlines the transfer of experimental research to clinics and speeds up epidemiological studies to identify links between illness and health risk factors. These studies are conducted by analysing data from sources such as biobanks, health data registries, and diagnostic quality registries.

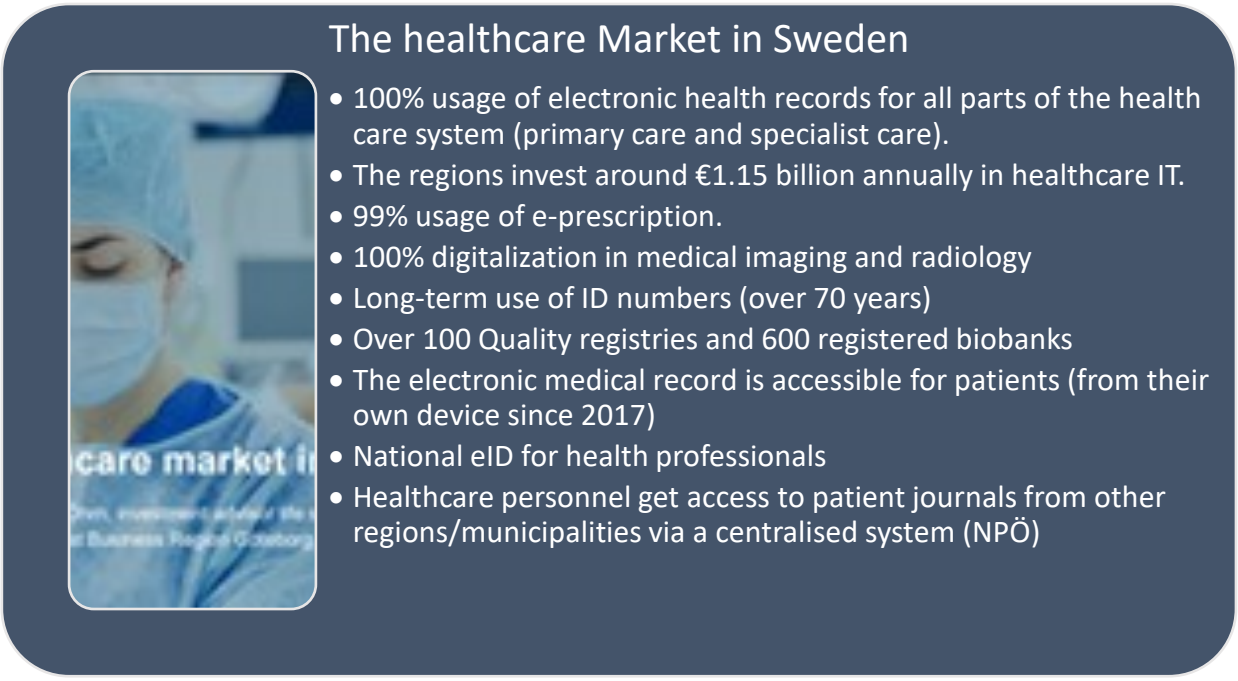
Biobank Sweden is a unique resource containing over 150 million tissue samples and their accompanying healthcare data, with 95% of the samples collected for diagnosis. Healthcare centers and hospitals also collect samples for research purposes, such as registry analysis and clinical trials. This resource is highly valued and is being utilized to its fullest potential through cooperation between academia, the healthcare sector, and businesses both nationally and internationally. Improving the biobanking infrastructure and increasing access to samples and linked data is a priority. The utilization of biological samples in biobanks for research, screening, and treatment is vital for the advancement of healthcare.

The Analytic Imaging Diagnostics Arena (AIDA) is a national arena that focuses on using AI for medical image analysis. AI has great potential to improve healthcare quality and efficiency, particularly in image diagnostics such as radiology and pathology. AIDA brings together academia, healthcare, and industry to translate AI advancements into benefits for patients.

Healthcare IT: key facts and some examples of companies

"Invest in Gothenburg 2022"[6] highlights the following elements about healthcare IT sector in Sweden:

[6] https://www.investingothenburg.com/sites/investingothenburg/files/downloadable_files/the-healthcare-market-in-sweden-2022.pdf



Source: The healthcare market in Sweden - Invest in Gothenburg (Iris Öhrn, 2022)

These facts provide to the country a quite unique positioning in the European landscape. This situation is also reflected in the type of existing companies. Here we list a few examples:

Aleris: provides private healthcare services, including diagnostic imaging and laboratory services, they also have a digital platform that enables patients to schedule appointments, view test results, and communicate with their healthcare providers.

Coala Life is a Swedish medical technology company active in smartphone and cloud-based heart and lung diagnostics.

Elekta AB: provides solutions and services for the treatment of cancer and brain disorders, with advanced software and technology for radiation therapy planning and delivery.

Getinge: develops and sells products and services for the healthcare and life sciences sectors, including infection control and surgical equipment, they also have a digital solution to optimize the use of their products.

Medivir: develops and markets drugs for the treatment of cancer and other diseases and also has a digital solution for patient management, drug administration and clinical data collection.

Mölnlycke Health Care: is a global provider of single-use surgical and wound care solutions, they also have a digital solution to optimize the process of wound management.

Next Step Dynamics is a provider of solutions related to fall prevention (assessment, care, cooperation and monitoring) aimed at caregivers and care organisations.

Sectra: specializes in enterprise imaging solutions for healthcare providers, including software for managing and sharing medical images, in addition, their platform enables the integration of data from various sources and the use of artificial intelligence to support diagnosis and treatment.

TietoEVRY: provides a wide range of IT services and solutions for the healthcare industry, including electronic health records, telemedicine, and health data analytics.

Visiba Care developed a virtual care platform, aimed at making healthcare more accessible by enabling patients to easily and securely communicate with healthcare professionals online.

In addition, it is worth to mention that the four largest existing online consultation companies (Kry, Min Doktor, Doktor 24 and Doktor.se) own 87% of the market. Market which has strongly grown and represented – already in 2020, so before the full development of the pandemic - nearly 11% of all the primary care consultations and 2% of the total primary care costs (source: Invest in Gothenburg 2022).

An overview of the digital health companies' landscape has been compiled by MSC Nordics (https://mscnordics.com/), a strategy and consulting company specialised in Nordics life sciences. Here we include a snapshot of the map, which can be fully consulted at MCS Nordics website, where the selection criteria are also explained.

Figure n.4 – The Swedish digital health companies map by MSC Nordics (2022) https://mscnordics.com/swedish-digital-health-2022-unique-list-of-promising-companies/

2 – Existing legal framework

The Swedish law does not define the concept "digital health", but rather the eHealth definition: "*the use of digital tools and the digital exchange of information to achieve and maintain health*"

The core regulatory framework for eHealth in Sweden (mostly only in Swedish) is:

- Patient Data Act (SFS 2008:355): regulates how personal data may be processed within the healthcare sector. It allows healthcare providers to process sensitive personal data for treatment, follow-up, quality assurance, administration, and planning without patient consent. However, sharing of patient data between care providers requires the patient's consent. The Act also regulates internal confidentiality within healthcare organizations, granting access to patient data only to those who need it for care or work purposes. The Act prohibits collecting and handling personal data from multiple healthcare providers, except in regional or national quality registries subject to specific regulation. A municipality or region may process data for follow-up and quality assurance, but only from its own organizations, and it does not allow access to data from private contractors, even if funded by the municipality or region. The Patient Data Act regulates secondary use of personal data, such as in regional or national quality registers. Patients have the right to receive information about the registration and opt-out. Quality registers may handle health information, including genetic information, as it is considered part of a patient's health status for quality assurance purposes, not as separate or deviant.
- Patient Data Regulation (SFS 2008:360): regulation that applies to processing of personal data within health and medical care that is fully or partially automated and that is regulated by the Patient Data Act (2008:355).
- The National Board of health and Welfare's regulations and general guidelines concerning patient records and processing personal data within healthcare (HSLF-FS 2016:40)
- The National Board of health and Welfare's regulations and general guidelines concerning management system for systematic quality work (SOSFS 2011:9)
- The National Board of health and Welfare's regulation on the use of medical devices in healthcare (HSLF-FS 2021:52)

Other regulatory schemes applying in terms of data privacy and security are

- The General Data Protection Regulation (EU 2016/679) (GDPR)

  The handling of personal health data is strictly regulated in Sweden due to its classification as sensitive information. The GDPR requires that personal data be collected for specific, clearly stated, and justified purposes, with the amount kept to a minimum. Only necessary data for the purpose may be processed, and it must be deleted once no longer needed. Protection of the data from unauthorized access is also required. The purpose for collecting and handling personal data must be explicitly stated, and broad terms such as "future research" or "improving user experience" are not acceptable. Some personal data is classified as sensitive, including information about ethnicity, political views, religion, and union membership, as well as health, genetic, and biometric data. Processing sensitive personal data is generally prohibited, but can be done under certain conditions, such as with explicit consent or in specific circumstances like health care, social care, statistics, research, and important public interest.
- The Swedish Act with Supplementary Provisions to the EU's Data Protection Regulation (SFS 2018:218)

Additionally, other regulatory schemes apply to consumer devices:

- The Medical Device Regulation 2017/745 and supplementary regulations.
- Consumer Purchase Act (SFS 1990:932).
- E-commerce legislation such as the Distance and Doorstep Sales Act (2005:59).

Some organisations have a key role in the Healthcare system organisation:

- Besides managing several different registers in the healthcare area, the **National Board of Health and Welfare** produces and develops standards, statistics, regulations and knowledge for the government and for those working in healthcare and social services.
- The **Medical Products Agency (MPA)** regulates and surveys the development, manufacturing and marketing of drugs and other medicinal products and also assumes the responsibility for market surveillance related to medical devices. The MPA issues directives with the support of legislation.
- The **Health and Social Care Inspectorate** supervises health and social care, healthcare and social care staff, social services and activities in accordance with certain acts.
- The **Data Protection Authority** works to prevent encroachment upon privacy through information and by issuing directives and codes of statutes. The authority also handles complaints and carries out inspections.
- The **Consumer Agency** safeguards consumer interests and is among other things the regulatory authority for the Product Safety Act. The Agency may require companies to comment on notifications against their goods and report on how they have ensured that the applicable security requirements are met The Agency shares responsibility with other authorities that oversee specific goods or risks.
- The **Swedish eHealth Agency** is the data controller and data processor for several registries and databases that link healthcare, pharmacies, and patients. The eHealth Agency facilitates the work of healthcare and create the conditions for better health.

It's worth mentioning that there are specific regulations that apply to the use of software as a medical device for clinical use. First, it must comply with the EU Medical Device Regulation 2017/745 (MDR) that became applicable on 26 May 2021 (it might benefit from the transitional provisions). In order to be placed on the European market, the software must of course be CE-marked, which may require approval by a notified body.

Products incorporating the use of AI or machine learning need to comply with general product legislation as applicable to the product in question. See the table below for core issues applying to eHealth Technologies in Sweden.

Core issues regarding digital health technologies

Telemedicine/virtual care	Integrity and data security issues. All medical data regarding a patient must be kept confidential and leaks or losses of data may result in fines, damages and potential bad will
Robotics	A core issue is foreseeing liability under mandatory legislation and proving the cause of damage.
Wearables	Integrity and data security issues, e.g., theft or loss of personal data, potentially sensitive personal data

Software as a Medical Device	Under the MDR more stringent rules apply. Most medical device software is furthermore up-classified under the MDR.
AI/ML powered digital health solutions	Risk of bias. Security issues, e.g., data storage and access to data as well as data transit to servers, must be secured to ensure the data is not improperly accessed, shared or tampered with. The GDPR also prohibits transfer of data to countries outside the EU/EEA unless certain requirements are met. Issues relating to liability in terms of recommendations or advice given by AI is an ongoing debate and will most likely be important when algorithms assist in healthcare.
IoT and Connected Devices	Integrity and data security issues, e.g., hackers' intrusion in networks in smart homes taking control of devices and theft of personal data. Data generated through the use of internet of things (IoT) is almost always personal data, which means that specific rules apply, notably the GDPR.
3D Printing/Bioprinting	This technology is not well developed in Sweden, hence there are little or no guidelines regarding its use. Liability in terms of malfunctioning prosthetics or procedures involving 3D-printed or bio-printed objects that lead to complications are issues that could arise. Furthermore, issues related to ethics, personal data and product safety are debated.
Digital Therapeutics	GDPR and more stringent rules imposed under the MDR.
Natural Language Processing	Training data may be limited as Swedish is a language which is spoken by a small population. Training data may be protected by copyright and/or contain personal data and may therefore not be used without appropriate consent/permission.

Figure 5 – Synopsis of the main issues related to digital health technologies. Source: https://iclg.com/practice-areas/digital-health-laws-and-regulations/sweden

2.1 - Primary use (for provision of health and social care by health and care providers to the patient)

National Patient Summary

For several years, Patient Summaries have been in use in the Swedish healthcare system, particularly in local regions and municipalities through the Nationell patientöversikt (NPÖ), which is the national patient overview service.

First introduced in 2014, the NPÖ enables healthcare providers to access and share medical record information (current medications, allergies, ongoing treatment, and diagnoses etc.) across different care providers' organizational boundaries and systems, utilizing a centralised national service platform.

The content of a Patient Summary and its full implementation may vary since each healthcare provider has the option to decide whether to provide information via the service platform and the provider has the discretion to determine the level of information they wish to share.

In any case, for what attains the primary use of health data, electronic prescriptions, electronic dispensations, medical images and medical reports, laboratory results as well as discharge reports are already digitalised.

2.2 - Secondary use (for planning, management health systems improvement)

The NPÖ has several benefits for patients, including improved quality of care, reduced risk of medical errors, and faster and more efficient healthcare services. By providing healthcare professionals with a

comprehensive summary of a patient's medical history, the NPS can help to ensure that patients receive the right treatment at the right time.

2.3 - Secondary use (for scientific or historical research by both public and private sector organisations)

In Sweden the general provisions of the GDPR are applied to the processing of health data for research. The legal implementation of GDPR Article 9.2 permitting the processing of special categories of data for scientific research is provided in the complementary Data Protection Act (lag 2018:218). Ethical review is required for all processing of special categories of data for scientific research regardless of whether the processing is based on consent or not.

The Register Utiliser Tool (RUT), is the web-based metadata tool developed by the Swedish Research Council. The aim of RUT is to optimize data usage in research and function as a national portal for register data sources. RUT is set up for researchers to find metadata from Swedish national registers, as well as biobank sample collections and other major research databases.. The Swedish Research Council manages the RUT.

The NBHW also has its own metadata catalogue for the national health registries they maintain

In general, both national and international researchers can get access to aggregated data in the same way. For individual level data, researcher must first acquire Swedish ethical approval prior to applying for the data holders' approval to access. International researchers can only get ethical approval if collaborating with a Swedish partner. For accessing biobanks samples and genomics data, researchers need to apply to each data holder separately, and need patient consent and ethical approval.

2.4 - Legal or regulatory mechanisms which address the use of health data for research purposes

The Ethical Review Act governs the use of health data in research and applies to research on humans and human biological material, both physically and through sensitive personal data. To conduct registry studies, approval is required from the Ethical Review Board (Ethical Review Board since 2019), sometimes without consent from individuals included in the study. However, research can be conducted on anonymized data without approval if the data is completely de-identified, meaning identification is impossible through other data or encryption. Disclosing data for research also requires the organization issuing the data to assess the risks involved in accordance with the Public Access to Information and Secrecy Act. This assessment determines if the data can be disclosed without risk to security or harm to the individual or those close to them.

Under Section 5 of the Act (2003:460) concerning the Ethical Review of Research Involving Humans (the Ethical Review Act), ethical review is only applicable on research conducted in Sweden. The Ethical Review Act thus has a narrower territorial scope than the complementary Data Protection Act and GDPR.

Currently, the government is reviewing the regulations for secondary use of health data to assess how they function in practice and how they may be updated in order to be useful towards, e.g. precision medicine applications. The results of this activity are due in September 2023.

2.5 - Patients' rights

Citizens can control 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.

The rules governing processing of personal data within health and medical care can be found in the Patient Data Act (2008:355), which is applied by all care providers, both public and private. As the GDPR is directly applicable as Swedish law, care providers must thus apply the GDPR and the complementary Data Protection Act and Patient Data Act if these are compatible with the GDPR. In health and medical care there are national and regional quality registers that are used to develop and secure the quality of care systematically and on a continuous basis.

The legal basis for processing personal data in quality registers lies in the Patient Data Act which contains provisions to the effect that the patient has the right to be given information about the registration, the right not to be registered in a quality register (opt-out), and the right to subsequently be erased from the register. If the patient opposes the processing of personal data after the care has already begun, data must be erased from the register as soon as possible. Data from quality registers may be processed for research purposes.

The Freedom of the Press Act (1949:105) and the Public and Secrecy Act (2009:400) govern whether and how information from official registers in Sweden may be disclosed. Secrecy applies to the specific activities of authorities that produce statistics for the data relating to an individual's personal or financial circumstances and that can be attributed to the individual. Data used for research and statistical purposes and information that is not by name or similar directly attributable to the individual may be disclosed if it is clear that the information can be disclosed without damage or harm for the individual or any related party.

Secrecy in the health and medical care sector applies to information about an individual's health status or other personal circumstances, unless it is clear that the information can be disclosed without harm to the individual or any related party. Secrecy does not prevent an authority that conducts health services from providing information to another such authority for research, if it is clear that the information can be disclosed without harm to the individual or any related party. The secrecy may be waived by the individual for research purposes.

Each authority is to decide independently whether a disclosure of information can be made in accordance with applicable legislation. If an authority has rejected a request to obtain a document or if it has supplied an official document subject to a reservation, the applicant is generally entitled to appeal the decision.

2.6 - Electronic Health Records (Journalen) and technical standards

Sweden has a national system for electronic health records that is used to collect and share health data across the country. Additionally, each region can choose the EHR system to be used. The National Board of Health and Welfare (NBHW) maintains the six national health registries with individual level health data. Medical records (which are in electronic format) are available for the patient through "Journalen". However, these data can be very scattered, and not easily shared between healthcare providers. This system has been in place since the early 2000s and is widely used by healthcare providers in Sweden. Journalen contains information such as diagnoses, test results, prescribed medications, and care plans, and patients can access their information through the portal 1177.se. Patients can use the tool to monitor their health and communicate more effectively with their healthcare providers. Patients can also grant healthcare providers access to their Journalen, which can help providers make more informed decisions about a patient's care. The system is designed to increase patient engagement and promote patient-centered care. Journalen has been shown to improve patient safety by reducing the risk of medical errors.

To access Journalen, patients must have a Swedish personal identity number, a mobile BankID (which is Sweden's main eID) and a computer or smartphone. The system is free to use, and patients can choose which information they want to share with healthcare providers. Overall, patient accessible electronic health

records are an important aspect of Sweden's eHealth strategy, and Journalen has been well-received by both patients and healthcare providers.

2.7 – The Swedish eHealth Agency

The Swedish eHealth Agency is a government agency that works to digitalise and improve the sharing of information between patients, the healthcare system and pharmacies in Sweden.

It offers a number of e-health services and digital solutions for individuals as well as staff working in healthcare and social services. The e-prescription service and the Covid certificates service are the most well-known. The Swedish eHealth Agency has many responsibilities. Here are some examples:

- National contact point for eHealth (NCP) and Digital Health Authority
- Competent Authority in EHDS preparatory EU projects such as X-eHealth (primary use of health data), and Joint Action TEHDAS (secondary use of health data).
- It carries out the government's e-health initiatives.
- It stores digital prescriptions from doctors and forwards them to pharmacies.
- It offers a Medicine Check service that allows the citizens to view information about their prescriptions and if they are eligible for the high-cost protection card, which allow to receive medicines free of charge for a set period of time
- It collects information about the quantities of and which medicines have been sold in Sweden.
- It offers the Electronic Expert Support service to help pharmacies check whether your prescription medicines work together.

The Swedish eHealth Agency coordinates the government's e-health initiatives and monitors developments in the e-health field, both nationally and internationally. It is also responsible for registers and IT services used by individuals, healthcare providers and pharmacies.

3 – Innovation agenda in the field

3.1 – The national "Strategy for eHealth"

The strategy related to health data in Sweden is included in a series of clearly identifiable documents. The first one entitled "Strategy for eHealth" has been issued in 2016 as part of the national initiative called "Vision eHealth 2025"[7].

The document defines the new national vision on the topic, replacing the previous strategy issued in 2010 and is completed by a series of action plans, more concrete and more detailed, the last available of which covers the period 2020-2022.

The most important part of the document is the statement about the strategic vision for 2025, which reads as follows:

"In 2025, Sweden will be best in the world at using the opportunities offered by digitalisation and eHealth to make it easier for people to achieve good and equal health and welfare, and to develop and strengthen their own resources for increased independence and participation in the life of society"

[7] https://ehalsa2025.se/english/

The document acknowledges different fundamental principles such as equality, gender perspective, efficiency, accessibility, usability, digital participation, privacy, and information security. The 2010 eHealth strategy targets individuals, healthcare staff, decision-makers, and children/youth, with a focus on the first two groups. The strategy also recognizes the potential contribution of private, non-profit and research communities in giving the vision concrete form. It states that the digitization should support equal access and tailoring services to individual needs, with a gender perspective and protecting personal privacy. The goal is efficient and sustainable healthcare and social services, with universal accessibility and usability.

The vision of digitization and eHealth is to improve people's health and welfare through the use of technology. This involves utilizing IT support to activate users' own resources and improve health and participation. The digitization also improves access to information, support, and health care, and makes it easier for families to participate. To fulfil the vision, there must be adequate support for staff and a supportive digital working environment. Digitization can create new career paths and a better working environment for those in the services. The necessary conditions must be created for social services and health care to fully utilize digitization, and skills in IT systems must exist at all levels. Sweden's strong IT sector and the potential of the life science sector should be considered. The business sector can also contribute by developing services and identifying new business opportunities. E-Health is a high priority globally and has been identified as a strong area of growth in Europe, with Sweden playing a preeminent role.

In the implementation plans four objectives and three fundamental conditions have been identified, as explained in the following picture.

Figure n.6 – The three levels of the strategy (source: "Vision for ehealth 2025)

Objective n.1 – The individual as co-creator

There is a clear need for patients, users, and their families to be thoroughly informed and able to actively participate in the healthcare and social services they receive. These services should be provided in a variety of ways to accommodate people's different needs, circumstances, and preferences. The use of digital support can allow for greater involvement and break down existing barriers within the system. In 2020-2022, the parties focused on initiatives that provide greater security, participation, and independence for individuals using digital services and improved infrastructure and basic services in healthcare. In particular:

- Digital services to increase security and independence
- Digital services that make provision accessible and present
- Joined-up infrastructure and basic services

Objective n.2 – The right information and knowledge

The information required to perform tasks at work must be easily accessible, and the best available knowledge or evidence must be present at all occasions and the digital workplace must support the

processes of employees. Several regions and municipalities are modernizing their digital support by implementing new healthcare information systems or improving existing ones. The aim is to have a more modern IT environment that makes all relevant information easily available when needed, making things easier for both patients and staff. Some municipalities are also upgrading their social service systems. However, many Swedish municipalities still use outdated systems that don't support effective information processing, hindering new work methods, quality improvement, and learning. To improve information processing, the parties have prioritized the following initiatives in 2020-2022.

- Support for more effective information processing (e.g. national catalogues and registers of providers, secure digital access to information needed in encounters with patients etc.)
- Digital knowledge-based support, so employees have easy access to the best available knowledge tailored to their situation.
- Data-driven development: data should be converted into information and knowledge that can be used to develop new working methods and smart services.

Objective n.3 – Safe and secure information processing

Individuals want to have access to information about their health and status in their interactions with providers. It is crucial to ensure the safety and security of this information, protecting it from unauthorized access and ensuring its accuracy. Individuals should have control over how the information is used and be able to know what information is being stored, how it is being used, and by whom. Ensuring the security of information processing is essential in maintaining and building trust in digitization efforts. Systematic efforts in information security are necessary to avoid incidents and protect against hacking and data breaches and are a fundamental aspect of digital operations development. To prioritize safe and secure information processing, the priorities for 2020-2022 have been the following:

- Systematic work on information security
- Exchanging information securely

Objective n.4 - Development and digital transformation hand in hand

The advancements in technology have led to changes in people's behaviour and increased their expectations of welfare services, which pose a challenge to existing organizational structures, regulations, skills, perspectives, and relationships, testing the capacity for change among different service providers. For Sweden to fully take advantage of digitalization, proactive measures must be taken to support the development of the capacity of individuals and providers, equip them with the necessary skills and resources, and allow them to influence behaviours and adapt to new ways of working. A strong collaboration between industry and the health care and social service sectors is considered also crucial in speeding up the adoption of digital solutions and maximizing the innovation potential of industry. So to support the digital transition, in 2020–2022 the priorities have been identified in:

- Digital skills at all levels (lifelong learning)
- Support for introducing new technologies and integrating them in a sustainable, secure, and economically effective way
- Implementation support, through new forms of collaboration and coordination between government agencies, regions, municipalities, private providers and industry.

Regarding the fundamental conditions, the document builds on what was already envisaged for the previous period since here the goal is to improve stability and predictability of the operating conditions, so it is going to be easy to transfer information for various purposes such as research, quality assurance, and data collection and across administrative borders.

Regarding regulations, the envisaged work involves balancing the protection of privacy, equality, patient safety, and accessibility, with a long-term approach. Personal data processing in social services and healthcare relates to people's health and personal information, which is considered sensitive but, at the same time, access to such information is crucial for service providers to deliver quality care. Official goals in this area:

- create appropriate regulations that both guarantee the privacy and security of the individual and promote digital transformation.
- and facilitate the application and introduction of these regulatory frameworks in relevant services.

Regarding a more consistent use of terms, it is mentioned the fact that the information in social services and health care is meant to support individual-centered services, but it must also be capable of being utilized effectively for purposes such as operational monitoring but also for research and national statistics. To accomplish this, the information must be organized in a consistent manner using common terminology, which could also represent an opportunity for greater national coordination and consistent application with regards to semantic interoperability, thus promoting efficient information transfer within and between services. Official goals in this area:

- Ensure that the concepts, terms and classifications necessary for services can consistently be managed uniformly and interpreted in a similar manner in exchanges between systems or services;
- and increase the rate of introducing common concepts, terms, and classifications in services' IT support.

Regarding standards the work and initiatives of international and European standardization organizations, are highly considered, as they can impact Swedish eHealth standards. In this case the goal is to support the use of common and cross-sectoral solutions to prevent the development of national or sector-specific unique solutions. Official goal in this area:

- Enable services' information and communications systems to send and receive relevant amounts of information in an appropriate manner, without need for additional measures.

3.2 – Health data in the Swedish National Life Sciences Strategy (2020)

In 2020 the topic of health data has also been clearly addressed in the Swedish National life science strategy[8], which contains a full section entitled "Unlocking the potential of health data".

The text highlights the fact that to fully realize the potential of health data, Sweden needs effective system solutions. There is a constant generation of vast amounts of "real-world data" from self-management, health care, and social care. To utilize this data for the development of future care and preventive measures, it must adhere to privacy protection laws such as processing personal data, public access to information, secrecy, information security, and security protection. With advancements in technology, the volume of health data is more extensive and potentially more accessible. The shift to digital management

[8] https://www.government.se/information-material/2020/11/swedens-national-life-sciences-strategy/

of personal data in health care and social services has coincided with changes in their organization and responsibilities. This has increased the need for information sharing between care providers while still maintaining privacy and security. As a result, the government has initiated a review to address these issues.

To use health data for research, innovation, and development, interoperability is essential. This includes technical interoperability to share data, semantic interoperability through the use of consistent terms, and legal interoperability to have a legal basis for processing data generated elsewhere. Secure identification and authorization solutions are also crucial.

The current legislation regulating the use of data for research and innovation is interpreted differently by different stakeholders and the increasing use of new technology and innovations poses new challenges for information management in health and social care. This is particularly true for medical records and registers, which contain sensitive personal data, and raises questions about public access to information, secrecy, data protection, and privacy protection. The sharing of patient data and access to various registers highlight these issues, as do assistive technologies in health and social care, research, and infrastructure.

Data generated in the healthcare and social care sectors is stored in various systems, such as medication databases, imaging diagnostic systems, laboratory reports, and medical record systems. To make this data accessible, the regions need to ensure that their investments in future medical information systems consider international standards and open platforms and are developed to comply with strict information security standards. This also involves enabling data analysis and eliminating the need for data to be transferred from multiple sources for use in research and innovation through processes such as data federation.

In the framework of the **Vision for eHealth** there is a clear commitment to clarifying and changing regulatory frameworks, developing a more consistent use of terms, and standardization, which is being coordinated by the Swedish eHealth Agency. Proper access to current data is crucial in monitoring and improving the quality of healthcare and social care services, as well as in making these services more effective, gender-equal, and equitable across the country. Government agencies such as the Dental and Pharmaceutical Benefits Agency rely on data to carry out their tasks, which requires access to quality-assured data on care interventions and outcomes for different stakeholders. To broaden data accessibility,

Funded by
the European Union

especially with the shift towards providing more quality and localized healthcare, the National Board of Health and Welfare has been tasked with developing the national follow-up plan for primary care.

Certain health data is transferred to different types of national or regional registers, including diagnosis-specific quality registers, which have been developed over time to improve and ensure the quality of healthcare. In recent years, the central government and regions have made joint investments in these registers, and they are meant to be used as a source of knowledge for clinical research and cooperation with the life sciences sector. Other types of registers include individual-based national health data registers provided by the National Board of Health and Welfare, covering inpatient and outpatient care interventions, dental care, causes of death, and prescribed drugs. There are also biobanks, which are collections of human biological samples such as blood, that regions and higher education institutions are working to build into an integrated healthcare infrastructure through Biobank Sweden. The Biobank Inquiry has submitted proposals to adapt legislation to facilitate developments and improve conditions for using samples and information in Swedish biobanks for the benefit of patients, healthcare, and research, and has also proposed establishing a national sample register, the national biobank register.

In addition to public registries, individuals also store their health data privately in health and medical device apps to track personal progress or manage chronic diseases. Surveys indicate that the Swedish population is generally favourable towards the use of their anonymized data in healthcare research and development, but they want to be informed and have the option to opt-out. Chronic disease patients, known as 'lead user patients', are already actively contributing self-generated data and knowledge.

To enable the sharing of self-reported data, solutions must be developed to maintain information security and privacy protection while promoting access and unlocking the potential of health data for research and innovation. The interest of global tech companies in accessing and utilizing public health data for research and innovation is increasing, driven by potential synergies with life sciences stakeholders. However, these efforts must be balanced with protecting individual rights and freedoms, including privacy protection, and preserving public trust in the open society.

The Swedish Government has set several objectives for its healthcare system, with a focus on effectively and securely sharing patient data, increasing the use of health data in research and innovation, promoting the ethical use of register data, better utilization of biobanks, and improving the ability to follow-up using real-world data. In particular:

- Effective and Secure Sharing of Patient Data: the government believes that regions and municipalities need better conditions for sharing patient data between different care providers. The goal is to improve data sharing while ensuring the delivery of safe and quality health care, respecting privacy and meeting information security requirements.
- Increased Use of Health Data in Research and Innovation: the government aims to increase the use of health data in research and innovation while maintaining privacy protection, to contribute to better patient care and industry development. Addressing ambiguities and ethical considerations is essential to enhance Sweden's position in digital transformation and data use. At the same time, improving sectoral knowledge of the applicable legislation is important.
- Effective, Secure, and Ethical Use of Register Data: the government intends to increase the life sciences sector's use of register data for research and innovation. For this to be possible, infrastructure, legislation, guidelines, and other forms of support must contribute to the effective, secure, and ethical use of quality and health data registers. The government also plans to review patient opportunities to self-report their data.

- Better Use of Biobanks: the government will consider the proposal for a new biobank act submitted by the Inquiry on the regulation of biobanks during this electoral period. Developing the use of biobank samples is possible as long as donor privacy is respected, and secure and stable structures are needed for storing, searching, and retrieving information and samples from biobanks.
- Follow-Up Using Real-World Data: the government recognizes the need to improve the ability to follow-up and use real-world data, which requires good conditions for collecting and analysing such data, including self-reported data.

4 – SWOT Analysis on digital health innovation

Sweden is undoubtedly one of the most advance countries in Europe in terms of digital health innovation, here we try to highlight some elements which characterize this advanced ecosystem.

The country has a collaborative approach to health data that involves a wide range of stakeholders, including healthcare providers, researchers, policymakers, and patient advocacy groups. This approach is built on the principle that sharing health data can lead to improved health outcomes and more effective healthcare services. One of the key organizations responsible for promoting collaboration related to health data in Sweden is the National Board of Health and Welfare. The Board works closely with other organizations, including universities, research institutes, and industry partners, to support research and innovation in healthcare.

The following lines analyse the enablers and the barriers to digital health innovation and the opportunities for the EHDS deployment in the country.

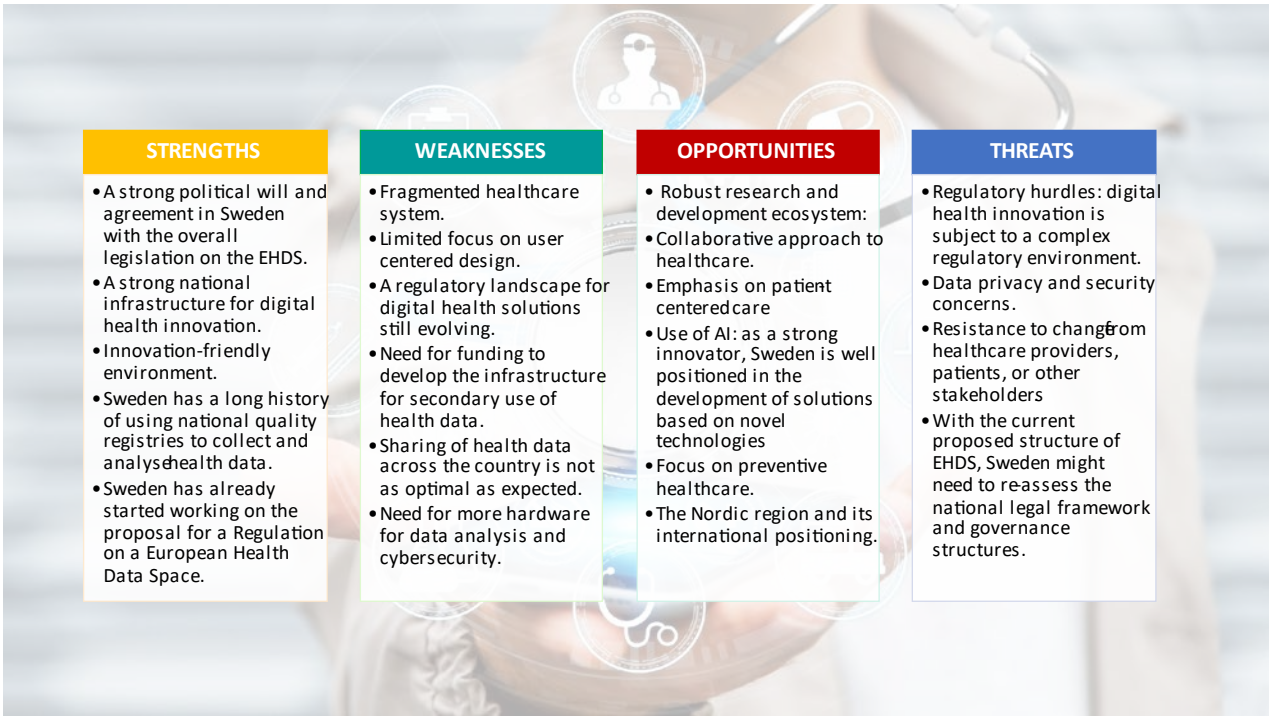


Figure n.7 – Main findings of the SWOT analysis- THE SLIDE NEEDS TO BE UPDATED

4.1 - Strengths

- In general, there is strong political will and agreement in Sweden with the overall legislation on the EHDS. Some aspects are already under development, or already existing, to facilitate Sweden joining the EHDS. However, other aspects remain to be addressed. The newly elected government has indicated development of a common infrastructure for the Swedish health care sector as a priority, and the EHDS will be a focus during the Swedish presidency of the Council of the EU in the first half of 2023.
- Sweden has a strong infrastructure for digital health innovation, deeply rooted in the daily use, even if distributed in the regions, this resulting into a – at least partially – fragmented data infrastructure.
- There is a semi-national platform for health information (1177.se), however excluding many private healthcare providers. From this platform patients can get access to own EHR data, lab results etcetera. This infrastructure provides a solid foundation for digital health innovation and enables collaboration and sharing of health data across the country although it could be better shared.
- Sweden has a reputation as an innovation-friendly country, with a high level of investment in research and development (ranks world's n.3 in the Global Innovation index 2022). In addition, the Swedish government has been a strong advocate for digital health innovation, providing funding and support for initiatives that promote the development and adoption of new technologies. This environment has helped to foster a culture of innovation in the field of digital health, with many start-ups and established companies working on new technologies and solutions.
- Sweden has a strong research culture, with many universities, research institutes, and other organizations working on digital health innovation. This culture of research has helped to generate new ideas and technologies in the field of digital health and has contributed to the development of new solutions and products.
- Sweden has a long history of using national quality registries to collect and analyse health data. These registries provide a wealth of information on health outcomes and treatment effectiveness, which can be used to inform digital health innovation and improve patient care.
- Sweden has a policy of open access to health data, which means that researchers and other stakeholders can access and use health data for research and development purposes. This policy has helped to facilitate innovation and collaboration in the field of digital health.
- Sweden has 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. For secondary use it is not decided yet who will take on the role.

4.2 - Weaknesses

- Since responsibility for providing healthcare is distributed to the 21 counties/regions (and somewhat also to the 290 municipalities) which are all autonomous when it comes to choosing and procuring EHR systems, there is a rather fragmented health data infrastructure. This fragmentation can limit the capability to implement digital health solutions on a national scale and can result in variations in quality of care across the country.
- While Sweden has a national system for electronic health records, there are still limitations in interoperability between different systems and providers. This can make it difficult to share health data and coordinate care between different providers, which is essential for effective digital health solutions.

- While Sweden has a strong research culture and invests in innovation, there is still a limited focus on user-centered design in digital health solutions. This can result in products that are not well adapted to the needs and preferences of users, which can limit their effectiveness and adoption.
- The regulatory landscape for digital health solutions in Sweden is still evolving and there is some uncertainty around how existing regulations will be applied to new and emerging technologies, and there are ongoing discussions about whether new regulations or guidelines are needed.
- Need for skilled staff such as experts on the interplay between health and technology, data stewards, informatics specialists, and lawyers.
- Need for funding to 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.
- Sharing of health data across the country is not as optimal and efficient as would be expected. The government is now looking into this more in detail, e.g., with government assignments to the Swedish eHealth Agency to present analyses and proposals for national digital infrastructure.

4.3 - Opportunities

- Robust research and development ecosystem: Sweden has a strong tradition of research and development, with world-class universities and research institutes. This provides a strong ecosystem for the development of new digital health technologies and solutions.
- Collaborative approach to healthcare: Sweden has a collaborative approach to healthcare, with a strong tradition of partnerships between the public and private sectors, as well as between different healthcare providers. This provides opportunities for digital health solutions that can facilitate collaboration and coordination between different stakeholders in the healthcare system.
- Emphasis on patient-centered care: Sweden has a strong emphasis on patient-centered care, which provides opportunities for digital health solutions that can improve patient engagement, empowerment, and self-management.
- Focus on preventive healthcare: Sweden has a strong focus on preventive healthcare, which provides opportunities for digital health solutions that can help individuals monitor their health and prevent the onset of chronic conditions.
- Use of AI: as a strong innovator, Sweden is well positioned in the development of solutions based on novel technologies. Several initiatives, partnerships, projects and start-ups have already been launched on this topic.
- The Nordic region and international positioning: Sweden has always maintained strong relationships with the neighbouring Nordic countries as well as important connections with other highly innovative countries (see section 7).

4.4 - Threats

- Digital health innovation is subject to a complex regulatory environment, with different requirements for data privacy, security, and medical device regulations. These regulations take time to be deployed and can create barriers for start-ups and small businesses that may not have the resources to navigate the regulatory landscape.

- As with any use of health data, there are concerns around data privacy and security. The sensitive nature of health data means that there is a high risk of data breaches or misuse, which can damage public trust in digital health solutions.
- Healthcare is a highly regulated industry, and introducing new technologies and processes can be challenging. There may be resistance from healthcare providers, patients, or other stakeholders who are hesitant to adopt new technologies or change established practices.

5 – Transferable Good practices

5.1 – Good practice n.1 - Centre for Health Data in Region Stockholm

Region Stockholm created the Centre for Health Data in 2019 with the aim of providing researchers with access to health data in a more efficient and coordinated manner. Health data is often stored in various locations and is subject to strict privacy and security regulations so, by centralizing the access to it, CHD aims to make the process of accessing and utilizing the data more streamlined. The centre retrieves data for research purposes from Region Stockholm's healthcare system as well as from Region Stockholm's Public Healthcare Services Administration (sjukvårdsförvaltningen).

One of the key services provided by the Centre is assistance with ethical approval and research plans. This is important because the use of health data for research purposes is subject to a wide range of ethical and legal considerations. By providing guidance and support in these areas, the Centre for Health Data helps to ensure that research is carried out in an ethical and responsible manner.

Another important role of the Centre is to provide healthcare providers with a one-stop-shop for the sharing of health data. This means that rather than having to approach multiple healthcare providers to access data, researchers can go to the Centre to obtain the data they need. This helps to streamline the sharing process and ensure that the data is shared in a coordinated and secure manner.

Overall, the Centre for Health Data is an important resource for researchers in the healthcare field, as well as for healthcare providers who own and manage health data. By providing a centralized location for the sharing and utilization of health data, the Centre is helping to advance research and improve healthcare outcomes in the region.

It is important to mention that the CHD does not maintain its own database. Rather, its main role is to coordinate – through a federated solution - the release of health data for research purposes that are permitted under applicable confidentiality and data legislation. Before releasing any data, an extensive confidentiality examination takes place to ensure that the recipient could guarantee confidentiality and security in relation to the data. To apply for access to health data, individuals must be actively engaged in research at a university, higher education institution, or within healthcare. Life science companies and other external organisations are requested to coordinate their applications through one of three aforementioned representatives.

To apply for access to health data, in addition to the application form, applicants must submit several other documents. These include a complete application to the Swedish Ethical Review Authority (EPM), including appendices and additional applications, as well as a decision from the EPM. The applicant must also provide information for patients and the consent form, and if there are multiple versions of the form, all must be enclosed. If consent is not obtained, the Swedish Ethical Review Authority's decision must indicate this. Additionally, a variable list that specifies the personal data required for the purpose of research must be

provided, as well as a Data Processing Agreement and Data Transfer Agreements or standard contractual clauses for transfers to third countries.

At present, Region Stockholm does not charge researchers who require access to health data for research purposes. However, an investigation is ongoing to determine the fee structure for future use. It should be noted that in cases where Region Stockholm engages subcontractors to handle the data retrieval process, a fee may be charged by these subcontractors.

Overall, the process for applying for access to health data is quite thorough, with multiple documents required to ensure that the data is used for research purposes only and that the privacy of individuals is protected. While fees may be charged in certain circumstances, the current policy is to provide free access to researchers who require the data for research purposes.

Source: Stockholm Center for Health Data[9]

5.2 – Good practice n.2 - The Health Portal 1177.se

The 1177.se portal is a Swedish healthcare website that provides a wide range of e-health services and reliable health information to the public. The portal is operated by the Swedish County Councils and Regions, which are responsible for providing healthcare services in Sweden.

The idea for the portal was first proposed in 2008, as part of a national initiative to improve healthcare access and outcomes in Sweden through the use of e-health technologies. The portal was designed to provide a central resource where people could access reliable and up-to-date health information, as well as connect with healthcare providers and access a range of e-health services. The development of the portal was a collaboration between the Swedish County Councils and the Swedish Association of Local Authorities and Regions (SALAR), which represents the interests of local and regional government in Sweden.

The portal was officially launched in May 2010, with the initial rollout including a range of e-health services, such as online consultations with healthcare professionals, appointment booking, prescription renewal, and access to medical records. The portal was also designed to be a central resource for reliable health information, with content provided by medical experts and reviewed by a team of editors to ensure accuracy and comprehensibility.

Since its launch, the 1177.se portal has continued to evolve and expand, with new services and features being added on a regular basis. For example, in 2013, the portal added a new feature called "Mina vårdkontakter" (My Care Contacts), which allows patients to keep track of their healthcare appointments and communicate with their care team online. In 2015, the portal launched a mobile app, making it even easier for people to access health information and services on the go.

In 2019, an incident occurred which led to sensitive personal information of patients, including confidential conversations with healthcare professionals, being publicly exposed. It was considered a serious violation of patient privacy and led to an investigation by the Swedish Authority for Privacy Protection (IMY), which identified shortcomings in the system and recommended measures for improving data protection and security. In response to the incident, the Government passed a new data protection law in 2019, which includes stricter data protection rules, stronger enforcement measures, and increased fines for violations of data protection laws.

[9] https://www.regionstockholm.se/om-regionstockholm/Information-in-English1/Research/the-centre-for-health-data/

The 1177.se portal is nowadays an important resource in Sweden for several reasons.

Firstly, it provides reliable and trustworthy information on a wide range of health-related topics. The information is produced by healthcare professionals and is based on the latest scientific research, so people can be confident that the information they are reading is accurate and up to date. This can help people make informed decisions about their health and wellbeing and can also reduce the risk of misinformation and incorrect self-diagnosis.

Secondly, the portal provides people with access to a range of self-help tools and resources that can help them manage their health and wellbeing. This includes advice on healthy living, information on managing chronic conditions, and guidance on when to seek medical care. By providing people with the information and tools they need to take control of their health, the portal can help to promote better health outcomes and reduce the burden on the healthcare system.

Finally, the 1177.se portal provides a phone service where people can speak to a nurse for healthcare advice and guidance. This service is available 24 hours a day, seven days a week, and is free of charge. This can be particularly important for people who are experiencing health problems outside of normal healthcare hours and can help to ensure that people get the care and support they need when they need it.

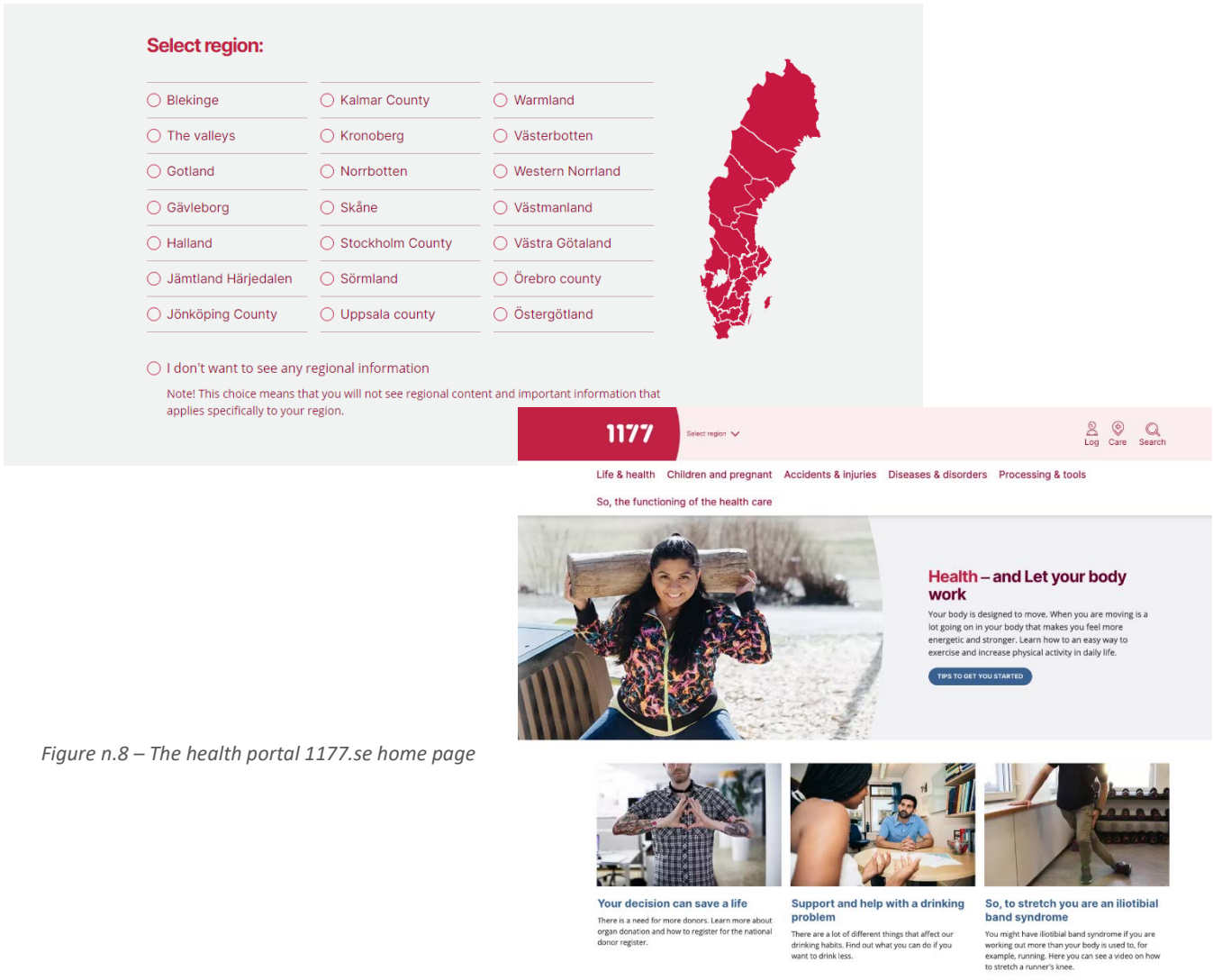


Figure n.8 – The health portal 1177.se home page

Some of the key services that are currently available through the portal include:

- Health information: The portal provides a comprehensive range of reliable and up-to-date health information, covering a wide range of topics such as symptoms, diseases, treatments, and prevention. The information is available in multiple languages and is designed to be accessible to people with varying levels of health literacy.
- Online consultations with healthcare professionals: Patients can connect with healthcare professionals online to discuss non-emergency medical issues, ask questions about medications or treatment plans, and receive advice on how to manage health conditions.
- Appointment booking: Patients can use the portal to book doctor's appointments and view available time slots at healthcare clinics throughout Sweden.
- Prescription renewal: Patients can use the portal to renew prescriptions and view their medication history.
- Access to medical records: Patients can view their medical records and test results online, as well as keep track of their healthcare appointments and communicate with their care team (see the following section on e-health records “Journalen” in 5.3).
- Covid-19 information and advice: The portal provides up-to-date information on Covid-19, including guidance on how to prevent infection, what to do if you suspect you have Covid-19, and information on vaccines.
- Mental health support: The portal offers information and resources for people struggling with mental health issues, including advice on how to access mental health care and resources for self-care.
- Child health services: The portal offers information and resources for parents and caregivers, including advice on child development, vaccinations, and child health care.

For a detailed history of the first developments of the Swedish Patient Portal it is possible to refer to: *Sellberg, N., Eltes, J. (2017). The Swedish Patient Portal and Its Relation to the National Reference Architecture and the Overall eHealth Infrastructure. In: Aanestad, M., Grisot, M., Hanseth, O., Vassilakopoulou, P. (eds) Information Infrastructures within European Health Care. Health Informatics.*

5.3 – Good practice n.3 - National Quality Registries

Sweden has a long history of using national quality registries to collect and analyze health data. These registries contain individualised data concerning patient problems, medical interventions, and outcomes after treatment, within all healthcare production.

Around one hundred existing Quality Registries provide the Swedish health care system with a unique opportunity to monitor quality and results. These registries, even if distributed to different counties and other hosting institutions, as well as based on a number of different technical platforms, contain national data about medical interventions, procedures and outcomes. They are already integrated into clinical workflows and have the capacity to generate data in real time. Each registry is supported by an organisation of health care professionals and patient representatives that are jointly responsible for developing the registry.

National Quality Registries contribute to Sweden's strong position on health care results. Sweden has among the best survival rates after heart attack, stroke, breast- and colorectal cancer and is also a leader in the areas of acute cardiac care, diabetes care and hip replacement surgery. The registries also contribute

to innovative eHealth services, patient-centred approaches and decision support functionalities, as well as IT development and integration.

Very recently the Swedish eHealth Agency completed a government assignment on this topic, presenting proposals to the government to integrate all of them into a newly developed national platform for quality registries[10].

Additionally, both the eHealth records (Journalen) and the National Patient Summary, already described in section 2, can be considered good pratices.

5.4 - A potential future good practice: the EDIH Health Data Sweden

At the beginning of 2023 a new initiative called “Health Data Sweden” started its activities as one of the recently funded European Digital Innovation Hubs.

The European Digital Innovation Hubs (EDIHs) constitute a network of organizations that provide support and expertise to businesses and organizations in their digital transformation efforts. The EDIHs aim to bridge the gap between digital technology providers and end-users, by offering services such as advice, testing facilities, skills development, and access to funding.

The EDIHs are part of the European Commission's wider Digital Single Market strategy, started in Horizon2020 but planned to continue under Horizon Europe. The EDIHs are located across the European Union, with at least one hub in each member state. They vary in size and scope, with some focusing on specific sectors or technologies, while others offer a broader range of services.

According to the European Catalogue of EDIH, Health Data Sweden is a hub that brings together two EDIH candidates (HDS and Health Innovation of Sweden) from Stage 1 of the call into a Swedish national system of services for SMEs, small mid-caps, and the public sector. The objective is to cover the complete value chain in digital health, enabling users to benefit from entry-level services related to health data as well as more complex development aimed at preparing for future advancements in the field.

The HDS consortium comprises 18 partners, including regions, universities, innovation hubs, research institutes, and science parks, all of which play a leading role in Swedish and European healthcare. KTH Royal Institute of Technology leads the consortium, which includes Blekinge Digital Health Blue Science Park, Bron Innovation, Compare/DigitalWell Arena, EIT Digital, EIT Health Scandinavian CLC, Future Position X / Geolife Region, Halmstad University/Leap for Life, Karolinska Institutet, Linnaeus University, Livsmedicin Region Västerbotten, Region Stockholm, Region Kalmar län / eHealth Arena, RISE, Stockholm University, Stockholm Science City, STUNS Life Science, and Uppsala University.

The project aims to have 1700 Swedish and 200 European SMEs/mid-caps, and 455 Swedish and 95 public-sector organizations utilizing their services by the end of the 3-year project. HDS aims to contribute to the secure digital health services of the future, with a focus on health data and high-quality, accessible, and sustainable healthcare/welfare services for European citizens.

[10] https://www.ehalsomyndigheten.se/globalassets/ehm/3_om-oss/rapporter/rapporter_regeringsuppdrag/forstudie-digital-nationell-infrastruktur-nationella-kvalitetsregister-slutrapport.pdf (in Swedish)

6 – Good practices related to gender diversity and inclusiveness

6.1 – Gender equality in Sweden

As clearly stated by the Swedish Gender Equality agency "*Equality between women and men is a fundamental constitutional norm and an explicit policy objective in Sweden (…). The ultimate aim of Swedish gender equality policy is for women and men to have the same opportunities, rights and responsibilities in all areas of life*."

The Swedish government has been actively working to promote gender equality for several decades (for example it was the firts country in the world to replace gender-specific maternity leave with parental leave back in 1974) and nowadays Sweden is generally considered to be one of the most gender-equal countries in the world. This is confirmed by the European Gender Equality Index, where Sweden ranks first.

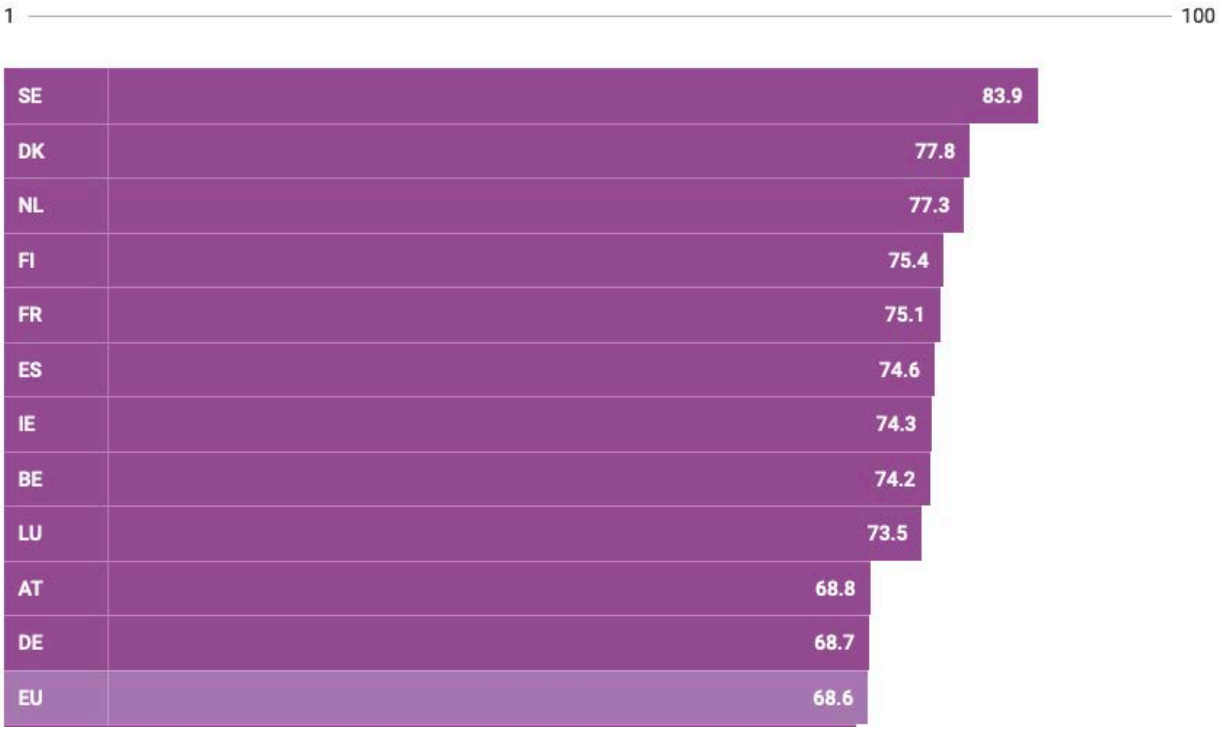


Figure n.9 – European gender Equality index scores 2022 (data from European Institute for Gender Equality)

Source: https://eige.europa.eu/countries/sweden

Since 2018, the Swedish Gender Equality Agency is tasked by the Swedish government to support government agencies with the work of integrating a gender perspective in all of their operations. The initiative is called the Gender Mainstreaming in Government Agencies (GMGA) programme, and its goal is to integrate gender equality in all aspects of each agency's work. At present, Sweden ranks well above the European average in almost all the indicators (Work, Money, Knowledge, Time Power and Health).

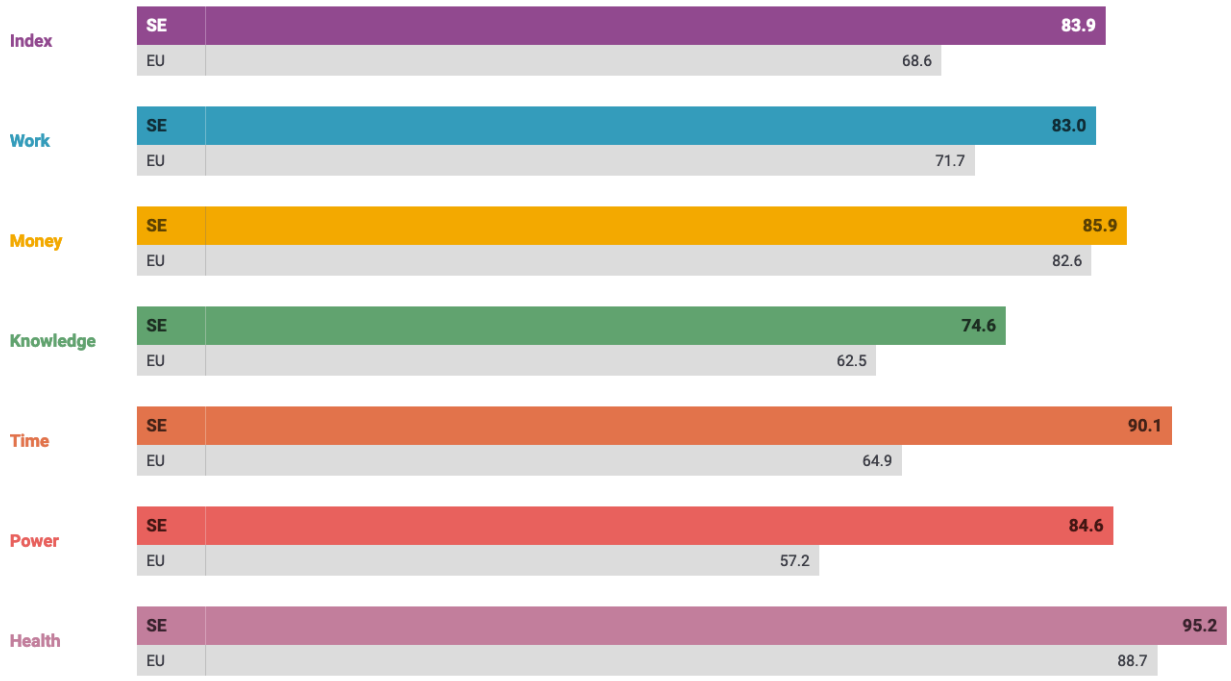


Figure n.10 – Sweden score compared to EU average on the main gender equality indicators.

(Source: European Institute for Gender Equality, 2022)

Since 2010, Sweden's score has improved the most in the domain of power (+ 6.8 points), maintaining its leading position in the ranking. The improvement was driven by a score increase in the sub-domain of economic power (+ 10.7 points since 2010).

Another area where Sweden has made significant progress worth to mention is in terms of women's representation in politics. In the Swedish Parliament, women currently make up over 46% of the members (Statista 2022), which is much higher than the average percentage of women in national parliaments globally, which is 26.5% (IPU.org 2022).

Sweden has also made progress in terms of women's participation in the labor force: according to data from the Swedish National Agency for Education, in 2020, the employment rate for women in Sweden was 77.4%, compared to 80.8% for men. While there is still a gap between men and women in terms of employment, this gap has been narrowing over time. In terms of the gender pay gap, recent data from Eurostat (2020) shows that women in Sweden earn on average 11,2% less than men. While this is lower than the EU average of 13%, there is still a gap that needs to be addressed. The situation can partly be explained by differences in profession, sector, position, work experience and age but some of them seem to have more to do with gender.

Despite these overall successes, Sweden still faces challenges when it comes to gender equality. For example, women are still underrepresented in certain industries, such as technology and engineering (a quite critical report about inequality among tech start-ups in Sweden has been written by the Allbright Foundation in

2020[11]), where only 29 percent of senior positions within tech companies are held by women, similar to the situation among the listed companies where the corresponding number is 24 percent.

Moreover, women in Sweden are more likely to experience sexual harassment and violence than men, and this is an issue that the government and civil society organizations are working to address.

Nevertheless, in such kind of generally equal environemnt ,it is possible to find several good practices. Here we selected two of them, strictly related to research and innovation.

6.2 – Good practice n.1 - VINNOVA - Equal funding of innovations

Every year, the Swedish Innovation Agency, VINNOVA, invests approximately SEK 3 billion (approx. €270 million) in research and innovation. Since 2015, it has successfully integrated a gender perspective in its activities and promoted gender equality in the distribution of funds for research and innovation. VINNOVA makes an effort to include gender perspectives in the projects financed, recognising gender equality as a prerequisite for sustainable societal development and innovation. The funds managed by VINNOVA must benefit women and men equally. Since 2015, the number of women project managers has increased by approximately 10 % (from about 30 % to 40 %) and the total distribution of funding now has a range of 40–60 % and is thus in line with national gender equality objectives. VINNOVA's work is based on three key questions:

- Who is being financed? The focus is on the project team and its gender composition, e.g. how many women and men are project leaders, how are time and resources allocated to different positions and tasks from a gender perspective, etc.;
- What is being financed? This tries to incorporate a gender perspective in project aims and methodology, if relevant. Applicants have to provide information on their motivation for (or justification against) incorporating a gender dimension. The call manager at VINNOVA is supported to incorporate gender-related topics and criteria when setting up the call;
- How is the process conducted? Firstly, applications are designed in a way that makes it possible to assess their gender aspects. Secondly, the review committee is composed in a gender-equal way, trained in gender bias, and knows how to assess the relevance of gender to the subject area.

VINNOVA set up a task force to plan and coordinate the work. The task force supports implementation through coaching and training, and also monitors and evaluates the work. Managers are responsible for implementation and the work is guided by government instructions and internal steering documents. In 2021, VINNOVA is working to integrate a gender perspective into its 10 mission areas to ensure more systematic application of gender mainstreaming in its work procedures. This is expected to lead to a better set of actions to promote gender equality and equal funding.

Vinnova dedicated webpage: https://www.vinnova.se/en/m/equal-innovation/

[11] 'Tech Dudes Caught in Their Own Myth' is the title of the report

6.3 – Good practice n.2 - Swedish Royal Institute of Technology (KTH) – Equality Office

KTH appointed a Vice-President for Gender Equality and Core Values in 2017, whose task is to promote gender mainstreaming and equal opportunities. HEIs in Sweden must work according to several government objectives and legal obligations within the broader equality framework.

KTH also set up an Equality Office to coordinate implementation and support different units and management levels. Through the Equality Office, KTH is conducting research-based proactive work at both the strategic and practical level, with the aim of promoting gender equality, diversity and equal terms from an intersectional perspective. The KTH Equality Office comprises six people: the Vice-President, a special expert, three Gender Equality strategists and a pedagogical advisor. KTH also includes faculty positions with responsibilities for gender equality and equal opportunities. Work on gender mainstreaming and equal conditions at KTH's five schools is designed and implemented at local level, but coordinated via the Equality Office.

The activities of the Equality Office include training initiatives, leadership development, recruitment and assessment, as well as career support, monitoring and evaluation. It works through dialogue and interactive working methods, with the experts at the Equality Office working together with staff and students. Although covering all university members, the Equality Office is mainly focused on educating and supporting leadership and managerial functions.

In 2017, it started a one-year programme in Gender and Change Management (GOFL) for women in senior positions at the university. The programme aimed for participants to act as change leaders, advocates and multipliers in their areas of the organisation. An important prerequisite for the work of the Equality Office is that gender mainstreaming and equal opportunities are anchored in KTH's steering documents and central work processes.

The Equality Office has been received positively: its coordination with gender mainstreaming and equal opportunities work has resulted in clearer anchoring at management level, together with operational support for trade unions and the student union. Training and different working methods have been created to facilitate management and other key positions know-how on integrating gender equality. Regular meetings with responsible staff provide the Equality Office with an overview of the overall gender equality and equal opportunities work. Knowledge and awareness of gender equality has increased at KTH, and longer term effects at societal level are expected when graduates spread their knowledge of gender equality, diversity and equal opportunities beyond the university itself.

KTH Equality Office web presence: https://www.kth.se/en/om/equality/equality-office-1.840276

7 – Synergies with other EU regions

Sweden has always been an active and influential player in promoting innovation and cross-border services in the Nordic region. Its efforts have helped to create a more integrated and connected Nordic community and have positioned the region as a leader in digitalization and innovation. Here are a few examples of cooperation initiatives in the area.

7.1 - The Nordic eHealth Research Network

A cornerstone initiative has been the Nordic eHealth Research Network, a collaborative network of researchers and healthcare professionals from the Nordic countries (Denmark, Finland, Iceland, Norway, and Sweden) who are interested in eHealth research. The network aimed to promote interdisciplinary research in eHealth, with a focus on patient-centered care and the use of digital technologies to improve health outcomes.

The network was established in 2012 and funded by the Nordic Council of Ministers. It had several working groups focused on different topics related to eHealth, such as patient safety, patient engagement, and health informatics. The network organized conferences, workshops, and other events to promote knowledge sharing and collaboration among its members.

After four mandates, the activities of the network were concluded in 2020 but the gained experience paved the way to some of the following initiatives.

7.2 - Nordic commons

The Nordic Commons is a collaborative project aimed at exploring methods and practical solutions for sharing health data among regional and national stakeholders in the Nordic countries (Denmark, Finland, Iceland, Norway and Sweden). The initiative is in line with The Nordic Council of Ministers' goal of prioritizing the secure and efficient sharing of health data between the Nordic countries. The exchange of health data in a secure and efficient manner is expected to have a significant impact on research, innovation, healthcare, and the overall promotion of health and welfare across the Nordic region and beyond.

In December 2019, NordForsk released a report, "A vision of a Nordic secure digital infrastructure for health data: The Nordic Commons" which outlines proposals and recommendations that have been integrated into The Nordic Council of Ministers' four-year action plan (2021-2024). The plan is part of the broader Vision 2030 strategy approved by the Ministers for Nordic Co-operation and includes initiatives that correspond with three strategic priorities: a green Nordic Region, a competitive Nordic Region, and a socially sustainable Nordic Region.

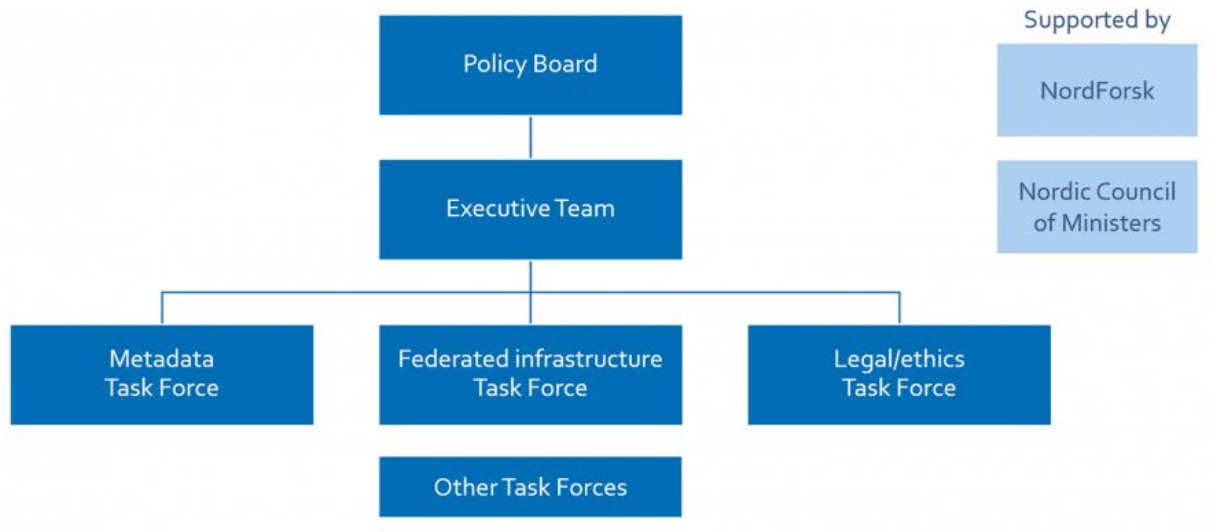


Figure n.11. - Nordic Commons organisation for the implementation of the Action plan 2021-2024

The action plan is divided into 12 sections, each corresponding to one of the 12 objectives linked to the strategic priorities: digitalisation and healthcare mainly falling into Objective 8 and Objective 9. The activities of the Nordic Council of Ministers will be governed by these priorities and objectives over the next four years.

The project – which was somehow delayed by the COVID-19 pandemic, has already three task forces working on the topics of Metadata, Federated infrastructure, and Regulation and is also addressing the preparatory work for the EHDS.

Website of Nordic Commons: *https://www.nordforsk.org/nordic-commons*

7.3 - Nordic countries cross border data exchange

Within the same framework, but responding to another of the 12 abovementioned objectives, is the project entitled ”Achieving the World's Smoothest Cross-Border Mobility and Daily Life Through Digitalisation: Launched in 2021 and planned to last up to 2023, the project aims to create a common model and practices for improving and increasing the effectiveness of cross-border data exchange, in three main areas, the second one being health services.

Typically, services in the Nordic countries are developed and intended for use within a single country, with cross-border services being the exception rather than the norm: digital health care services and data transfers, such as electronic prescriptions and patient records, have the potential to enhance safety, facilitate travel, and ensure continuity of care for citizens across borders. The Nordic countries are going to be the first test-bed but the initiative has the potential to be enlarged to other interested countries.

The project will involve Nordic key actors in designing elements of forthcoming measures and their implementation. Interoperability of the eServices to be promoted will be defined based on lengthy international standardization work and previous projects, especially at the EU level. The Nordic Council of Ministers (NCM) eHealth Standardization group has already committed to being one of the partner groups in this work package, comprising representatives from various national health ministries and authorities.

Throughout the project, the aim is to identify the fastest-growing elements and barriers for development and to propose measures to remove or alleviate them, allowing the Nordic and Baltic region to stay ahead of these issues. The proposed resources will make progress possible by avoiding duplication with work at the EU level as much as possible and by supporting Nordic and Baltic cooperation in existing forums. At the end each country will make its own decision on concrete implementation and its timetables.

Further details can be found at this link: https://pub.norden.org/temanord2021-547/#88562

7.4 - NorDEC – Nordic Digital health Evaluation Criteria

Another project being implemented at the level of Nordic countries is called NorDEC and it claims to be the world's first cross border digital health framework programme.

The objective of this project launched in 2022 is to create a framework i.e. a set of shared criteria enabling healthcare providers to assess and recognize reliable digital health technologies for use in healthcare and preventative care. Additionally, the project aims to offer product developers and owners a transparent understanding of the ideal product features to inform their development, market entry strategies, and overall commercial positioning. The project is based on three pillars:

- Patient safety: **w**ithout regulation on app stores, 80% of apps do not meet minimum quality standards. Assessing apps against a clear requirement will give confidence that only safe apps are recommended to patients.
- Interoperability: By implementing a shared standard across the Nordic countries, apps can achieve compliance across a larger market, covering an entire region instead of a single country, and facilitate data collection that can guide early intervention and prevention strategies. This also ensures consistency of experience for patients and professionals. The shared standard is an important aspect of interoperability.
- Industry growth: the health tech sector is expanding in the Nordic countries. The project offers a desirable platform for suppliers to access the entire Nordic healthcare system, eliminating current obstacles to market entry. With numerous international standards, it also provides suppliers with a strong starting point to meet the criteria for entering other regions, such as the UK, Netherlands, Canada, and the US.

The assessment model is intended to cover the areas of Data and Privacy, Professional Assurance, Clinical Safety, Usability and Accessibility and Security + Technical Stability.

The scoring and questions that make up the criteria can be accessed at this link.

7.5 - Global digital health partnership

The Global Digital Health Partnership (GDHP) is a collaboration of governments and governmental organizations from around the world working together to promote the use of digital technology in health. Its mission is to improve health outcomes through the best use of evidence-based digital technologies.

The GDHP was launched in February 2018 it has since grown through the years; at present it includes 33 nations (including Sweden) and 3 international organisations, including OECD and WHO.

The partnership has several key objectives, including sharing best practices in digital health, fostering collaboration between countries and organizations, and developing guidelines and standards for digital health implementation. The GDHP also aims to promote innovation in digital health and to help countries

address common challenges related to the implementation of digital health solutions. To achieve its goals, the GDHP has established several working groups (called work streams), each focused on a specific area of digital health, such as policy environments, clinical and consumer engagement, cyber security, evidence and evaluation, and interoperability.

GDHP website: https://gdhp.health/

7.6 - Selected European Projects in the field of Health data with partners from Sweden

Following a dedicated analysis on CORDIS project repository, it has been possible to identify a series of projects related to the topic of "Health Data" where one or more partners come from Sweden. Here is a selection of some of them: for each we report a short summary, the total budget and the names of the Swedish partners involved. Data are extracted from CORDIS database, IMI and other EC official sources.

X-eHealth (2020 – 2022)

The X-eHealth initiative, funded by the EU, set the groundwork for a practical, secure, and cross-border Electronic Health Record exchange format to promote the growth of the eHealth sector. With the backing of over 40 entities, the project targeted a faster and more sustainable digital transformation of the EU, consisting of eight work packages, four of which focused on technical and functional activities. The goal was to develop a standardized data-sharing format structure, building on the existing Patient Summary service and establishing a common foundation for medical imaging, discharge letters, laboratory results, and rare diseases.

Total budget: €3 M

Swedish partners: Swedish eHealth Agency (E-hälsomyndigheten, National Competent Authority for the project) and Equalis AB

Website: https://www.x-ehealth.eu/

Joint Action TEHDAS – Towards the European Health Data Space (2021 – 2023)

The TEHDAS project develops joint European principles for the secondary use of health data, thanks to a consortium composed by members from 25 countries. The project's main objectives are as follows:

- Initiate a conversation with European projects and policymakers regarding the EHDS.
- Ensure the durability of health data's secondary use in Europe.
- Formulate a governance structure for cross-border co-operation among European countries for the secondary use of health data.
- Boost the consistency, compatibility, and accessibility of health data for secondary use.
- Clarify the position of individuals in the secondary use of health data and incorporate them in discussions about health data usage for policymaking and research.

The outcomes of the TEHDAS project will provide key inputs for the European Commission's legislative proposal on the European Health Data Space and contribute to the broader pan-European discussion that will follow the proposal.

Total budget: €4.16 M

Website: https://tehdas.eu

Swedish partners: Swedish eHealth Agency (E-hälsomyndigheten, National Competent Authority for the project), Public Health Agency of Sweden and Swedish National Board of Health and Welfare

PHIRI - Population Health Information Research Infrastructure (2020-2023)

The PHIRI project aims to facilitate open and data-driven research on the broader impacts of COVID-19 on the health of populations in Europe by sharing cross-country COVID-19 population health information and best practices related to data collection and processing. It seeks to provide a Health Information portal for COVID-19 with FAIR catalogues on health and health care data, structured exchange between countries on COVID-19 best practices and expertise, and to promote interoperability and tackle health information inequalities. The project includes work packages to develop a research infrastructure, assess the impacts of COVID-19 on population wellbeing, conduct research on specific subgroups, provide swift responses to research and policy questions, and model scenarios for national situations.

Total budget: €5 M

Swedish partner: Folkhalsomyndigheten – Public Health Agency of Sweden

Website: https://www.phiri.eu/

IMI BIGPICTURE (2021 – 2027)

The BIGPICTURE project, funded under IMI – Innovative medicine Initiative – aims to create a repository of digital copies of around 3 million slides covering a range of disease areas. This repository will then be used to develop artificial intelligence tools that could aid in the analysis of slides. The project will first create the infrastructure needed to store, share and process millions of (often heavy) image files; secondly, legal and ethical issues to ensure patient privacy and data confidentiality will be addressed. Finally, the project aims to develop functionalities to facilitate the use of the database as well as the processing of images for diagnostic and research purposes.

In the long term, the project will develop sustainability plans to maintain and continue to develop the platform beyond the end of the IMI project.

Total budget: €70 M

Swedish partners: Linköpings University and Region Östergötland (+ Uppsala University as third party)

Project website: https://bigpicture.eu/

B1MG – Beyond 1 Million Genomes (2020 – 2023)

The B1MG project aims to establish a support and coordination structure for the European 1+ Million Genomes initiative, which involves 20 EU states and Norway committing to the sequencing of at least 1 million genomes in the EU by 2022. The project will help to create a pan-European genome-based health data infrastructure that includes data quality and exchange standards, access protocols, and legal guidance. B1MG will collaborate with international initiatives and consult with various stakeholders to provide concrete guidance on implementing personalized medicine at the local, regional, and national level. The benefits of personalized medicine include faster, more accurate diagnostics, the development of pharmacogenomics, and the advancement of preventative medicine, resulting in better health, quality of

life, and more efficient national health systems. The project will develop a methodology for economic evaluation, which will form the basis of future business-cases for implementation in the health sector.

Total budget: €4 M

Swedish partner: Karolinska Insitute and Uppsala University (+ Stockholm University as third party)

Project website: https://b1mg-project.eu/

GDI - Genomic Data Infrastructure (2022 – 2026)

The Genomic Data Infrastructure (GDI) project aims to create a secure and sustainable infrastructure for accessing genomic, phenotypic, and clinical data held in databases across Europe. This project builds upon the Beyond 1 Million Genomes (B1MG) project and supports the ambition of the 1+Million Genomes (1+MG) initiative by establishing a federated network of national reference genome collections. The GDI project involves experts from various fields and organizations to ensure ethical and legal compliance while allowing access to secure datasets. The project will use "real" synthetic data for validation before making the data accessible through the infrastructure. The €40M project is building on the work of 1+MG and B1MG projects and aims to create the technical capacity for accessing genomic data to realize the vision of the 1+MG initiative.

Total budget: €40 M

Swedish partners: Uppsala University and Vinnova, the Swedish Agency for Innovation Systems

Project website: https://gdi.onemilliongenomes.eu/

EUCAIM – European Cancer Imaging Initiative (2023-2026)

The European Federation for Cancer Images (EUCAIM) has partnered with 76 other organizations to create a pan-European digital infrastructure that will collect and share de-identified cancer-related images from real-world sources. The purpose of this infrastructure is to support the development and testing of AI tools for precision medicine. EUCAIM aims to address the problem of fragmented cancer image repositories by combining existing repositories and including a variety of clinical data, such as pathology and molecular information. The infrastructure will be compliant with legal regulations and will define common data models, ontologies, quality standards, and de-identification procedures. The platform will provide a dashboard for data discovery, annotation, and distributed processing, including privacy-preserving learning. A central hub will be created to host the Atlas of Cancer Images, which will be used to develop reliable AI tools. EUCAIM will assist new providers in joining the federation and monitoring the infrastructure. The goal is to create a sustainable repository of high-quality data and tools that will benefit clinicians, researchers, and innovators working on cancer diagnosis, treatment, and predictive medicine.

Total budget: €17.8 M.

Swedish partners: Linköping University, Karolinska Insitutet, Västerbotten region, Umeå University, Uppsala University

Project website: www.cancerimage.eu (not yet online as of end February 2023)