EOSC-Life

EOSC-Life: Building a digital space for the life sciences

D4.5 – Public database inventorying the national health databases and registries and describing their access procedures for reuse for research purposes

WP4 – Policies, specifications and tools for the management of data for biological and medical research
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Executive Summary

The digitisation of healthcare has brought new opportunities to complement and enhance the data traditionally utilized in regulatory decision-making. According to the EMA, real world evidence (RWE) has been defined as the information derived from analysis of routinely collected real world data (RWD) relating to a patient's health status or the delivery of healthcare from a variety of sources other than traditional clinical trials. Before fostering the enormous potential presented by the use of routinely collected RWD (e.g. electronic health records, medical claims, insurance data etc.) several challenges need to be addressed: operational, technical, methodological and ELSI. Reusing RWD for research purposes in Europe and especially in a cross-border manner is hampered by the fact that health databases and registries are not easily discoverable and, even when they are, understanding what data they contain and their suitability for addressing a specific research question remains not trivial due to the lack of detailed data catalogues with adequate metadata (especially in English).

The present report is entitled "*D4.5 Public database inventorying the national health databases and registries and describing their access procedures for reuse for research purposes*". As the title indicates, the report delivers an inventory of national health databases and registries covering 15 European countries: Austria, Czech Republic, France, Germany, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland. For each country the reader can find information on the national healthcare system, a list of health databases and registries, their description (or links to websites where this description can be found) and information on data access for research purposes. Although this deliverable was initially conceived as a "public database" in the form of a website, the EOSC-Life WP4 partners agreed that this would be unnecessary as the European Health Information Portal[1] is already playing this role. Instead, this report will become publicly available through Zenodo and disseminated to relevant stakeholders working on similar issues (including the actors behind the Health Information Portal) as a way to "join forces" and complement each other's work instead of duplicating efforts.

In summary, we conclude that the picture across Europe is diverse and at times patchy as the health databases and registries are subject to different governance and sustainability models but also to different local laws and access rules. Interestingly, there is still, on a European level, great debate around the terms "anonymisation", "pseudonymisation" and "de-identification" and when data can be considered anonymised and as such exempted from the GDPR. Additionally, even when the current barriers of discoverability and accessibility (that are the main focus of this report) are lifted, there remains the major question of whether such data sources are suitable for research, as concerns around their quality, completeness and structure (or lack of) are still to be addressed.

[1] https://www.healthinformationportal.eu/

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Introduction

The potential of using Real World Data and Real World Evidence

The use of computers, mobile devices, wearables and other biosensors to gather and store huge amounts of health-related data has been rapidly accelerating. These data hold the potential to allow for a better design and conduction of clinical studies in the healthcare setting to answer questions previously thought infeasible. In addition, with the development of sophisticated, new analytical and computational capabilities, including those emerging from the application of artificial intelligence, we are now able to better and faster analyse these data and apply the results of our analyses to medical product development and approval.

According to the European Medicines Agency (EMA), real world evidence (RWE) has been defined as the information derived from analysis of routinely collected real world data (RWD) relating to a patient's health status or the delivery of healthcare from a variety of sources other than traditional clinical trials.

RWD can come from a number of sources, for example:

- Electronic Health Records (EHRs)
- Medical claims, billing data, and insurance data
- Data from product and disease registries
- Patient-generated data, including from in-home-use settings
- Data gathered from other sources that can inform on health status, such as mobile devices.

The use of RWE to support regulatory decision-making is not new. For decades, such data have been used in the post-authorization phase for safety signal evaluation, risk management, and for studies to support life cycle benefit-risk evaluation. A recent review conducted by the EMA describing the characteristics of RWE included in new marketing authorization applications (MAAs) and extensions of indication (EOIs) for already authorized products submitted to the EMA in 2018 and 2019 indicated that: For MAAs, 39.9% of the products contained RWE and the most common data sources were registries (60.3%) followed by hospital data (31.7%). For EOIs, 18.3% of the products contained RWE and the data sources were mainly registries (35.6%) and hospital data (27.0%) [1].

Despite the increasing potential of RWD and RWE, the best available standard of evidence to date is the randomised controlled trial (RCT). RCTs will, in our view, remain the best available standard and are required in many circumstances, but the rapid pace of change in the scientific and technological landscapes is shifting the regulatory landscape. We are seeing an increasing number of products that face challenges to align with the traditional drug development pathway, e.g. advanced therapies or orphan products for conditions with significant unmet needs and for which a traditional RCT may be unfeasible or unethical. In addition, clinical trials have well-defined inclusion and exclusion criteria and rigid protocols, which give them greater internal validity, but which have also been criticised as reasons for poor external validity in "real-world" settings [2].

Although the interest in RWE for drug approvals has increased globally, the conditions for RWE acceptability and applicability by regulatory authorities have only recently been defined or in many cases remain still to be clarified [3]. In the U.S. the Food and Drug Administration (FDA)

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issued in 2018 the FDA RWE framework[2], Health Canada published in 2019 guidance in "Optimizing the use of RWE to inform regulatory decision making"[3], in Japan the Pharmaceuticals and Medical Devices Agency (PMDA) provided in 2021 basic principles on the use of registries in approval applications[4] and points to consider for ensuring reliability when registry data are used for approval applications[5], in China the National Medical Products Administration (NMPA) published in 2021 guidance on Real-world Data used to Generate Real-world Evidence[6].

In Europe, the EMA and the European Commission have been discussing the potential of RWD and RWE for several years. In 2015, the use of RWE for drug regulation was explored within the EMA Adaptive Pathways Pilot[7]. In 2019, the EMA published the Operational, Technical, and Methodological (OPTIMAL) framework for regulatory use of RWE in regulatory decision making [4]. In 2020, two strategic documents were published: the Regulatory Science to 2025[8], which promotes high-quality RWD in decision making to generate complementary evidence across the product life cycle and the EMA's Network Strategy to 2025[9], which includes focus areas on data analytics, digital tools, and digital transformation to enable access to and analysis of routine healthcare data, to promote standardization of targeted data, and to build sustainable capability and capacity within the network, including statistics, RWD, and data analytics.

In summer 2022, the EMA endorsed a joint statement published by the International Coalition of Medicines Regulatory Authorities (ICMRA)[10] calling for international collaboration to enable the generation and use of RWE for regulatory decision-making. The statement was developed following a workshop co-organised by the EMA, the FDA and Health Canada, held in Amsterdam in June 2022. In their statement, ICMRA members pledge to foster global efforts and further enable the integration of RWE into regulatory decision-making.

Challenges around the use of Real World Data in Europe

From a European perspective, utilising RWD comes with several challenges: operational, technical, methodological and ELSI. Operational challenges include discoverability, feasibility, governance, and sustainability issues, which complicate access to and the routine use of multiple national data sources. In addition, different data sources have different legal and ethical requirements for data sharing (e.g. different legal basis for data processing such as informed consent vs public interest, different levels of data de-identification such as pseudonymisation vs anonymisation etc.). The General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679 of the European Parliament and of the Council) is currently the main regulation governing data processing in the European Economic Area (EEA) and its exemptions to data processing applicable

[2] https://www.fda.gov/media/120060/download
[3] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/optimizing-real-world-evidence-regulatory-decisions.html
[4] https://www.pmda.go.jp/files/000240810.pdf
[5] https://www.pmda.go.jp/files/000240811.pdf
[6] https://redica.com/wp-content/uploads/NMPA_-Attachment_-_Guiding-Principles-of-Real-World-Data-Used-to-Generate-Real-World-Evidence-Trial_.pdf
[7] https://www.ema.europa.eu/en/documents/report/final-report-adaptive-pathways-pilot_en.pdf
[8] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf
[9] https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf
[10] https://icmra.info/drupal/sites/default/files/2022-07/icmra_statement_on_rwe.pdf

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to clinical and scientific research have caused great confusion among the scientific community as its implementation is inconsistent throughout Europe due to different national derogations. In addition, the legal framework of the secondary use of health data for research purposes is about to change in the next years as the proposal for a Regulation on the European Health Data Space (EHDS)[11] is currently being discussed at the European Council and the Parliament.

Technical challenges encompass those associated with the data and the different terminologies, data formats, quality, and content that exist across multiple European health databases. Europe is fortunate in the richness of its healthcare data, which stems from the principle of universal healthcare coverage that applies in most countries. However, the data are heterogeneous as differences in healthcare systems, national guidelines, and clinical practice have driven different content. This poses problems when results from multiple datasets must be pooled in order to deliver evidence representative of the wider European population or when larger numbers are needed to explore rare diseases, events, or outcomes.

Methodological challenges arise from the fundamental fact that observational data are not collected with research as their principal purpose and as such these might suffer from missing data as well as from various biases and confounders.

Scope and methodology

The present report is entitled "*D4.5 Public database inventorying the national health databases and registries and describing their access procedures for reuse for research purposes*" and is a deliverable of the EOSC-Life project[12]. The EOSC-Life project brings together the 13 Life Science Research Infrastructures (LS RIs) within the European Strategy Forum for Research Infrastructures (ESFRI)[13] to create a European Open Science Cloud (EOSC) for the life sciences. The ambition of the EOSC is to provide European researchers, innovators, companies and citizens with a federated and open multi-disciplinary environment where they can publish, find and reuse data, tools and services for research, innovation and educational purposes. The EOSC is recognised by the Council of the European Union among the 20 actions of the policy agenda 2022-2024 of the European Research Area (ERA)[14] with the specific objective to deepen open science practices in Europe. It is also recognised as the "science, research and innovation data space" which will be fully articulated with the other sectoral data spaces defined in the European strategy for data[15].

Within the EOSC-Life project, WP4 is concerned with policies, specifications and tools for the management of data for biological and medical research. The D4.5 report aims to provide an inventory of RWD sources in Europe (*"national health databases and registries"*) and describe their *"access procedures for reuse for research purposes"*. The main data sources listed are EHR and product and disease registries. Other data sources, such as medical claims have also been considered depending on their potential relevance for research purposes. Patient-generated data and data generated with wearables are out of the scope for this report.

[11] https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en
[12] https://www.eosc-life.eu/
[13] https://www.esfri.eu/
[14] https://ec.europa.eu/info/sites/default/files/research_and_innovation/strategy_on_research_and_innovation/documents/ec_rtd_era-policy-agenda-2021.pdf
[15] https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en

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Currently, there is not a uniform European definition of "EHR" (although some EU countries have provided definitions in their legislation) and what in detail it comprises but for the purpose of this report we define "EHRs as an organized set of healthcare data, which can be accessed electronically". They can contain a diversity of data, the most frequent being medical records from general practitioners, specialists or hospitals, pharmacies and prescription data. We also define "registries as organised systems that use observational methods to collect longitudinal, uniform data on a population defined by a particular disease, condition, or exposure".

The methodology that we followed for the identification of national health databases and registries consisted of:

- Identification of national experts (e.g. local scientists, data managers, members of ethics committees etc.)
- Interviews with key national experts when relevant/possible
- Screening of publicly available inventories created for European Commission-funded research projects (e.g. https://www.healthinformationportal.eu/)
- Screening of national sources (e.g. website of Ministry of Health, national institutes, research bodies) both in English and local language
- Search on literature databases (e.g. PubMed) in English and local language

As a first step, and in order to better understand the European landscape, we started collecting information through interviews with identified representatives of selected national initiatives (identification of several European data sharing initiatives and provision of a semi-structured interview guide for the collection of information have been reported in a previous deliverable of WP4, *D4.2 Report on requirements for regulatory compliance of sensitive health data and biological and medical research data management*[16]).

In total, experts from 13 countries were identified and interviewed in the period from October 2019 to March 2021. The interviews were conducted through video calls of about a 1-hour duration and the interviewees were **guaranteed anonymity**. Although the interview phase provided valuable input that has been included in the individual country reports that can be found in the following sections, it soon became clear that single country experts do not have an overview of the health databases and registries existing in their countries. Obtaining information on specific requirements for data access for research purposes during the interviews was also a challenge and in several cases the experts were referring us to other key legal or technical people that could help us comprehend better the situation in the country. This led to "snowballing" of experts that were largely not EOSC-Life beneficiaries and as such had limited time to invest to this task. In addition, as most of the people contacted are working in health-related organisations, their responsiveness and priorities during the COVID-19 pandemic switched towards tackling the pandemic.

The above challenges narrowed the geographical scope of this report to the following 15 countries, which are either represented in EOSC-Life WP4 or sufficient information could be obtained via interviews with external national experts:

- Austria
- Czech Republic
- France
- Germany

[16] https://zenodo.org/record/3820390#.YysiAuzMKLp

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- Hungary
- Ireland
- Italy
- The Netherlands
- Norway
- Poland
- Portugal
- Slovakia
- Spain
- Sweden
- Switzerland

The information found in this report has been collected with the help of partners from ECRIN[17], BBMRI[18], EATRIS[19] and their national collaborators. Having people speaking the local language on-boarded in the task was key as in several countries (e.g. Czech Republic, Slovakia, Poland, etc.) the information regarding the description of the national health databases and registries and the relevant requirements for data access was only available in the local language.

Figure 1: Geographical scope of the present report (map designed with https://www.mapchart.net/)

[17] https://ecrin.org/
[18] https://www.bbmri-eric.eu/
[19] https://eatris.eu/

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For each of the 15 countries an individual country report is provided. In terms of content, each country report includes:

I. Key information regarding the country's healthcare system
II. Listing of national health databases and registries and descriptions (or links to descriptions) of what they contain
III. Information on requirements for data access.

Each country report is 2-8 pages long and has been written by (or with the contribution of) one or several national experts. Having the input of at least one national expert per country was seen as crucial for writing these reports. The information provided for each country is given in **different granularity** (e.g. some authors have chosen to describe in detail the processes for data access while others simply provide a link leading to the website where this information can be found). In addition, the data sources listed for each country **should not be seen as an exhaustive national inventory**. The authors tried, to the best of their capacity, to provide a good overview of the situation in each country but it might well be that important data sources have been omitted. There has also been no intention by the authors to "evaluate" the data sources listed and their potential for scientific research. The focus of this report is to list for each country relevant health databases and registries, describe them or provide links to their description and give information on data access requirements. The provision of links to the relevant websites is also seen as particularly important as the data access policies are constantly changing, reflecting also the changes in the legal landscape.

The report will be made publicly available in Zenodo and promoted to inform existing similar initiatives[20]. The European Health Information portal is an already existing "public database" with the scope of enhancing the discoverability of RWD sources in Europe and provide guidance on access procedures.

1. Austria

1.1. Healthcare system

In Austria, at the national level, the healthcare system is managed by the Federal government, through the Ministry of Health Federal Ministry of Labour, Social Affairs, Health, and Consumer Protection (BMSGPK)[21], which is responsible for general health policy, the protection of the health of the population, the regulation of the health professions, pharmacies and medicines, as well as for legislation and the supervision of the social insurance funds. It prepares federal legislation, draws up administrative regulations, is active as a decision-maker and also as a supervisory authority, and acts as a coordinator among the most important stakeholders in the healthcare system. Alongside the Federal government, the nine (9) provinces (Länder) within Austria at a regional level are also jointly responsible for the operation of hospitals, and pre-clinical emergency care (alongside the local authorities). In addition, the provinces enact important legislation in the social sector and are responsible for the provision of social services (including nursing care and long-term care).

[20] E.g. https://www.healthinformationportal.eu/
[21] https://www.sozialministerium.at/

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The Austrian healthcare system is characterised by a high density of easily accessible healthcare facilities. Austria has a high standard of compulsory state-funded (i.e. public) healthcare. Enrolment in the public healthcare system is generally automatic and is mostly linked to employment, however, insurance is also guaranteed to co-insured persons (i.e. spouses and dependants), pensioners, students, the disabled, and those receiving unemployment benefits. The first point of contact for patients is the general practitioner (GP) or "Hausarzt/in". They provide healthcare services ranging from standard gynaecological and paediatric examinations, while when needed, they are the ones to refer patients to other services such as hospitals, specialists, home midwifery and physiotherapy.

There exist three (3) areas of social insurance within Austria; namely: Health, accident and pension[22]. The Austrian healthcare system is based on statutory social insurance, regulated by law, with the most important legislative instrument being the General Social Insurance Act ("Allgemeines Sozialversicherungsgesetz" – "ASVG"). Until recently, there were about twenty-eight (28) social insurance institutions permitted under public law, however, these have now been narrowed down to five (5) institutions under the Social Insurance Organisational Act ("Sozialversicherungs-Organisationsgesetz" – "SV-OG"). As regards health, the Austrian health insurance fund: ("Österreichische Gesundheitskasse" – "ÖGK"[23]) provides cover for all primary healthcare services delivered by contract physicians of the Austrian social health insurance fund, special in-patient and out-patient care, emergency care, maternity services, x-ray and laboratory test, dental services, ambulance services, including other medical care.

1.2. Health databases and registries

- **BBMRI.at - Biobanking and BioMolecular resources Research Infrastructure, Austria**

BBMRI.at[24] is the Austrian Node of BBMRI-ERIC[25], the European Biobanking Research Infrastructure, which is jointly operated by twenty-three (23) countries and one (1) international organisation (WHO/IARC). It supports biomedical research and facilitates access to human and animal samples and collaborations. As a partner[26] to the following institutions namely: Medical University of Graz (with Biobank Graz), Medical University of Vienna (with MedUni Wien Biobank), Medical University of Innsbruck (with Biobank Innsbruck), Johannes Kepler University (Linz) (with Biobank), Paracelsus Medizinische Universität, Salzburg (Biobank Salk), University of Vienna (BBMRI.at ELSI Experts), Alpen Adria Universität Klagenfurt (BBMRI.at ELSI Experts) and University of Veterinary Medicine (VetBioBank); and to this end, it aimed to establish a state-of-the-art biobanking infrastructure in Austria and to increase close cooperation and harmonization between biobanks as well as a one-stop-shop for facilitating access and fostering the use of biological samples and data for academic and industrial research projects.

- **The Austrian Cancer Registry (Österreichisches Krebsregister)**

The Austrian Cancer Registry[27], as maintained by Statistics Austria[28], collects data on cancer incidence and mortality, as well as population, from ages 0-95. Data collection began in 1983 and

[22] https://www.sozialministerium.at/en/Topics/Social-Affairs/Social-Insurance.html
[23] https://www.gesundheitskasse.at/cdscontent/?contentid=10007.866742&portal=oegkportal
[24] http://bbmri.at/home
[25] https://www.bbmri-eric.eu/national-nodes/
[26] https://bbmri.at/partners
[27] https://ghdx.healthdata.org/organizations/austrian-cancer-registry

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has since continued annually. The information it collects comprises newly diagnosed cancer patients in Austria, including cancer diagnosis, tumour staging, tumour site (topography) and morphology (histology), co-morbidity at diagnosis and treatment received directly after diagnosis. Some overview information is publicly available through Statistics Austria[29] (and does not require any formal access process), although the data available in "Guest Access" is restricted with respect to structural depth and volume and the size of query tables is limited.

- **COVID-19 Data Platform (Datenplatform COVID-19)**

Founded in May 2020, the Federal Ministry of Labour, Social Affairs, Health, and Consumer Protection (BMSGPK)[30] commissioned the Gesundheit Österreich GmbH (GÖG)[31] to set up the COVID-19 data platform[32]. This was intended to support both the national and international scientific community in increasing the evidence and understanding of SARS-CoV-2 and COVID-19 by providing access to data from the Austrian epidemiological reporting system, data on hospital and intensive care unit admissions due to COVID-19 as well as data on SARS-CoV-2 genome sequencing for academic and scientific institutions.

Access to data from the COVID-19 Data Platform

The following criteria must be met by research institutions in order to receive accreditation by GÖG and subsequent access to the data in the platform:

- The applicant organization must meet at least one of the following two requirements:
  1. The applicant institution is a research institution that falls under Section 2c (1) of the Research Organization Act - FOG[33].
  2. The applicant institution corresponds to the definition of a scientific institution according to § 2b Para. 12 FOG.
- The applicant institution must provide the following information in its application submitted using the online form[34]: The full name of the institution, the short title, if available, the address, the name of the organizational unit, the name, job title, telephone number and e-mail address of the authorized representative, a declaration of intent by the applicant institution that the results of the work or parts thereof will be published within a reasonable period of time after the data has been transmitted.
- The research institution applying must justify in a factually comprehensible manner that the data from the epidemiological reporting system are required for the intended research project (purpose of use). The probable duration of the research project must also be stated. The research institution applying must state whether the research project in question is financed from third-party funds.

In summary the process:

[28] https://www.statistik.at/en
[29] https://www.statistik.at/en/statistics/population-and-society/health/cancer
[30] https://www.sozialministerium.at/
[31] https://goeg.at/Ueber_uns
[32] https://datenplattform-covid.goeg.at/
[33] https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10009514
[34] https://datenplattform-covid.goeg.at/antrag

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1. **Submitting the application**

   After an application for accreditation has been submitted online, GÖG checks it for formal correctness and completeness and, based on the examination of the specified accreditation criteria, makes a non-binding recommendation regarding the accreditation decision to the advisory board. Here is the online application[32].

2. **Application review: The Advisory Board reviews the application - Conclusion of contract**

   GÖG notifies the applying research institution about the outcome of the accreditation procedure. If the Advisory Board decides positively, the GÖG will conclude a corresponding free data usage contract. This regulates, for example, the purpose and research goal/question, rights of use (criteria for publication), confidentiality and data protection, organizational criteria, etc. If the Advisory Board comes to a negative decision (rejection of the accreditation application), this will be justified in writing and communicated to the respective institution accordingly.

3. **Granting of data access**

   After the contract has been concluded, the access data will be transmitted and access to the data platform will be set up.

Regional and international rare diseases (RD)-related registries

There are a number of patient registries and databases in Austria that constitute key instruments for developing clinical research in the field of rare diseases (RD), to improve patient care and healthcare planning.

The Orphanet network[35] offers a unique catalogue with reports including data about EU countries and other countries that participate in the network. There are about thirty-three (33) registries comprising a list of regional and national RD-related registries, including national registries part of or participating in larger European or international registries within Austria. These include but are not limited to:

- **AGMT (Arbeitsgemeinschaft medikamentöse Tumortherapie): Adult acute lymphoblastic leukaemia (ALL) - Registry and Biobank**

This Austrian ALL study group was established as the first step as a registry with a standardized data set to harmonize diagnosis and treatment and to make optimal therapy available for Austrian patients. Therefore, the information on these patients was prospectively collected, analysed and used for the generation of treatment protocols. For more information see:

http://agmt.at/wp-content/uploads/2019/04/AGMT_ALL_Register_Poster_OeGHO_2019_web.pdf

- **Austrian Haemophilia Registry - Registry for patients with inborn coagulation defects**

This was a joint initiative between Austrian haemophilia treaters, represented by the Austrian Haemophilia Society's scientific advisory board, and the Austrian Haemophilia Society ("Österreichische Hämophilie Gesellschaft" – "ÖHG"[36]). The registry's main objective was to

[35] https://www.orpha.net/orphacom/cahiers/docs/GB/Registries.pdf
[36] http://bluter.at/joomla/new_site/

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record information on patients with haemophilia, such as the severity of disease, types of treatment and general health status. The registry also aims to improve the planning of supply of factor concentrates and to provide an instrument for early detection of side effects, such as an increase in inhibitor development or certain infections. The registry consists of three (3) parts: the first contains basic information on quality control, the second contains extended data for quality control collected annually, and the third, the study part, covers scientific data and is also updated annually. For the latter, written informed consent of each patient is a prerequisite. Data is stored centrally on a server of an independent, public institution. For more information see [5].

- **Ceprotin Treatment Registry**

The Ceprotin Treatment Registry is a prospective, international, multi-center, open-label, non-interventional, observational study designed to examine the long-term safety and effectiveness of protein C concentrate (human) in the clinical setting. For more information see [6].

- **Disorders of Cornification Innsbruck**

On the basis of existing structures at the Medical University of Innsbruck, which bring extensive expertise in the field of rare genetic skin diseases to this initiative, the Center for Genodermatoses with a focus on cornification disorders was founded as the core area of the Center for Rare Diseases Innsbruck (ZSKI) which cooperates closely with human genetics to tackle rare diseases that show a primary manifestation on the skin, on other ectodermal structures such as hair, nails and teeth, or on connective tissue. For more information see:

https://dermatologie.tirol-kliniken.at/page.cfm?vpath=expertisezentren/zentrum-fuer-genodermatosen-verhornungsstoerungen/ziele-des-zentrums.

1.3. Access to data

In Austria, there are different institutions providing public access to aggregated data that can be useful for scientific research purposes:

Statistics Austria[37] provides public access to various anonymized health data such as COVID-19 data[38], cancer data[39], data on health determinants such as nutrition[40] or smoking[41], data on hospital discharges[42] and so on. The same applies to the Austrian social insurance system, which publishes statistics on the number of insured persons (pension insurance, health insurance, accident insurance) and on care recipients as well as on the number of employed persons in Austria[43]. The hospital discharge database[44] includes information on procedures, diagnosis (coded according to ICD-10), length of stay, department and selected sociodemographic characteristics such as age, gender and place of residence, with aggregated data at the federal state level being publicly available[45].

[37] https://www.statistik.at/en
[38] https://www.statistik.at/en/statistics/population-and-society/health/covid-19
[39] https://www.statistik.at/en/statistics/population-and-society/health/cancer
[40] https://www.statistik.at/en/statistics/population-and-society/health/health-determinants/nutrition
[41] https://www.statistik.at/en/statistics/population-and-society/health/health-determinants/smoking-habits
[42] https://www.statistik.at/en/statistics/population-and-society/health/health-care-and-expenditure/inpatient-health-care-hospital-discharges
[43] https://www.sozialversicherung.at/cdscontent/?contentid=10007.821590&portal=svportal
[44] http://www.kaz.bmg.gv.at/ressourcen-inanspruchnahme/stationaere-aufenthalte.html
[45] http://www.kaz.bmgf.gv.at/

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Researchers interested in obtaining access to data that is not publicly available should contact the respective database to explore the requirements for data access. Statistics Austria for example operates the statistical database STATcube[46], which can provide, under payment, retrieval of large volumes of data and access to datasets locked under the publicly available "Guest Access" (subject to data privacy restrictions).

Health databases and registries in Austria have to be in compliance with the EU General Data Protection Regulation (GDPR)[47], as they process personal data and often sensitive data. It must be emphasized that two (2) legal acts in Austria ensure the proper application of the GDPR. Firstly, the Austrian adaptation to the GDPR (in Austria, "Datenschutzgrundverordnung – "DSGVO"), the Federal Act concerning the Protection of Personal Data ("Datenschutzgesetz" – "DSG")[48]. The national supervisory authority on the proper implementation of data protection is entrusted to the Austrian Data Protection Authority ("Datenschutzbehörde" – "DSB")[49], which is supervising the processing of personal data in order to ensure compliance with the GDPR and the DSG. Secondly, the specific law when it comes to research, the Austrian Research Organisation Act ("Forschungsorganisationsgesetz" – "FOG")[50] as relating to Article 89 GDPR ensuring derogations from data subject rights where personal data are processed for scientific/historical research or statistical purposes. The Federal law on Data Security Measures when Using Personal Electronic Health Data and Genetic Data (Health Telematics Act 2012 - GTelG 2012)[51], which in turn was enacted by the Electronic Health Records Act ("Elektronische Gesundheitsakte-Gesetz" – "ELGA")[52], which is an integral part of the Austrian Penal Code, is also applicable in the case of health databases and registries and it states that participants in medical research must be adequately informed on the research conducted and that permission is needed to access their data. The ELGA system simplifies the process of accessing and regulating patient health records on access and exchange of these health data within healthcare.

2. Czech Republic

2.1. Healthcare system

The Czech statutory health insurance system is based on universal coverage and a basic universal benefit package provided as benefits-in-kind for all insured individuals. Universal accessibility of healthcare is stipulated by the legislation, particularly the law on public health insurance (Zákon o veřejném zdravotním pojištění 48/1997 sb). The system is financed primarily through mandatory, wage-based statutory health insurance contributions administered by the health insurance funds. The health insurance funds are quasi-public self-governing bodies that act as payers and purchasers of healthcare and they compete for insured individuals. The biggest one, the General Health Insurance Company (Všeobecná zdravotní pojišťovna)[53] covers approximately 60% of the

[46] https://www.statistik.at/datenbanken/statcube-statistische-datenbank
[47] https://eur-lex.europa.eu/eli/reg/2016/679/oj
[48] https://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf
[49] https://www.dsb.gv.at/
[50] https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10009514
[51] https://www.ris.bka.gv.at/Dokumente/Erv/ERV_2012_1_111/ERV_2012_1_111.pdf
[52] https://www.gesundheit.gv.at/gesundheitsleistungen/elga.html
[53] https://www.vzp.cz/

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population. Membership in one of the seven health insurance funds is compulsory for all Czech citizens residing in the country, as well as for other permanent residents in the Czech Republic. Other sources of financing include general taxation and out-of-pocket payments. The state is represented by both the Parliament, which is the main legislative body in the country, and the Ministry of Health (Ministerstvo zdravotnictví)[54], the responsibilities of which include setting the healthcare policy agenda and supervising the health system, as well as running several healthcare facilities. Additionally, the National Institute of Public Health (Státní zdravotní ústav, SZÚ)[55], the State Institute for Drug Control (Státní ústav pro kontrolu léčiv, SÚKL)[56] and regional public health authorities are subordinate to the Ministry of Health.

2.2. Health databases

In their majority, healthcare providers in the Czech Republic use a computerized information system to charge the health insurance funds for goods and services. Nevertheless, the collected data are largely unsuitable for uses other than reimbursements due to their structure and legal considerations. Data for health policy and research purposes are collected, instead, by the Czech Institute of Health Information and Statistics (Ústav Zdravotnických Informací a Statistiky, ÚZIS)[57], which was founded in 1960 by the Ministry of Health.

ÚZIS manages and refines the National Health Information System (NHIS).

NHIS is a unified nationwide information system designated for:

- processing data on the health status of the population, on activities of healthcare providers and on their economy, on healthcare professionals and other workers in health services, to obtain information about the extent and quality of provided health services, their management and creation of health policy,
- maintaining National Health Registers and processing the data stored in them,
- maintaining the National Register of Health Services Providers and the National Register of Healthcare Professionals and processing the data stored in them,
- performing and processing sample surveys on the health status of the population, on health determinants, on the need and consumption of health services and satisfaction with the services and on expenditure on health services,
- the needs of science and research in the field of health,
- processing of data for statistical purposes and for providing data and statistical information.

In terms of data collection, NHIS includes:

- Data from the departmental Program of Statistical Surveys and from statistical surveys carried out by the Ministry outside the Program of Statistical Surveys collected under the Act on the State Statistical Service[58],
- National Health Registries[59],
- National Register of Providers[60],

[54] https://www.mzcr.cz/en/the-ministry-of-health/
[55] http://www.szu.cz/
[56] https://www.sukl.cz/
[57] https://www.uzis.cz/index-en.php
[58] https://www.uzis.cz/index.php?pg=registry-sber-dat--vykazy
[59] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry
[60] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-registr-poskytovatelu-zdravotnich-sluzeb

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- National Register of Healthcare Professionals[61],
- National health registers kept under the law governing transplantation[62],
- Data taken from infectious disease information systems maintained under the Public Health Protection Act[63],
- National Register of Paid Health Services[64],
- Data from the Examination Letters[65],
- Data on the cost of hospitalization transmitted to providers from the reference network of providers according to the Public Health Insurance Act[66],
- Data from statistical surveys carried out by ÚZIS.

ÚZIS collaborates with the WHO, OECD, UN, and EUROSTAT and contributes with Czech national data to the following international health databases: European Core Health Indicators[67], OECD Health Data[68], European Health Information Gateway (WHO)[69].

2.3. Registries

As of 1 July 2016, and as stated in the Act. no. 147/2016 Sb[70]. The national health registers are the following:

- National Cancer Register (Národní onkologický registr)[71]
- National Register of Hospitalised Patients (Národní registr hospitalizovaných)[72]
- National Register of Reproduction Health (Národní registr reprodukčního zdraví)[73]
- National Register of Cardiovascular Surgery and Intervention (Národní registr kardiovaskulárních operací a intervencí)[74]
- National Register of Joint Replacement (Národní registr kloubních náhrad)[75]
- National Register of Occupational Diseases (Národní registr nemocí z povolání)[76]
- National Register of Therapy of Drug Users (Národní registr léčby uživatelů drog)[77]
- National Register of Injuries (Národní registr úrazů)[78]
- National Register of Persons Permanently Excluded from Blood Donation (Národní registr osob trvale vyloučených z dárcovství krve)[79]

[61] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-registr-zdravotnickych-pracovniku
[62] https://www.uzis.cz/index.php?pg=registry-sber-dat--ostatni-rezortni-registry--registry-kst
[63] https://www.uzis.cz/index.php?pg=registry-sber-dat--ochrana-verejneho-zdravi
[64] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-registr-hrazenych-zdravotnich-sluzeb
[65] https://www.uzis.cz/index.php?pg=registry-sber-dat--ostatni-rezortni-registry--list-o-prohlidce-zemreleho
[66] https://www.uzis.cz/index.php?pg=o-nas--projekty&prid=9
[67] https://health.ec.europa.eu/other-pages/basic-page/european-core-health-indicators-echi_en
[68] https://data.oecd.org/health.htm
[69] https://gateway.euro.who.int/en/
[70] https://www.zakonyprolidi.cz/cs/2016-147
[71] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-onkologicky-registr
[72] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-hospitalizovanych
[73] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-reprodukcniho-zdravi
[74] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-kardiovaskularnich-operaci-a-intervenci
[75] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-kloubnich-nahrad
[76] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-nemoci-z-povolani
[77] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-lecby-uzivatelu-drog
[78] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-urazu
[79] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-osob-trvale-vyloucenych-z-darcovstvi-krve

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- National register of Autopsies and Toxicological Examinations Performed at Forensic Medicine Departments (Národní registr pitev a toxikologických vyšetření prováděných na oddělení soudního lékařství)[80]
- National Diabetological Register (Národní diabetologický registr)[81]
- National Register of Intensive Care (Národní registr intenzivní péče)[82]

The purpose of the registries is among others the monitoring of the evolution, causes and consequences of serious diseases, including their economic consequences and the impact on the social sphere and the economy of the social system, the monitoring of patients with injuries, the statistical and scientific processing of the registered data, focusing particularly on the analysis of the health status of the population and the utilisation and quality of healthcare, with the aim of improving the health of the population.

2.4. Access to data

Individual data from the registries are not publicly accessible. Data from the registries are provided to users only in aggregated form (e.g. for territories, kinds of health establishments, groups of diagnoses or individual diagnoses). Anonymised individual data may be provided for secondary use of the data for scientific research. Except for cases when data are directly used in the provision of healthcare, identification of subjects of data does not apply to identification of persons but only to determine whether different reports to the registers pertain to the same person or to different persons. Such identifiers of persons aim to enhance the precision of statistical processing by allowing removal of duplicate notifications, supplementing, purging for deaths when applicable etc.

To access the data held by ÚZIS for research purposes, an application needs to be sent according to the information provided in the following link:

https://www.uzis.cz/index.php?pg=registry-sber-dat--registrace-a-vstup-do-registru.

A difficulty for data requestors is that the page itself and much of the documentation is at the moment only available in Czech.

The Czech Republic does not have specific legislation regulating the secondary use for research of data collected initially for healthcare purposes. However, the following are applicable:

Art. 73 para 8 of the Health Services Act states that data collected in National Health Registries can be provided by the Statistics Institute for scientific and statistical purposes **based on request**, only in the form from which no specific natural person or legal entity can be identified. Furthermore, the Health Services Act deals with using human body parts removed during the provision of health services (such as tissue) for research purposes in Art. 81.

Act No. 110/2019 Coll., Processing of Personal Data Act does not contain specific rules for the processing of health data Art. 16 para 1 specifies safeguards referred to in Art. 89 of GDPR that are necessary when processing personal data (including health data) for scientific or historical research or statistical purposes.

[80] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-pitev-toxikologickych-vysetreni#o-registru
[81] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-diabetologicky-registr
[82] https://www.uzis.cz/index.php?pg=registry-sber-dat--narodni-zdravotni-registry--narodni-registr-intenzivni-pece

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Multiple legal bases are possible, e.g. explicit consent, broad consent, public interest in the field of public health and research purposes. Therefore, the legal basis used by researchers may differ depending on the research project and the questions it addresses.

The Additional Protocol to the Convention on human rights and biomedicine, concerning biomedical research[83], entered into force in the Czech Republic on the 1st September 2020.

3. France

3.1. Healthcare system

The French healthcare system is funded by a dual system of health insurance comprising:

- A State-controlled health insurance social security system, "l'assurance maladie".
- A separate voluntary health insurance system called "assurance complémentaire" provided through mutual organisations and private insurers.

The main health insurance fund is the General Fund (Régime Général), which covers about 85% of the population working in industry and commerce, as well as the unemployed and those retired and not affiliated to another fund. At a local level, the General Fund is administered by a health authority, the Caisse Primaire d'Assurance Maladie (CPAM). There are also separate health insurance funds for agricultural employees, called the Agricultural Fund ("Régime Agricole"), as well as other Special Funds ("Régimes Spéciaux"), covering certain professional groups (e.g. marines, railway workers).

The Ministry of Solidarity and Health (Ministere des Solidarites et de la Santé) administers public healthcare in France, with primary and secondary care services delivered by various different healthcare providers. France offers a high level of preventative healthcare, with available services including addiction prevention, regular medical check-ups, and the promotion of physical activity and healthy eating.

3.2. Health databases

The National Health Data System (Système National des Données de Santé - SNDS)

In France, the National Health Data System (Système National des Données de Santé - SNDS)[84] is managed by the National Health Insurance Fund for Salaried Workers (Caisse Nationale de l'Assurance Maladie - CNAM)[85]. CNAM is the part of the "Régime Général" concerned with disease (sickness, maternity, disability, death) and accidents/occupational diseases.

The SNDS aims to link:

- health insurance data (SNIIRAM database);
- hospital data (PMSI database);

[83] https://rm.coe.int/168008371a
[84] https://www.snds.gouv.fr/SNDS/Accueil
[85] https://assurance-maladie.ameli.fr/qui-sommes-nous/organisation/cnam-tete-reseau

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- the medical causes of death (Inserm's CépiDC database);
- data relating to disability (from the Maisons Départementales des Personnes Handicapées – MDPHs and from the Caisse Nationale de Solidarité pour l'Autonomie – CNSA)
- a sample of data from complementary health insurance organizations.

The components of the SNDS are described below.

The SNIIRAM database

SNIIRAM was created in 1999 by the Social Security financing law and is managed by CNAM.

The information concerning the beneficiary that SNIIRAM brings together includes:

- data on patients such as age, sex, the benefit of complementary universal health coverage, the municipality and the department of residence, as well as possibly the diagnosis of long-term illness and date of death;
- all services reimbursed within the framework of care provided: the information available on the care provider and possibly the prescriber (specialty, mode of practice, sex, age, implantation department), detailed coding (medicines, technical acts of doctors, medical devices, biological samples) as well as the date of treatment and the amounts reimbursed by Health Insurance and paid by patients;
- data on the consumption of in-patient care: SNIIRAM centralizes data relating to stays billed directly to Health Insurance, mainly by private clinics and data from the Programme for the Medicalisation of Information Systems (Programme de Médicalisation des Systèmes d'Information, PMSI) for the whole health facilities. Data on the pathologies treated are available in SNIIRAM through data from the medical service or hospital diagnoses from the PMSI.

The data in SNIIRAM have been collected and organized gradually since 2002 into three groups:

- 15 thematic databases of aggregated data called "datamarts" dedicated to a particular purpose: monitoring of expenses (Damir), analysis of the liberal care offer, biology, pharmacy, medical devices, private establishments;
- a general sample of beneficiaries (EGB) at 1/97th of the protected population: the EGB makes it possible to carry out longitudinal studies and to analyse the individual path of nearly 660.000 beneficiaries;
- an individual database of beneficiaries (DCIR) to carry out studies on the consumption of care.

The PMSI database

The Programme for the Medicalisation of Information Systems (Programme de Médicalisation des Systèmes d'Information, PMSI) was first introduced in 1983 and is managed by the Technical Agency for Information on Hospitalization (ATIH). Within the framework of the PMSI, any stay in a health establishment, public or private, is the subject of a systematic and minimal collection of administrative and medical information, which is used mainly for the financing of health establishments and for the organization of the healthcare offer. The information collected at the establishment is then centralized at the national level in the form of an anonymous discharge summary (Résumé de Sortie Anonymisé, RSA). Each RSA contains medical information (related diagnoses, medical procedures performed, etc.) as well as administrative information (identification of the establishment, length of stay, mode of entry and exit including, possibly,

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death) and on the patient (sex, age, geographic code of residence based on postal code of residence). In addition to the RSA, establishments must produce information on the number of consultations and external procedures performed, on the consumption of certain drugs and implantable medical devices (prostheses, implants) used.

Inserm's CépiDc database

Since 1968, Inserm has been responsible for producing annually the national statistics on the medical causes of death in collaboration with the National Institute of Statistics and Economic Studies (Institut National de la Statistique et des Etudes Economiques, INSEE). Statistics are established from the information collected from the death certificate. The certificate includes the illnesses or morbid conditions causing the death as well as other contributing factors. The identification of the underlying cause of death is linked to the doctor's declaration and to international classification rules. The content of the death certificate, for the part on the causes of death, meets the international recommendations of the World Health Organization (WHO). Inserm's CépiDc (Centre d'épidémiologie sur les causes médicales de Décès) manages the Base of Medical Causes of Death.

3.3. Access to data

The Health Data Hub

The creation of the Health Data Hub (HDH)[86] came as a response to the challenge of using Artificial Intelligence in the health sector and followed the recommendations of the report by Cédric Villani of March 2018 entitled "Giving meaning to artificial intelligence: for a national and European strategy"[87]. Shortly after the publication of the Villani Report, the President of the Republic affirmed his plan to make health one of the priority sectors for the development of Artificial Intelligence in France. More information about the French National Artificial Intelligence plan can be found in the "AI for Humanity" commitments[88] and more information on the creation of the Health Data Hub can be found in the prefiguration report[89].

The Health Data Hub has been provided for by the 24 July 2019 Law on the organisation and transformation of the healthcare system[90]. The HDH is constituted as a public interest group, whose constituent agreement was approved by ministerial decree on 29 November 2019[91]. The group brings together 56 stakeholders presented in the decree and implements the major strategic orientations relating to the National Health Data System (SNDS)[92] as set by the State and in particular by the Ministry of Solidarity and Health.

In a nutshell, the Health Data Hub aims to facilitate the sharing of health data in order to promote research of public interest. Its vast data catalogue includes the "historic" SNDS, which as described above includes administrative data from SNIIRAM and PMSI, causes of death from Inserm's CépiDC database, medico-social data from the MDPHs and a representative sample of

[86] https://www.health-data-hub.fr/
[87] https://www.vie-publique.fr/rapport/37225-donner-un-sens-lintelligence-artificielle-pour-une-strategie-nation
[88] https://www.aiforhumanity.fr/
[89] https://www.health-data-hub.fr/sites/default/files/2020-11/181012_-_rapport_health_data_hub_compressed.pdf
[90] https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038886833/
[91] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000039433105
[92] https://www.snds.gouv.fr/SNDS/Accueil

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reimbursement data transmitted by complementary health insurance organizations. This data collection has recently been enriched with data related to the COVID-19 pandemic (SI-DEP & Contact COVID). SI-DEP is the secure platform where the results of the laboratory COVID-19 tests are systematically registered and Contact COVID is a tool used by all health professionals to facilitate the identification of "contact persons" when a COVID-19 case emerges.

Data security

The data in the Health Data Hub's technological platform are pseudonymised, meaning that direct identifiers such as surname, first name, date and place of birth, address, etc., have been removed. Data in the HDH are not anonymised as this often involves data aggregation which can be a barrier in answering certain medical research questions that require access to finer data.

Since the data are not anonymous, important security measures need to be in place to guarantee that confidentiality is respected in compliance with the GDPR, the State's Information Systems Security Policy and the National Health Data System (SNDS) security referential[93].

Organizational and technical security measures include:

Encryption: data is stored in an encrypted format, as well as all storage space and flows. The HDH generates its own master encryption keys using its own proprietary hardware security module.

Segmentation of operating rights: the technological platform is only operated by Health Data Hub agents, called operators, who have defined and compartmentalised roles.

Secure management of accounts and permissions: any access to the technological platform is controlled through robust authentication procedures to prevent identity theft.

The provision of a secure workspace: after logging in to the platform, users have access through a virtual office to an isolated space dedicated to their project on which they have neither administrative rights nor internet access and where only the data validated beforehand and necessary for the conduct of their research project are available. Only anonymised results can be exported from the platform.

The use of independent technical security bricks: the architecture of the technological platform presents several levels of security, according to the principle of "defence in depth", based on independent solutions, such as flow filtering, malware detection, etc.

Trace analysis, or "logs": the Health Data Hub records all the actions carried out by users and operators.

Hosted in the European Union: The health data on the Health Data Hub's technological platform are hosted in Microsoft data centres in the Netherlands.

The choice of the Health Data Hub to use the services of Microsoft (AZURE cloud computing), a company headquartered in the U.S.A has been a point of criticism. This has been based on concerns around the application of the USA Patriot Act of 2001 and the judgement of the Court of Justice of the European Union of July 16 2020 known as "Schrems II"[94], which highlighted that the surveillance exercised by the American intelligence services on the personal data of Europeans was excessive, insufficiently supervised and without any real possibility of appeal. As such,

[93] https://www.legifrance.gouv.fr/loda/id/JORFTEXT000034265125/
[94] https://www.cnil.fr/fr/invalidation-du-privacy-shield-la-cnil-et-ses-homologues-analysent-actuellement-ses-consequences

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transfers of personal data from the European Union to the United States are contrary to the GDPR and the Charter of Fundamental Rights of the European Union, unless additional measures (safeguards) are put in place or if the transfers are justified under Article 49 of the GDPR, which provides for exemptions in specific situations.

Due to the sensitivity and the volume of data handled by the Health Data Hub, the National Commission for Data Protection and Liberties (CNIL) has expressed its wish[95] that its hosting and the services related to its management can be reserved for entities falling exclusively under the jurisdictions of the European Union.

Following the "Schrems II" judgment, guarantees have been given to conclude that there has been no transfer of data outside the EU within the framework of the day-to-day operation of HDH's technical solution.

For more information, see the Health Data Hub's commitments to civil society[96].

Data access procedure

The data, within a well-defined research scope, can become accessible to projects contributing to the public interest, following an approval process involving an independent expert committee (Comité d'Expertise pour les Recherches, les Etudes et les Evaluations dans le domaine de la Santé, CEREES)[97] and the CNIL.

Step 1: Projects who wish to access the data make an access request to the Health Data Hub.

Step 2: The request is sent to CEREES. It verifies that the subject of the study is relevant and of public interest, that the data requested is in line with the project and that the proposed methodology is scientifically robust.

Step 3: On the basis of these elements, which characterize the purpose of the data processing, the CNIL is seized to give its authorization according to criteria of data protection and respect for citizens' rights.

Step 4: Once the CNIL's authorization has been obtained, the Health Data Hub consolidates the required data and prepares a secure "project space" on its technological platform, which contains only the necessary data.

Step 5: Users of the technological platform have remote access to their "project space" and process the data on the platform without being able to retrieve it. The Health Data Hub can charge for access to its services.

Step 6: The project results are made public on the Health Data Hub website, with due respect for academic and industrial competitiveness.

Private actors requesting access to the data will have to prove the public interest of their project in the same way as public actors. The Article L. 1461-1 of the Public Health Code[98] explicitly excludes and criminalizes any use of health data for the commercial promotion of products to health professionals. The same applies to any use that may lead to the exclusion of guarantees, changes in contributions or insurance premiums for a person or group of persons.

[95] https://www.cnil.fr/fr/la-plateforme-des-donnees-de-sante-health-data-hub
[96] https://www.health-data-hub.fr/sites/default/files/2020-11/Engagements%20Citoyens.pdf
[97] https://www.health-data-hub.fr/cesrees
[98] https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000031923887/2016-01-28/

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4. Germany

4.1. Healthcare system

The German healthcare system is financed by statutory and private health insurances. As insurances were made mandatory, approximately 88% of all inhabitants are covered by statutory health insurances. According to the classification as a self-administration system, the state defines the framework for medical care and its responsibilities. But how the system is organized and structured in detail and above all what medical treatments, operations, therapies and medicinal products are financed by the health insurance funds and those that aren't – these questions are decided jointly by representatives of doctors, dentists, hospitals, health insurance funds and each insured. The supreme decision-making body of the self-administration health care system is the Federal Joint Committee (G-BA). The G-BA defines in binding guidelines the healthcare services to which those covered by statutory health insurances are entitled. So the healthcare system in Germany is based on four basic principles: compulsory insurance, funding through insurance premiums, principle of solidarity and principle of self-governance. The German healthcare system is divided into three main areas: outpatient care, inpatient care (the hospital sector), and rehabilitation facilities. The institutions responsible for running the healthcare system include the associations and representatives of various providers and professions, health insurers, regulatory bodies, the Federal Ministry of Health, patient organizations and self-help groups.

Further information can be found in the publication "The German Healthcare System"[99].

4.2. Health databases and registries

Nationwide, statutory insurance data

- **Research Data Centre, establishing phase**[100]:

Settlement data from hospitals, practitioners, specialists and pharmacists submitted to the statutory health insurances have to be forwarded in part and in pseudonymised manner to the Research Data Centre (FDZ) associated with BfArM[101]. With the aim of making the data usable for research purposes, the FDZ makes an important contribution to better healthcare. The new Research Data Centre is under construction. The set-up will take place in phases. Applications are expected to be submitted online from 2022 onwards via the Research Data Centre website. In general, universities, university medical centres and other public funded research institutions are allowed to use this data for research purposes. However, detailed procedures and information on the application process are currently under development.

[99] https://www.bundesgesundheitsministerium.de/service/publikationen/details/das-deutsche-gesundheitssystem-englische-ausgabe.html
[100] https://www.forschungsdatenzentrum-gesundheit.de/
[101] https://www.bfarm.de/EN/Home/_node.html

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Nationwide, cancer centre data (preparation phase)

Clinical and epidemiological data from the cancer registries of the German federal states are to be merged at the Centre for Cancer Registry Data (ZfKD) at the Robert Koch Institute[102]. The main aim is to provide a more comprehensive database for cancer research.

In the first step - at the beginning of 2023 - the data set currently transmitted annually by the cancer registries to the ZfKD will be supplemented with various clinical data. In particular, the most important information on therapy and the course of the disease will be added. Furthermore, the deadline for transmitting the data will be reduced from two years to one year. As before, the data set may also be made available to third parties for scientific research upon application. A new scientific committee will be founded to accompany the ZfKD on these points and assess the applications. In the second stage, a platform will be created to allow access to additional and more up-to-date data in the registries as well as enable linkage of cancer registry data with additional data not available to the registries (for example from scientific studies). The ZfKD will then serve as a central contact point for applications and data use registration. By the end of 2024, the cancer registries, the ZfKD and other stakeholders from the fields of healthcare and research will develop a concept for such a platform. More information: www.krebsdaten.de

Federal-based Cancer registries (current status)

- **Association of Population-based Cancer Registries in Germany (GEKID)**

It is the main task of the association to achieve a German-wide methodological uniformity of cancer registration standards – although there are different registration laws within the federal states in Germany. Only a German-wide cooperation will assure comparable results of cancer registration. Moreover, GEKID is the common contact institution for interstate questions of population-based cancer registration. Further aims are e.g. promotion of scientific use of cancer registry data, definition of methodological standards as base of comparability between population-based cancer registries and usage of cancer registry data for quality assurance in cancer care.

Population-based (federal) Cancer Registries in Germany

Overview provided at: https://www.gekid.de/overview

Nationwide, population-based prospective cohort

The German National Cohort (NAKO Gesundheitsstudie/NAKO) has been inviting men and women aged between 20 and 69 to 18 study centres throughout Germany since 2014. The participants are medically examined and questioned about their living conditions. The NAKO's aim is to investigate the causes of chronic diseases, such as cancer, diabetes, cardiovascular diseases, rheumatism, infectious diseases, and dementia in order to improve the prevention, early diagnosis and treatment of these very widely spread diseases. The multicentre project is funded by the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF), the participating federal states and the Helmholtz Association. By the beginning of March 2017, over 100,000 people from all over Germany had already participated in the study [7].

[102] https://www.rki.de/EN/Home/homepage_node.html

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Application for Data usage for health research projects via transfer hub[103].

The National Pandemic Cohort Network (NAPKON) is a stand-alone project. It was brought together from several individual project applications for cohort structures within the German Netzwerk Universitätsmedizin (NUM). The main goal of NAPKON is to establish a harmonized, extensible, and interoperable network, focusing on two different approaches. First, the study of COVID-19 and its consequences, and second, the establishment of structures and infrastructures for possible future pandemics. In the context of COVID-19 research, NAPKON comprises three cohort platforms: the cross-sector platform (SÜP) focuses on all COVID-19 patients from different facilities and institutions, the high-resolution platform (HAP) focuses on inpatients and severe disease progression from all German university hospitals, and the population-based platform (POP) is based on a one-year study program and focuses on follow-up and patient-reported outcomes.

The GECCO core dataset is an important component of NAPKON. The GECCOplus dataset is the intersection of all three cohort datasets. Various standards and terminologies such as LOINC, SNOMED -CT, ATC, and others are used as part of interoperability.

COVID-19 data and biosamples – usage via U&A committee: https://proskive.napkon.de

Download of an anonymised public data set: https://napkon.de/statistik/

Further national initiatives on Health Research data and their use for research projects

- **Medical Informatics Initiative**

The medical informatics initiative (MII) was created to close the gap between research and healthcare and to enhance research and patient care through the sharing and use of data from healthcare and from clinical and biomedical research – across multiple entities and sites, while ensuring robust data protection and security. Participating university hospitals and their partners have formed consortia. These are tasked with developing strategies for shared data use and exchange. They will subsequently establish the data integration centres. Usage of data for health research projects has to be approved by the Use-and-Access Committees of the individual data integration centers.

Overview over data integration centers:

https://www.medizininformatik-initiative.de/index.php/en/consortia/data-integration-centres

- **National Research Data Infrastructure for Personal Health Data (NFDI4Health)**

NFDI4Health - the National Research Data Infrastructure for Personal Health Data - deals with data generated in clinical trials, epidemiological and public health studies. The collection and analysis of these data on health and disease status and important factors influencing it are an essential component for the development of new therapies, comprehensive care approaches and preventive measures in a modern healthcare system. Although these data already meet high content quality standards, they often do not fulfil the requirements of the FAIR principles:

- The findability of data is often limited due to the lack of international standards for registration and publication.
- Possibilities for data use by third parties are usually unclear.

[103] https://transfer.nako.de/

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- Databases are often not interoperable, e.g. due to the great methodological heterogeneity in the recording of exposures and health endpoints.
- Furthermore, privacy requirements and informed consent of study participants restrict the reuse of data

For more information: https://www.nfdi4health.de/en/

- **The German Human Genome-Phenome Archive (GHGA)**

GHGA (German Human Genome-Phenome Archive) is building a national infrastructure for human genome data. This will allow highly sensitive genome data to be merged, saved and analysed in a uniform, data protection-compliant framework. This makes the data sets easy to find, accessible and optimally usable for national and international research. GHGA relies and builds on existing national omics data suppliers and their IT infrastructures in order to create a harmonized, interoperable infrastructure.

For more information: https://www.ghga.de/

4.3. Access to data

Nationwide, statutory insurance data

In general, universities, university medical centres and other publicly funded research institutions are allowed to use this data for research purposes. However, detailed procedures and information on the application process are currently under development[104].

Nationwide, cancer centre data (preparation phase)

Data Access is not yet established. By the end of 2024, the cancer registries, the ZfKD and other stakeholders from the fields of healthcare and research will develop a concept of a central contact point for applications and data use registration[105].

Federal-based cancer registries (current status)

Population-based (federal) Cancer Registries in Germany

Overview provided at: https://www.gekid.de/overview

Data Access differs between those federal cancer registries. Interested researchers should seek direct contact with the local registries.

Nationwide, population-based prospective cohort (The German National Cohort (NAKO Gesundheitsstudie/NAKO)

Application for Data usage for health research projects via transfer hub: https://transfer.nako.de

National Pandemic Cohort Network (NAPKON) within the German Netzwerk Universitätsmedizin (NUM)

[104] https://www.forschungsdatenzentrum-gesundheit.de/
[105] http://www.krebsdaten.de/

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COVID-19 data and biosamples – usage via U&A committee: https://proskive.napkon.de

Download of an anonymised public data set: https://napkon.de/statistik/

5. Hungary

5.1. Healthcare system

The Hungarian healthcare system is principally a comprehensive, compulsory, employment-based national health insurance scheme that provides near-universal coverage both in terms of treatments and in terms of population, with nearly all citizens receiving care whether they contribute or not. The current structures were introduced beginning in 1990. Prior to then, the healthcare system operated as an integral part of the government with no separate budget or accounting system. Within the new scheme, the purchasing and service-provision functions are separated with the National Health Insurance Fund Management (NEAK) entering performance-based contracts with hospitals, outpatient clinics and independent caregivers. Following a series of reforms initiated in 2011, the Hungarian health system has become highly centralized. The national government is now responsible for setting strategic direction, controlling financing and issuing and enforcing regulations, as well as delivering most outpatient specialist and inpatient care. The Ministry of Human Capacities administers the health system through the National Healthcare Service Centre (OKFŐ), whose responsibilities include care coordination, hospital planning and management, and medical licensing. The OKFŐ also serves as the umbrella organization for regional and local health system agencies. The central government resumed control of local hospitals from the county and municipal governments in 2012 (the OKFŐ serves as the managing authority running these state-owned hospitals). In 2018, the National Health Program was adopted; this defines the main government health policy priorities in the fields of cardiovascular, oncological and rheumatological diseases, as well as mental and child health. The 1997 CLIV. law on health is a comprehensive framework of all aspects regarding human health[106].

5.2. Health databases

Health Insurance Databases

The Hungarian health system is organized around a single health insurance fund providing health coverage for nearly all residents. Funding comes from payroll contributions from employers and employees, and from direct government transfers. The fund is administered by the National Institute of Health Insurance Fund Management[107], which is a government organization currently under the supervision of the Ministry of Human Capacities[108]

- The NEAK database is comprised of the following data:
    - TAJ-BSZJ database: insurance status of individuals

[106] https://net.jogtar.hu/jogszabaly?docid=99700154.tv
[107] http://www.neak.gov.hu/
[108] After the 2022 parliamentary elections the Hungarian Healthcare is managed by Ministry of Internal Affairs through its Secretary of State for Healthcare. The handover of the roles and responsibilities is in progress.

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  - Records of data on funded healthcare: data provided by healthcare providers that have contract with NEAK (e.g., GP, Dental Practitioners)
  - Records of financial data related to reimbursement of accident allowances and travels
- Master data on medicinal product and medical devices
- Public master data on medicinal products
- Public master data on medical devices/aids

Public Health Databases

- National Centre for Epidemiology (http://www.oek.hu/oek.web) tasks related to epidemiology, epidemiology and clinical microbiological tests and immunobiological preparations, laboratory diagnostics of infectious disease.
- Hungarian Central Statistical Office (https://www.ksh.hu/egeszsegugy-baleset) provides data on the health status of the population, the presence of lifestyle risks that have the strongest impact on health in the population, the most common diseases, and how much the population is doing for their health. It monitors the changes in the financial, personal and material conditions that ensure the operation of the different levels of the healthcare system.
- National Healthcare Service Centre (https://okfo.gov.hu/nemzetkozi-adatszolgaltatas) data provided to international organizations (OECD Health Data, WHO Health for All, EU EUROSTAT)
- National Institute of Pharmacy and Nutrition (Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (gov.hu)[109]) registries and databases on drugs, paramedicines, food supplements, pharmacies

The role of the EESZT in Hungarian Healthcare

The National eHealth Infrastructure (EESZT) is a central IT system that has set the foundations for ensuring communication between healthcare service providers. Today, more than 26 thousand health professionals and 13 thousand pharmacy staff use the system in Hungary. Starting from 2020, more than 22,000 institutions have access to the EESZT infrastructure, including private service providers.

The EESZT is a system that facilitates information flow and makes it easier and faster for the data sent to the infrastructure to reach the relevant professionals. It is a Hungarian integration platform, available 24 hours a day. Its central services are available anywhere and anytime. The system transfers the health data of every patient to a central database which the various health professionals can consult through the corresponding hospital, general practitioner or pharmacy systems with the appropriate authorization. It is essential for modern healthcare that all patient data be readily accessible to every therapist from one single source, regardless of whether the health services used by the patient were from a publicly funded or private provider system. The services of the EESZT provide more information to health professionals about the patient, allowing them access to information about any drugs, referrals or medical records prescribed by other therapists. This greatly improves the quality and effectiveness of healthcare: unnecessarily repeated examinations can be avoided, and health professionals get a much more accurate picture of their patient which promotes a more definite diagnosis and faster recovery. Meanwhile, citizens have access to more and more data concerning their medical treatment

[109] https://ogyei.gov.hu/nyitooldal

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through a single centralized interface. Personal medical data can be accessed on the citizen portal of the EESZT (National eHealth Infrastructure) /eeszt.gov.hu/, after using Client Gate authorization. The portal contains all medical data uploaded after 1 November 2017 by institutions that joined the cloud.

5.3. Registries

Due to the public health importance of diseases of outstanding significance in Hungary some disease registries have been subject to centralized legal regulation. EMMI decree 49/2018. (XII. 28.) defines the registry list of diseases of major importance for public health or otherwise costly, the designation of the body responsible for the register, and the detailed rules for the notification and registration of concerned diseases.

- National Cancer Registry[110]
- National Paediatric Cancer Registry[111]
- National Stroke Registry[112]
- National Cystic Fibrosis Registry[113]
- National Myocardial Infarction Registry[114]
- National Heart Failure Registry[115]
- National Vascular Registry[116]
- National Kidney Replacement Care Registry[117]
- National Congenital Abnormalities Surveillance Registry[118]
- National Adult Cardiac Surgery Registry
- National Catheter Therapy Electrophysiology PM/ICD Registry
- National Hematologic Diseases Registry
- National Affective Diseases Registry
- National Rheumatology Registry
- National Infectious Diseases Registry
- National In Vitro Fertilization, Obstetrics and Perinatal Registry
- National New-born Audiometry Registry
- National Congenital Heart diseases Registry
- National COPD Registry

In Hungary, in addition to the legally regulated disease registries professional register developments have been conducted. Some of these are still in the development phase (e.g., Hypertension e-Registry), and some have been expanded to the national level (e.g., National Nosocomial Surveillance (NNSC) is a register for the purpose of monitoring intrahospital infections).

[110] https://onkol.hu/nemzeti-rakregiszter/
[111] https://www.gyermekdaganat.hu/szervezetek/magyar-gyermek-tumor-regiszter/
[112] https://tm-centre.org/hu/kutatas/bevezetes-hu-4/
[113] https://www.cisztasfibrozis.hu/index.php/magyar-cf-regiszter/
[114] https://ir.kardio.hu/ir/fooldal
[115] http://szer.praxisplatform.hu/
[116] https://vr.gokvi.hu/
[117] http://www.nephrologia.hu/info.aspx?sp=44
[118] https://www.antsz.hu/felso_menu/temaink/vrony_rbk/a_vrony.html

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5.4. Access to data

The personal data protection in Hungary is subject to Act CXII of 2011 on the Right of Informational Self-Determination and on Freedom of Information (the "Data Protection Act"). The Data Protection Act was amended on 26 July 2018 to implement the changes of the GDPR. The GDPR has been applied since 25 May 2018. The protection of health data is subject to Act XLVII of 1997 on the Processing and Protection of Health and Related Personal Data.

Access to citizens' electronic health files in EESZT is possible only for the patient, general practice and specialists.

Data for scientific research cannot be retrieved from the above-mentioned databases and registries. However, anonymised datasets are available upon request from the National Institute of Health Insurance Fund Management.

6. Ireland

6.1. Healthcare system

Healthcare in Ireland is provided by both public and private sectors. Public healthcare system is governed by the Health Act 2004 which has established an independent body called the Health Service Executive (HSE) that provides health and social services to all citizens in Ireland. Private healthcare is provided by a network of private hospitals and clinics and treatment for private patients is also provided in public hospitals.

Health Information in Ireland has a decentralised and fragmented system. Although there are multiple organisations that are responsible for health information in Ireland, there isn't a clear policy on how these different players are coordinated. The Department of Health (DoH) is responsible for the overall health information policy, the HSE for implementing national health information systems not only within the HSE but also for the wider health and social care systems. The Health Information and Quality Authority (HIQA) aims to develop recommendations, standards and guidance on health information, and assesses compliance with those national standards. Organisations with a legislative remit regarding health information include the Central Statistics Organisation (CSO), the National Cancer Registry (NCRI), the National Standards Authority of Ireland (NSAI) and the Data Protection Commissioner (DPC).

Summary of various key players in National Health System in Ireland include:

- The **Department of Health (DoH)**[119] provides leadership, policy direction, governance and performance oversight for the health sector, and also allocates the health budget.
- The **Health Service Executive (HSE)**[120] which is a government agency under the oversight of the Department of Health, manages and delivers publicly funded health and social care services. It does this through its own network of providers, including hospitals and community health organisations.

[119] https://www.gov.ie/en/organisation/department-of-health/
[120] https://www.hse.ie/eng/

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- The **Health Information and Quality Authority (HIQA)**[121] is an independent authority that aims to improve health and social care services of persons in Ireland. Its mandate extends across a specified range of public, private and voluntary sector services. It reports to the Minister for Health and engages with the Minister for Children, Equality, Disability, Integration and Youth Affairs.
- The **Data Protection Commission (DPC)**[122] is the Irish supervisory authority for the General Data Protection Regulation (GDPR). It also has functions related to other important regulatory frameworks including the Irish ePrivacy Regulations (2011) and the EU Directive known as the Law Enforcement Directive.
- **Central Statistics Office (CSO)**[123] **–** Ireland's National Statistics office, aiming to impartially collect, analyse and make available statistics on people, society and the economy in Ireland. Their official statistics help to inform decision-making across different areas including construction, health, welfare, the environment and the economy.
- **Health Protection Surveillance Centre (HPSC)**[124] (under HSE) **–** The Health Protection Surveillance Centre (HPSC) is Ireland's specialist agency for the surveillance of communicable diseases. HPSC is part of the Health Service Executive and works in partnership with health service providers and sister organisations in Ireland and around the world, to provide the best possible information for the control and prevention of infectious diseases. HPSC strives to protect and improve the health of the Irish population by providing timely information and independent advice, and by carrying out disease surveillance, epidemiological investigation and related research and training.
- **Healthcare Pricing Office (HPO)**[125] - is the section within the HSE that is responsible for the implementation of the Activity Based Funding (ABF) model in Irish acute hospitals. They have classification guidelines for COVID-19: Microsoft Word - ICS 2021 V2 October 2021 HPO[126]
- **Ordinance Survey Ireland (OSI)**[127] – Ireland's National Mapping Agency. It designed and developed a standardised, authoritative digital referencing framework that enables the consistent referencing and integration of national data related to location. This provides the means for GIS data users to accurately integrate and use multiple data sources to provide for better analysis and decision-making, optimising resources and delivering efficiencies. GeoHive is the State's geospatial data hub, a service provided by OSI, and existed long before COVID (since 2015). GeoHive aims to make all geospatial data in Ireland accessible in one place.
- **National Office of Clinical Audit (NOCA)**[128] - manages national clinical audits that aim to improve patient care and outcomes. NOCA enables the Irish healthcare system to continually improve its standards of care via maintenance of a portfolio of prioritised national clinical audits, standardised against national and international criteria.
- **Economic and Social Research Institute (ESRI)**[129] – produces independent, high-quality research aimed to inform policies that support a healthy economy and promote social progress.

[121] https://www.hiqa.ie/
[122] https://www.dataprotection.ie/
[123] https://www.cso.ie/en/index.html
[124] https://www.hpsc.ie/
[125] https://www.hpo.ie/
[126] https://www.hpo.ie/hipe/clinical_coding/irish_coding_standards/ICS_22X2_Novel_Coronavirus_(COVID-19)_October_2021.pdf
[127] https://osi.ie/
[128] https://www.noca.ie/
[129] https://www.esri.ie/

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6.2. Health databases and registries

Health data in Ireland are managed by a multitude of organisations. A comprehensive list of health data collections and the responsible organisations can be found at the Health Information and Quality Authority (HIQA) website here:

https://www.hiqa.ie/areas-we-work/health-information/data-collections

Some key national health databases and registries include the following:

National health databases and registries	Website links
Health Research Board (HRB): HRB Hosts 4 national health information systems: 1. Alcohol and drug treatment 2. Alcohol and drug deaths 3. Disability service use and need 4. Psychiatric admissions and discharges The HRB's NPIRS system collects data from private hospitals on psychiatric admissions and discharges	https://www.hrb.ie/data-collections-evidence/ https://www.hrb.ie/data-collections-evidence/psychiatric-admissions-and-discharges/how-data-is-collected/
Department of Health (DoH): • Healthy Ireland – Department of Health • Dual collection for Irish Health Survey	https://www.gov.ie/en/campaigns/healthy-ireland/
Irish Social Science Data Archive (ISSDA): • Holds a range of Irish and international social sciences datasets (e.g., Growing up in Ireland, TILDA, CSO surveys) Makes them available for secondary analysis by students, academics, and researchers in the public and commercial sectors	https://www.ucd.ie/issda/
Healthcare Pricing Office (HPO): • HIPE data: hospital inpatient enquiry • Pseudonymised version of medical record number • Based on episodes of care Includes data from all hospitals (including private)	https://www.hpo.ie/
Central Statistics Office (CSO): • Irish Health Interview Survey (European Health Interview Survey, every 5 years) • National Disability Survey • Vital statistics • COVID-19 Data Research Hub • Publish reports in collaboration with the HSE • Expansion to add socioeconomic data	https://www.cso.ie/en/index.html COVID-19 Data Research Hub - CSO - Central Statistics Office

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National health databases and registries	Website links
Health Service Executive (HSE): • Open data portal • PCRS – database of Primary Care Reimbursement Services, reports to CSO annually • National Screening Service • Health Protection Surveillance Centre (HPSC) • National Incident Management System (NIMS)	https://data.ehealthireland.ie/ https://www.hse.ie/eng/staff/pcrs/about-pcrs/ https://www.screeningservice.ie/ https://www.hpsc.ie/ https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/
Health Information and Quality Authority (HIQA): • NCEP (patient experience survey) • Lens Project data (incidents in nursing homes and residential centres)	https://www.hiqa.ie/areas-we-work/national-care-experience-programme https://www.hiqa.ie/areas-we-work/Database-of-Statutory-Notifications
National Office of Clinical Audit (NOCA): • Largest portfolio of clinical audits: currently 10 • Minimum dataset for each audit • Section 38 and 39 contracts define public hospital inclusion, private hospitals participation is voluntary Each audit has own method for tracking patients, to circumvent issue of not having a unique personal identifier (e.g., admission number)	https://www.noca.ie/
National Cancer Registry Ireland (NCRI)	https://www.ncri.ie/about-us
Patient Treatment Register (PTR)- National Treatment Purchase Fund	https://www.ntpf.ie/home/home.htm
Tusla (Child and Family Agency)	https://www.tusla.ie/research/databases/#DATABASE

6.3. Access to data

Secondary use of health data is currently governed by the Data Protection Act 2018 (Section 36(2)) (Health Research Regulations), otherwise known as the Health Research Regulations 2018, and as amended[130]. This legislation was enacted in 2018. The Health Research Consent Declaration Committee (HRCDC)[131] was established as part of the Health Research Regulations made under the Data Protection Act, 2018.

In 2021, the Minister for Health further authorised the use of COVID-19 heath data for health research purposes under the Section 31 of the Statistics Act 1993[132].

[130] https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
[131] https://hrcdc.ie/about-us/
[132] http://www.irishstatutebook.ie/eli/1993/act/21/enacted/en/html

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The DoH is in the early phases of preparing a Health Information Bill that will provide for more robust legal and operational infrastructure to support the secondary use of health data in Ireland. The main reason for creating national legislation is to ensure that the processing of health data can be carried out lawfully and in safeguarded transparent manner with robust governance and infrastructures and structures in place, and in the best interests of the public and patients. This will ensure there is clarity and consistency around the use of health data and foster public and patient trust in health and social care systems and research in Ireland.

The Department of Children, Equality, Disability, Integration and Youth[133] has responsibility for the Assisted Decision Making (Capacity) Act 2015. This legislation is currently being amended, with the amendment bill[134] now including reference to participation in research. This Bill further provides that the Minister shall make regulations to provide for consent and data protection in relation to research.

Access to data for research purposes is provided by the following key organisations

Central Statistics Office (CSO): The CSO has developed a **COVID-19 Data Research Hub**[135] to support the research community in COVID-19 related research. It facilitates the compilation of relevant COVID-19 health data in a format that is controlled, accessible and usable for approved researchers.

It makes individual-level administrative COVID-19 datasets available to researchers via the CSO Researcher Microdata Files (RMF) process under Section 20(c) of The Statistics Act, 1993. The datasets within the research hub contain individual-level data on COVID-19 cases, persons referred for testing, persons treated in hospital for COVID-19 or have been identified as being a close contact of a confirmed case. The provision for researcher access to the CSO COVID-19 Data Research Hub follows extensive consultation between CSO, the Health Research Board (HRB), DoH and the HSE. This consultation led to the establishment of the Research Data Governance Board. No directly identifiable data is made available to researchers, or any stakeholders or other persons by the project team under conditions of Section 34 of The Statistics Act of 1993.

The CSO also developed and maintains a **COVID-19 Information Hub**[136] reporting on the changing state of aspects of Ireland's economy and society since the COVID-19 pandemic hit. The statistics have been sourced from a broad range of sources including the Central Statistics Office, the Central Bank of Ireland, other Government Departments and bodies and international sources.

CSO:

- Positive HRCDC decision required, indicating that the research does not require consent as it is in the public interest
- Supports Citrix secure processing environment (SPE) for analysis
- CSO pseudonymises and links data, uploads it to the SPE for the researchers to use. Researchers cannot bring in their own data
- Offers 2 ways of accessing data:

[133] https://www.gov.ie/en/organisation/department-of-children-equality-disability-integration-and-youth/
[134] https://www.gov.ie/pdf/?file=https://assets.gov.ie/205177/7bc1a7de-8674-4911-a0c0-7418ba807056.pdf#page=null
[135] https://www.cso.ie/en/aboutus/lgdp/csodatapolicies/dataforresearchers/covid-19dataresearchhub/
[136] https://www.cso.ie/en/releasesandpublications/ep/p-covid19/covid-19informationhub/

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- AMF (anonymised microdata file): basic set of variables approved by the CSO for distribution by ISSDA, available to anyone who applies for research or teaching purposes
- RMF (research microdata file): individual level pseudonymised data with a wider set of variables, more involved application procedure, must be assigned as an officer of statistics
- Provides Access to RMFs: RMF register on CSO website
- RMF application form, requires approval by Director General of CSO
- Foreign research applications are considered on a case-by-case basis
- COVID-19 Data Research Hub: different application procedure, with specific governance process-Approval by the Research Data Governance Board (RDGB) Research Ethics approval and Consent declaration from the Health Research Consent Declaration Committee (HRCDC) is required for access to this hub by researchers.
- COVID-19 Information Hub: publicly available, AMFs for research.

Health Research Board (HRB): The HRB in close collaboration with the CSO, Department of Health and Health Service Executive in Ireland established the Research Data Governance Board (RDGB)[137] in March 2021 and provides secretarial support to oversee the application process for researcher access to the CSO COVID-19 Data Research Hub.

HRB has launched a dedicated funding call on Secondary Data Analysis to support health and social care research[138]. The overall objective of this scheme is to optimise the use of existing health and social care data sources in order to deliver high-quality, high-impact evidence for policy and/or practice. This funding call further encourages the development of improved protocols and tools that make the datasets more accessible for research purposes, and in accordance with best practice appropriate safeguards. This call provides funding for research utilising Irish (and in some cases international) health and social care datasets/data sources, and these are accessed through different mechanisms such as Data Access Committees, data controllers and governance mechanisms.

HRB Open data is available on website below:

https://www.hrb.ie/data-collections-evidence/alcohol-and-drug-treatment/request-data/

Data can be requested through publicly available data request form:

https://www.hrb.ie/fileadmin/2._Plugin_related_files/Publications/Data_Request_Form_NHIS_2022.pdf

HIQA: Lens Project data accessible, access policy available on website:

https://www.hiqa.ie/hiqa-news-updates/hiqa-publishes-open-access-database-statutory-notifications-received-social-care

HIPE: Data request process through HPO website:

http://www.hpo.ie/index.htm?HIPE_Data_Request

HSE:

- Public open data available

[137] https://www.hrb.ie/data-collections-evidence/access-covid-19-data-for-research/about/the-research-data-governance-board-rdgb/
[138] https://www.hrb.ie/funding/funding-schemes/all-funding-schemes/grant/secondary-data-analysis-projects-sdap-2021-next-call-tbc/

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- HSE has data request portal on website (for foreign and national researchers alike)
- Anonymised data is accessible, for pseudonymised data additional consent is needed from patients or from the HRCDC

https://hseresearch.ie/data-sources/

Private hospital data:

- Consent is given only for use of data for treatment or billing.
- Research ethics committee approval required.
- Data processor agreement (universities), data controller agreement (clinicians)
- University based research, in affiliation with a hospital specialist
- External researchers have access to anonymised data, but application process unclear

https://privatehospitals.ie/about-us/

NOCA:

- Primary use is for audit purposes, but secondary use is for research purposes.
- Quarterly reports to hospitals, and national reports annually from the datasets. Data is available for research after the annual report.
- Access procedure for research includes ethical approval --> data request process at NOCA (publicly available on website) --> audit manager review --> governance committee approval.
- Generally aggregated data but can be pseudonymised if required for the research project.
- Currently no secure processing environment, but included in IT strategy vision.
- No fee included/required.
- Time to access depends on size of request, max. 2-6 weeks
- Number of requests growing, increases as the audits mature, average 3 request per year for each audit
- A lot of the NOCA datasets are analysed in the UK (for benchmarking)

https://www.noca.ie/about-noca/access-to-audit-data/data-access-request-for-research

7. Italy

7.1. Healthcare system

The healthcare system in Italy is a regionally based National Health Service known as Servizio Sanitario Nazionale (SSN). It provides universal coverage to citizens and residents, with public healthcare largely free of charge as stipulated by article 32 of the Italian Constitution. The fundamental principles on which the NHS has been based since its establishment, which took place with law no. 833 of 1978, are universality, equality and equity.

The essential levels of assistance (LEA) are the performances and services that the NHS requires to provide to all citizens, free of charge or upon payment of a participation fee (ticket), with public resources and general taxation (taxes) as reported in the Decree of 12 January 2017. This decree identifies three major levels:

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- collective prevention and public health;
- district assistance, i.e. the health and social-health activities and services spread throughout the territory;
- hospital assistance.

Treatments that are covered by the public system and/or a small co-payment include tests, medications, surgeries during hospitalisation, family doctor visits and medical assistance provided by paediatricians and other specialists. Furthermore, medication, out-patient treatments, and dental treatments are also available. While the national level ensures the general objectives and fundamental principles of the national healthcare system are met, regional governments in Italy are responsible for ensuring the delivery of a benefits package to the population. Healthcare facilities vary in terms of quality in different regions of Italy.

Over the period 2010–19, the NHS suffered financial cuts of more than €37 billion, a progressive privatisation of healthcare services.

The European Health Insurance Card (EHIC) entered into force in Italy on 1 November 2004. The card, which is the reverse side of the National Health Card (Tessera Sanitaria Nazionale – TS) or the Regional Service Card, is used every time by the citizen (to buy drugs in a pharmacy, to benefit from a specialist visit in hospital or ASL, ...). The card, which is strictly personal, allows to obtain health services even in the countries of the European Union. It is issued to all citizens who are entitled to healthcare by the NHS. The EHIC is an important element to implement in Italy the health expenditure monitoring system aimed at knowing and managing the resources spent in health care, making better use of the public money[139].

7.2. Health databases

- The **Italian Ministry of Health**[140] provides a number of databases that can be accessed by citizens, patients and health professionals. Databases cover a broad range of topics including drugs, medical devices, rare diseases and statistical data relating to territorial basic assistance, to employees and to hospitalization and care facilities present in the territory of each Local Health Authority.
  For more information:
  https://www.salute.gov.it/portale/documentazione/p6_2_8_1.jsp?lingua=italiano
- The **Medicines Database** prepared by the Italian Medicines Agency (AIFA), is the only official database that allows consultation of the Summary of Product Characteristics (RCP) and the updated Illustrative Leaflets (FI) of the medicines authorized in Italy. All published documents have been checked and approved by AIFA or EMA. Updating the database is the exclusive responsibility of AIFA. This is a public database, intended for anyone interested in acquiring updated information on medicines authorized in Italy. Accessible at:
  https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/home
  AIFA also has an intense editorial activity, which is a direct expression of the Agency's commitment to guaranteeing high-level scientific information and is aimed at providing tangible tools for updating and continuous training of health professionals. Of note, the Annual national report on medicines use in Italy. More information:

[139] https://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=english&id=5272&area=healcareUE&menu=vuoto
[140] https://www.salute.gov.it

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https://www.aifa.gov.it/en/rapporti-osmed

- **National Database of medical devices**
  The research for a medical device can be carried out through the manufacturer's and/or authorized representative's data or through at least one of the device's data. The public consultation tool facilitates the dissemination and use of the registration number in the database established by the Decree of the Minister of Health on December 21, 2009. The public database is updated weekly and it is open; it is also possible to download the data set or the weekly updates on the Open Data Ministry website. Links:
  https://www.salute.gov.it/interrogazioneDispositivi/RicercaDispositiviServlet?action=ACTION_MASCHERA
  http://www.dati.salute.gov.it/dati/dettaglioDataset.jsp?menu=dati&idPag=1
- **Health for all – Italy**
  The database of indicators on the health system in Italy can be queried by the HFA software provided by the World Health Organization and adapted to national needs. Currently, the database contains 4000 indicators, which are updated to the last year.
  The software allows to represent statistical data in graphical and tabular form and to carry out simple statistical analyses: https://www.istat.it/it/archivio/14562
- **Profili di Salute** (Health Profiles), is an effective tool to evaluate the health profile of the Italian population in terms of mortality and hospitalizations (current data flows) at different levels: nation, regions, local health units: https://www.profilidisalute.it/index.php/en/

7.3. Registries

There are national registers among which:

- Italian arthroplasty registry (Registro italiano artroprotesi (RIAP))[141]
- AIDS national register (Registro nazionale AIDS (RAIDS))
- Italian Cystic Fibrosis register (Registro della fibrosi cistica (RIFC))[142]
- Italian registry of haemolitic-uremic syndrome (Registro italiano della sindrome emolitico-uremica)[143]
- National register of legionellosis (Registro nazionale della legionellosi)
- National register of growth hormone assumers (Registro nazionale degli assuntori di ormone della crescita (RNAOC))[144]
- The Italian twins register (Registro nazionale gemelli)
- Italian national registry of assisted reproductive technology (Registro nazionale della Procreazione medicalmente assistita (RPMA))[145]
- National register of congenital hypothyroid (Registro nazionale degli ipotiroidei congeniti (RNIC))[146]
- National register of rare diseases (Registro nazionale delle malattie rare)[147]
- National register of Creutzfeldt-Jakob disease and related syndromes (Registro nazionale della malattia di Creutzfeldt-Jakob (MCJ) e sindromi correlate)[148]

[141] https://riap.iss.it/riap/en/
[142] https://www.registroitalianofibrosicistica.it/
[143] https://www.epicentro.iss.it/en/hus/epidemiology-italy
[144] https://www.iss.it/rnaoc
[145] https://www.iss.it/rpma
[146] https://www.iss.it/web/guest/registro-nazionale-ipotiroidei-congeniti
[147] https://www.iss.it/web/guest/malattie-rare/-/asset_publisher/9PBa3dbogbRa/content/registro-nazionale-malattie-rare-1?

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- National ADHD registry Registro nazionale dell'ADHD (sindrome da iperattività con deficit di attenzione)
- National register of congenital coagulopathies (Registro nazionale coagulopatie congenite)[149]
- Italian registry of implantable prostheses (Registro italiano delle protesi impiantabili (RIPI))[150]
- Cancer registry (AIRTUM) [151]

7.4. Access to data

Individual data from the registries are not publicly accessible; most of the health databases described above provide free access to aggregated data. Usually, the data from national registries are published periodically through reports which include data presented by tables or graphs and summaries. In Italy, the Provision of the Guarantor of 5 June 2019 has highlighted the requirements regarding the processing of sensitive data for scientific research purposes. The processing of data is necessary for studies carried out with data previously collected for healthcare purposes or for previous research projects or obtained from biological samples previously taken for health protection purposes. In these cases, the research must be carried out on the basis of a project, subject to a reasoned favourable opinion from the competent ethics committee at the local level.

Useful links

- https://www.euro.who.int/en/countries/italy
- https://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?lingua=italiano&id=5073&area=Lea&menu=vuoto
- The Italian health system and the COVID-19 challenge. Armocida B et al. The Lancet, Public Health, 2020. DOI: https://doi.org/10.1016/S2468-2667(20)30074-8
- https://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?lingua=italiano&id=1300&area=Lea&menu=leaEssn
- https://www.salute.gov.it/portale/lea/dettaglioContenutiLea.jsp?lingua=italiano&id=4693&area=Lea&menu=leaEssn
- https://www.iss.it/registri-e-sorveglianze
- https://www.epicentro.iss.it/strumenti/BancheDatiItalia
- https://www.epicentro.iss.it/politiche_sanitarie/DpcmSorveglianze2017
- https://www.garanteprivacy.it/home

[148] https://www.iss.it/registro-mcj

[149] https://www.iss.it/web/guest/home?p_p_id=com_liferay_portal_search_web_portlet_SearchPortlet&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&_com_liferay_portal_search_web_portlet_SearchPortlet_mvcPath=%2Fview_content.jsp&_com_liferay_portal_search_web_portlet_SearchPortlet_redirect=https%3A%2F%2Fwww2.iss.it%2Fweb%2Fguest%2Fhome%3Fp_p_id%3Dcom_liferay_portal_search_web_portlet_SearchPortlet%26p_p_lifecycle%3D0%26p_p_state%3Dmaximized%26p_p_mode%3Dview%26_com_liferay_portal_search_web_portlet_SearchPortlet_redirect%3Dhttps%253A%252F%252Fwww2.iss.it%252Fweb%252Fguest%252Fhome%253Fp_p_id%253Dcom_liferay_portal_search_web_portlet_SearchPortlet%2526p_p_lifecycle%253D0%2526p_p_state%253Dnormal%2526p_p_mode%253Dview%26_com_liferay_portal_search_web_portlet_SearchPortlet_mvcPath%3D%252Fsearch.jsp%26_com_liferay_portal_search_web_portlet_SearchPortlet_keywords%3Dcoagulopate%26_com_liferay_portal_search_web_portlet_SearchPortlet_formDate%3D1582292550381%26_com_liferay_portal_search_web_portlet_SearchPortlet_scope%3Dthis-site&_com_liferay_portal_search_web_portlet_SearchPortlet_assetEntryId=4814422&_com_liferay_portal_search_web_portlet_SearchPortlet_type=content

[150] https://ripi.iss.it/ripi/en/

[151] https://www.registri-tumori.it/cms/

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8. The Netherlands

8.1. Healthcare system

In the Netherlands, the healthcare system is managed by the Dutch government, mainly via the Ministry of Health, Welfare, and Sport (Ministerie van Volksgezondheid, Welzijn en Sport - VWS)[152]. The government is thus responsible for three systems that together provide broad universal coverage: 1) a social insurance system for curative care carried out by competing private health insurers (Zorgverzekeringswet - Zvw); 2) a single-payer social insurance for long-term care (Wet langdurige zorg - Wlz); and 3) a social care system funded from taxes and implemented by the municipalities. The social insurance system for curative care is the largest and covers all specialist care, primary care, pharmaceuticals and medical aids, mental health, some allied care services and community nursing. The long-term care is addressed to people who need intensive and continuous care and is generally delivered on an in-patient basis. The social care system helps people to age in place by providing services such as housekeeping, help with daily activities and sheltered living.

The general practitioners (GPs) or "huisarts" are the first point of contact for patients and deal with routine health issues. They also perform standard gynaecological and paediatric examinations, while when needed, they are the ones to refer patients to other services such as hospitals, specialists, home midwifery and physiotherapy. The Netherlands' healthcare system is ranked number two on the 2018 Euro Health Consumer Index[153], having formerly been named the top-ranked nation. From 2012 to 2020, healthcare spending declined from 10.9% to 10.5% of the GDP.

8.2. Health databases and registries

- **Health-RI**

Health-RI[154] is a public-private partnership of organisations involved in health research and innovation aiming to realise the infrastructure necessary to give researchers, healthcare policy makers and individuals optimal access to knowledge, tools, facilities, health data and samples.

Initiated by BBMRI-NL[155], ELIXIR-NL[156], EATRIS-NL[157], NFU[158], DTL[159], Lygature[160] and Health~Holland[161], Health-RI has been turned into an independent not-for-profit foundation, and recently received a major grant from the national government from the economic revitalisation funding scheme. Its ultimate aim is to function as a one-stop-shop for researchers in life sciences by interconnecting biobanks, medical imaging and data collections, allowing for

[152] https://www.government.nl/ministries/ministry-of-health-welfare-and-sport
[153] https://healthpowerhouse.com/media/EHCI-2018/EHCI-2018-report.pdf
[154] https://www.health-ri.nl/
[155] https://www.bbmri.nl/
[156] https://www.dtls.nl/elixir-nl/
[157] https://eatris.eu/
[158] https://www.nfu.nl/
[159] https://www.dtls.nl/
[160] https://www.lygature.org/
[161] https://www.health-holland.com/

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mining and linking, and providing access to facilities and IT solutions. Health-RI also includes ethical and legal services, FAIR data stewardship, data management training and best practices. Several entry points for finding and acquiring samples and health data[162] in the Netherlands are provided via their website.

- **The PHARMO Database Network**

Founded in 1999, PHARMO[163] is an independent research organisation dedicated to the study of epidemiology, drug utilisation, drug safety, health outcomes, and utilisation of healthcare resources. PHARMO developed and maintains a large and high-quality Database Network and works closely with both national and international medical universities and European databases.

The network includes the following databases and registries (which can either be accessed independently or as part of the PHARMO Database Network):

- The General Practitioner Database

The General Practitioner Database comprises data from electronic patient records registered by GPs. The records include information on symptoms and diagnoses, laboratory test results, referrals to specialists and drug prescriptions. The prescription records include information on the type of product, prescription date, strength, dosage regimen, quantity and route of administration. It covers a catchment area representing 2.5 million residents.

- The Out-patient Pharmacy Database

The Out-patient Pharmacy Database comprises GP or specialist prescribed healthcare products dispensed by the out-patient pharmacy. The dispensing records include information on the type of product, date, strength, dosage regimen, quantity, route of administration, prescriber speciality and costs. It covers a catchment area representing 3.8 million residents.

- In-patient Pharmacy Database

The In-patient Pharmacy Database comprises drug dispensing from the hospital pharmacy, given during hospitalisation. The dispensing records include information on the type of drug, start and end date of use, strength, dosage regimen and route of administration. It covers a catchment area representing 2 million residents.

- Clinical Laboratory Database

The Clinical Laboratory Database comprises results of tests performed on clinical specimens. These laboratory tests are requested by GPs or medical specialists in order to get information concerning the diagnosis, treatment and prevention of disease. The electronic records include information on the date and time of testing, test result, unit of measurement and type of clinical specimen. It covers a catchment area representing 1.2 million residents.

- Hospitalisation Database (Dutch Hospital Data - DHD)

The Hospitalisation Database comprises hospital admissions for more than 24 hours and admissions for less than 24 hours for which a bed is required from the Dutch Hospital Data[164]. The records include information on hospital admission and discharge dates, discharge diagnoses and procedures. PHARMO has access to data from the majority of the hospitals in the Netherlands.

[162] https://www.health-ri.nl/services?portfolio=4&research_process=All
[163] https://pharmo.nl/
[164] https://www.dhd.nl/Paginas/home.aspx

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Permission on a project basis is needed to access these data (see more details in the dedicated section on the Dutch Hospital Data).

- The Netherlands Cancer Registry (NCR)

The Cancer Registry is maintained by the Netherlands Comprehensive Cancer Organisation (IKNL)[165] and comprises information on newly diagnosed cancer patients in the Netherlands, including cancer diagnosis, tumour staging, tumour site (topography) and morphology (histology), co-morbidity at diagnosis and treatment received directly after diagnosis. Permission on a project basis is needed to access these data (see more details in the dedicated section on the Netherlands Cancer Registry).

- PALGA's Pathology Registry

The nationwide network and registry of histopathology and cytopathology in the Netherlands is maintained by the PALGA foundation[166] and comprises excerpts of histological, cytological and autopsy examinations. Electronic records include a summary of the pathology report and the so-called PALGA diagnosis which is structured along five classification axes: topography, morphology, function, procedure and diseases. Permission on a project basis is needed to access these data (see more details in the dedicated section on PALGA's Public Pathology Database).

- The Netherlands Perinatal Registry

The Netherlands Perinatal Registry (PRN) is maintained by Perined[167] and comprises data on pregnancies, births and neonatal outcomes of births in the Netherlands. Records include information on mothers (e.g. maternal age, obstetric history, parity), pregnancy (e.g. mode of conception, mode of delivery) and children (e.g. birth weight, gestational age, Apgar score). Permission on a project basis is needed to access these data.

- Mortality Registry

The Central Bureau of Genealogy[168] is the Dutch information and documentation centre for genealogy, family history and related sciences. Data include mortality date (no information on reason of death available).

Access to data from the PHARMO Database Network is exclusively granted to researchers employed by universities and research institutes for scientific research. Interested researchers must submit the data application form, available both in Dutch[169] and English[170] and comply with the Terms and Conditions[171] of access (available also in Dutch here[172]). PHARMO, via its partner STIZON[173], provides access only to anonymous data, which cannot be traced back to individuals or healthcare providers/institutions. STIZON only provides patient identifiable information when written informed consent from the patients is obtained.

[165] https://iknl.nl/
[166] http://www.palga.nl/
[167] http://www.perined.nl/
[168] https://cbg.nl/
[169] https://www.pharmo.nl/wp-content/uploads/2018/09/Aanvraagformulier-data-toegang-PHARMO_v3.docx
[170] Links to downloadable word doc
[171] https://www.pharmo.nl/wp-content/uploads/2018/09/AH-Terms-and-Conditions_July2018.pdf
[172] https://www.pharmo.nl/wp-content/uploads/2018/09/Algemene-voorwaarden-toegang-PHARMO-Datanetwerk_juli-2018.pdf
[173] https://stizon.nl/

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- **The Dutch Hospital Data (DHD)**

The Dutch Hospital Data[174] collects, manages and processes data from hospitals and manages standards for its registration. DHD was founded by the Dutch Hospital Association (NVZ)[175] and the Netherlands Federation of University Medical Centres (NFU). DHD manages the National Registration of Hospital Care (Landelijke Basisadministratie Ziekenhuiszorg, LBZ)[176]. All Dutch hospitals supply data for the LBZ. The LBZ contains medical, financial and administrative data of patients who have undergone in-patient admission, daycare or long-term observation or who have been treated in an out-patient setting. The data is used, among others, for legally required submissions, scientific research (based on data requests[177]), additional analyses within hospitals (for example via their own data warehouse) and for education.

Researchers can request information from the LBZ data collection (care-related data and financial data). Data access requests should use the DHD application form[178] and be sent by e-mail[179]. DHD assesses data requests based on the following points: availability of the data, purpose of use, privacy and labour intensity. By submitting the data request, researchers declare to agree with the data protocol. Fees for data access might apply. DHD processes the patient and company data supplied exclusively on behalf of the hospitals. The hospitals remain the data controllers and are responsible for the data supplied, whereby DHD is only a data processor. Data with a high level of aggregation, i.e. data that cannot be traced back to individual patients and/or institutions, can be supplied directly by DHD in tabular form. If researchers need patient-level data, a written order from the hospital concerned is required. Researchers seeking access to patient-level data should contact the DHD in order for DHD to prepare an order for the relevant hospitals and submit it to the privacy committee for approval. If the committee agrees then the order form is signed by the board of directors of the hospitals concerned. More information can be obtained through the Service Desk[180].

- **The Netherlands Cancer Registry (NCR)**

The Netherlands Cancer Registry (NCR)[181] provides insights into the incidence and prevalence of cancer, which patients, which treatments and prognosis of cancer is important to improve care. The NCR is the only oncological hospital registry in the Netherlands with data on all cancer patients. Data are available on the national level from 1989 onwards. The registry is maintained by the Netherlands Comprehensive Cancer Organisation (IKNL). Data on incidence, prevalence, survival, mortality can be viewed in NCR data & figures[182].

Healthcare providers, (clinical) researchers and policy makers may apply for customised data sets[183] from the NCR. Each request is checked by both a privacy committee and a scientific committee. The procedure from first contact until the delivery of the requested data takes about 6 weeks. Patients, students and other interested parties may consult the publicly accessible data available on www.kanker.nl (in Dutch).

[174] https://www.dhd.nl/Paginas/home.aspx
[175] https://nvz-ziekenhuizen.nl/dutch-hospital-association
[176] https://www.dhd.nl/producten-diensten/lbz/Paginas/Dataverzameling-LBZ.aspx
[177] https://www.dhd.nl/producten-diensten/gegevensverzoek/Paginas/gegevensverzoek.aspx
[178] https://www.dhd.nl/producten-diensten/gegevensverzoek/documents/Aanvraagformulier%20gegevensverzoek%20DHD.pdf
[179] info@dhd.nl
[180] https://www.dhd.nl/klantenservice/paginas/default.aspx
[181] https://iknl.nl/en/ncr
[182] https://iknl.nl/nkr-cijfers?lang%7Clanguage=en
[183] https://iknl.nl/forms/dataapplication

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The following nine steps outline the data access procedure:

1. An applicant fills out the data application form[184].
2. A consultant from the NCR Analysis department will contact the applicant within 5 working days.
3. An application form will be completed in consultation with the researcher and assigned a reference number.
4. The NCR Analysis consultant sends the applicant the completed application form by e-mail.
5. The applicant is required to sign the application form and, upon signing, to return the document to the department of NCR Analysis by mail, together with required documents (in case the application concerns data containing identifiable information about individual hospitals, additional signing by a member of all Boards of Directors of all hospitals involved is mandatory. Additional signing is also needed in case data were requested by a non-practitioner working at the hospital.
6. The application is reviewed by the NCR's Supervisory Committee (SC) for the compliance with IKNL objectives as well as national privacy legislation. For several cancer types, data requests for the purpose of conducting scientific research are additionally reviewed by an external scientific committee. This applies to data on oesophageal, stomach, and pancreatic cancer, brain tumours and haematological cancers. More information on the scientific review procedures[185].
7. If applicable, following a positive feedback from the SC, the applicant will receive a quotation for the services provided by NCR Analysis to deliver the data. In case of a negative feedback, the applicant may opt to adjust and re-evaluate the data application.
8. If applicable, the applicant is asked to sign the quotation and return it by email.
9. The requested data will be made available to applicants via a secure download environment.

- **PALGA's Public Pathology Database**

In the Netherlands, all pathology results are digitally archived in the nationwide network and registry of histo- and cytopathology in the Netherlands (PALGA). The archive was founded in 1971 and achieved nationwide coverage in 1991. This means that all 46 pathology laboratories serving the pathology needs of every hospital in the Netherlands are connected to the national infrastructure. Each year, the pathology laboratories generate 2 million new test results in the areas of cytology (and population cytology), histology and autopsies.

The PALGA infrastructure consists of a decentralized databank in all pathological laboratories in the Netherlands, one national database for patient care and one national database for scientific research. All laboratories send their pathology reports to the two national databases either daily or weekly, which means the national databases are always up to date. PALGA's Public Pathology Database[186] contains data from the scientific research database.

The data in PALGA's Public Pathology Database are completely anonymous, and can not be traced to individual patients. Researchers can use diagnostic and retrieval terms to simplify the search for a specific diagnosis. A retrieval term is a collection of different terms that belong together. For example, search for all malignancies, or any skin topographies. Search can also be grouped by type of tissue or cells, gender, age group, and year of diagnosis. Searches of PALGA's Public

[184] https://iknl.nl/forms/dataapplication
[185] https://iknl.nl/en/ncr/apply-for-data/additional-procedure-for-scientific-review
[186] https://www.palgaopenbaredatabank.nl/

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Pathology Database will only retrieve sets of numbers. The *"Zoeken in de PODB"* (PALGA's Public Pathology Database manual) can be accessed here[187] (in Dutch). For further details about data access requests, the reader is redirected here[188] (information available in Dutch and English).

- **The Netherlands Institute for Health Services Research (NIVEL)**

NIVEL[189] is the national institute for health services research in the Netherlands. It is an independent organisation, which carries out research with a demonstrable impact upon society. NIVEL's research capacity and expertise are used by many organisations, such as: Governmental bodies (Dutch and foreign ministries, EC), scientific research organisations and organisations representing healthcare professionals, healthcare consumers, healthcare insurance companies.

NIVEL manages the Nivel Primary Care Database (Nivel Zorgregistraties Eerste Lijn)[190] which includes routinely recorded data from healthcare providers, in particular general practitioners, to monitor health and utilisation of health services in a representative sample of the Dutch population. Anonymised datasets can be shared with researchers upon agreement with certain conditions. Interested researchers are encouraged to contact NIVEL[191] to further discuss their research project.

- **The Dutch Foundation for Pharmaceutical Statistics (SFK) database**

Since 1990 the Dutch Foundation for Pharmaceutical Statistics (SFK)[192] has collected data regarding the kind and use of medicines dispensed by community pharmacies in the Netherlands. For each dispensation the SFK registers detailed information about the drug supplied, the dispensing pharmacy, the health insurance company, the prescribing doctor and anonymous information about the patient for whom the prescription was issued. The SFK has built and maintains the largest data warehouse in this field in the Netherlands. Annually the SFK publishes the results of the information gathered during the previous year in the brochure 'Data en Feiten'. The data collection is generated with data from more than 98% of community pharmacies in the Netherlands and covers a catchment area representing 16 million people.

Researchers seeking to obtain specific information from the SFK database must submit a request with a description of the organization they represent and provide background information on the reasons for the request. The information request form to be used is available here[193]. All requests need the approval of the SFK board (unless the requested information has been published). The SFK board checks whether the request is in line with its objectives[194] and statutes[195] and then makes a cost estimate[196] and time schedule for the delivery of the requested information. If approval is obtained and the applicant agrees with the estimated cost and time schedule for delivery then the SFK provides the requested data.

[187] https://www.palga.nl/assets/uploads/Openbare%20Databank/PODB_handleiding_website.pdf
[188] https://www.palga.nl/gegevensaanvragen/gegevensaanvragen.html
[189] https://www.nivel.nl/en
[190] https://www.nivel.nl/en/nivel-zorgregistraties-eerste-lijn/nivel-primary-care-database
[191] https://www.nivel.nl/en/nivel-zorgregistraties-eerste-lijn/nivel-primary-care-database
[192] https://www.sfk.nl/
[193] https://www.sfk.nl/informatie-aanvragen/aanvragen
[194] https://www.sfk.nl/over-de-sfk/doelstellingen
[195] https://www.sfk.nl/pdf-documenten/sfk-algemeen/statuten
[196] https://www.sfk.nl/informatie-aanvragen/uitzonderingen

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- **Statistics Netherlands (CBS)**

The national statistical office, Statistics Netherlands (CBS)[197], provides statistical information and data to produce insight into social issues, including on the theme Health and Welfare. StatLine[198] is the electronic database of CBS. It enables users to compile their own tables and graphs and the information can be accessed, printed and downloaded free of charge. All datasets in StatLine are available as open data. Datasets from StatLine can be found in the data portal[199]. The portal lists all available datasets by theme and/or keyword research. Each dataset includes a brief description and links to web services where the data can be retrieved.

Microdata, in the sense of linkable data at the level of individuals, companies and addresses can be made available to Dutch universities, scientific organisations and statistical authorities within the EU under strict conditions for statistical research.

To gain access, a number of steps must be completed (more details can be found on the CBS website[200]):

1. Application[201]: This step can be skipped if the research/statistical institution of the applicant is already authorised by CBS. If this is not the case, the head of the institution must submit a request[202] to the Director General of CBS. The application is reviewed and when authorisation is obtained applicants must submit a project application by sending a description to CBS Microdata Services[203]. This can be done by email using the template[204].
2. Substantive preparation[205]: A consultation with CBS experts will take place to determine mutually the set of data that can be accessed for conducting the research project. All data is pseudonymised. CBS then draws up a cost overview for the project (see the flyer[206] for cost examples) and if agreed a contractual agreement and confidentiality statements are prepared.
3. Technical preparation[207]: A project account is set up including access rights to the researchers and reading rights for the agreed datasets.
4. Project implementation[208]: New researchers will receive a hardware token and information[209] about working in the secure environment of CBS. A variety of standard software packages is available for analyses such as SPSS, Stata, R, Python. The results can only be published by adding them in an export folder, which is checked for disclosure risk by CBS employees.

[197] https://www.cbs.nl/en-gb
[198] https://opendata.cbs.nl/statline/#/CBS/en/
[199] https://opendata.cbs.nl/statline/portal.html?_la=en&_catalog=CBS
[200] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research
[201] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/welke-stappen/application
[202] https://www.cbs.nl/errors/pagina-niet-gevonden
[203] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/contact
[204] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/applying-for-access-to-microdata
[205] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/welke-stappen/substantive-preparation
[206] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/services-and-costs
[207] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/welke-stappen/technical-preparation
[208] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/welke-stappen/project-implementation
[209] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/log-in-to-ra

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5. Publication[210]: The results of research with CBS microdata must be made available to interested parties in full, immediately and free of charge.

- **The Netherlands Twin Register (NTR)**

The Netherlands Twin Register (NTR)[211] is the Dutch national registry in which twins, multiples and their parents, siblings, spouses and other family members participate. Since the early 1980s, the NTR has enrolled around 120,000 twins and a roughly equal number of their relatives. These resources, thanks to the longitudinal phenotyping, the extended pedigree structures and the multi-generation genotyping allow for future twin-family research that will contribute to gene discovery, causality modelling, and studies of genetic and cultural inheritance.

To submit a data sharing request, the process is outlined in the NTR data sharing request procedures[212] and the applicant should complete the NTR data sharing request form[213] and send it to the NTR Data management[214]. A checklist[215] has been created to facilitate the data sharing requests. The NTR Data management will check each request for completeness and feasibility. After this, the request is submitted for review by the Data Access Committee (DAC) which typically will need about 2 weeks for reviewing. Applicants are informed on the outcome and if the request is not approved they can revise the proposal and resubmit. Once the data request is approved, a Data Sharing Agreement is signed. Once the signed data sharing agreement is received by the NTR, data management takes approximately 2 weeks to prepare the dataset.

Other health databases and registries

In the Netherlands, there are several valuable data sources that can be used for scientific research. It is thus impossible to detail all the relevant databases and registries in the present report. For example, organisations like the National Health Care Institute (Zorginstituut Nederland, ZIN)[216] and the National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM)[217] also generate data of interest to medical and public health research and other large population cohort studies exist that can provide valuable insights to researchers such as LifeLines[218], the Rotterdam Study[219]. Notably, the joint Dutch population cohorts recently decided to initiate a close collaboration under the name Netherlands Cohort Consortium (NCC)[220]. NCC will closely collaborate with Health-RI to support large-scale cohort studies in the Netherlands through harmonization and pooling of data. In any case, the list in the present report should not be seen as an exhaustive inventory.

[210] https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research/welke-stappen/publication
[211] https://tweelingenregister.vu.nl/
[212] https://assets.vu.nl/fdcfbfb4-ea5f-0080-b339-861bb5cb584d/d45afcef-fc7b-4edf-9d47-af0fa5ab6410/NTR%20data%20sharing%20request%20procedures_v2021-1.pdf
[213] https://ntr-data-request.psy.vu.nl/DSR-forms.html
[214] ntr.datamanagement.fgb@vu.nl
[215] https://ntr-data-request.psy.vu.nl/checklist.html
[216] https://www.zorginstituutnederland.nl/
[217] https://www.rivm.nl/
[218] https://www.lifelines.nl/
[219] https://www.ergo-onderzoek.nl/
[220] https://www.demaastrichtstudie.nl/netherlands-cohorts-consortium-ncc

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8.3. Access to data

Health databases and registries in the Netherlands have to comply with the EU General Data Protection Regulation (GDPR)[221], as they process personal data and often sensitive data. The Dutch adaptation to the GDPR is the Uitvoeringswet Algemene Verordening Gegevensbescherming (UAVG)[222]. The national supervising authority on the proper implementation of data protection is entrusted to The Dutch Data Protection Authority (DPA)[223], which is supervising the processing of personal data in order to ensure compliance with the GDPR and the UAVG. The Medical Treatment Contract Law (WGBO)[224], which is an integral part of the Dutch Civil Code, is also applicable in the case of health databases and registries and it states that participants in medical research must be adequately informed on the research conducted and that permission is needed to access their data. The Law on Additional Provisions for the Processing of Personal Data in Healthcare Act[225] regulates patients' rights on access and exchange of their health data within healthcare.

9. Norway

9.1. Healthcare system

The healthcare system in Norway is public, and overseen by the Ministry of Health and Care services Ministry of Health and Care Services - regjeringen.no[226].

The healthcare system is divided into primary and secondary healthcare. Primary healthcare is governed by the local municipality, while secondary healthcare is governed by the 4 regional health authorities. In addition, there are private healthcare providers, some of which are hired by the municipalities or health authorities for their services. Across Norway, patients are free to choose in which hospital they want to receive their treatment. Healthcare in Norway has a dual financing system, with a basal allocation and an activity-based allocation – based on the services provided and the numbers of patients treated.

Patients pay a patient's fee for primary and secondary healthcare (children under 16 years, women during pregnancy and patients admitted to hospitals are exempt). The upper limit for total patient fee in a calendar year is 280 Euros as of 2022.

9.2. Health databases and registries

The public health registries, quality registries and databases are governed by various stakeholders in the Norwegian health system. The registries are regulated according to the Act relating to Personal Health Data Registries. The registries with personally identifiable information that are

[221] https://eur-lex.europa.eu/eli/reg/2016/679/oj
[222] https://wetten.overheid.nl/BWBR0040940/2020-01-01
[223] https://autoriteitpersoonsgegevens.nl/en
[224] https://wetten.overheid.nl/BWBR0005290/2012-06-%2013#Boek7_Titeldeel7_Afdeling5
[225] https://wetten.overheid.nl/BWBR0023864/2019-07-01
[226] https://www.regjeringen.no/en/dep/hod/id421/

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not based on consent are established after evaluation by the Norwegian government. Some of the national health registries do not contain personally identifiable data.

To access data from the various registries, researchers should apply directly to the registry, and the use of the data must be in line with the purpose of the registry, ethically sound, and the data processing compliant with the GDPR. If the data needed is potentially identifiable, the application process is much more extensive and will include approval from the Norwegian Ethical Committee and the Norwegian Data Protection Authority.

The Norwegian Institute of Public Health (NIPH) is a government agency under the Ministry of Health and Care services and has a central role in national health preparedness and in gathering information and conducting research on the health system. The institute is the national institute of contagious diseases and vaccinations. The institute is also responsible for all health-related population registries (except the cancer registry).

For more information on access to data: How to apply for access to data - NIPH (fhi.no)[227]

Registries under the responsibility of NIPH:

- Cause of Death Registry[228]
- Registry of Pregnancy Termination[229]
- Norwegian Cardiovascular Disease Registry[230]
- Medical Birth Registry of Norway[231]
- Norwegian Surveillance System for Communicable Diseases[232]
- Norwegian Immunisation Registry SYSVAK[233]
- Norwegian Surveillance System for Antimicrobial Drug Resistance (NORM)[234]
- Norwegian Surveillance System for Antiviral Resistance (RAVN)[235]
- Norwegian Prescription Database (NorPD)[236]

The Cancer Registry of Norway gathers data and provides statistics about the incidence of cancer in Norway. They also have the administrative responsibility of public cancer preventing screening programmes, such as mammograms and cervical cancer screening programs. Established in 1951, this is one of the oldest registries in Norway. The Cancer Registry also has the responsibility for eleven clinical registries for specific cancers, which gather data on the evaluation, treatment and outcomes for patients with the specific cancer diagnosis.

- Cancer Statistics[237] - statistical data is readily available in English
- Clinical Registries[238] for specific cancers

The Norwegian Department of Defence is responsible for the Norwegian Armed Forces Health Registry. This registry records health data from personnel that has been a part of the Norwegian

[227] https://www.fhi.no/en/more/access-to-data/applying-for-access-to-data/
[228] https://www.fhi.no/en/hn/health-registries/cause-of-death-registry/
[229] https://www.fhi.no/en/hn/health-registries/registry-of-pregnancy-termination/
[230] https://www.fhi.no/en/hn/health-registries/cardiovascular-disease-registry/
[231] https://www.fhi.no/en/hn/health-registries/medical-birth-registry-of-norway/
[232] https://www.fhi.no/en/hn/health-registries/msis/
[233] https://www.fhi.no/en/hn/health-registries/norwegian-immunisation-registry-sysvak/
[234] https://www.fhi.no/en/hn/health-registries/norm/
[235] https://www.fhi.no/en/hn/health-registries/norwegian-surveillance-system-for-virus-resistance-ravn/
[236] https://www.fhi.no/en/hn/health-registries/norpd/
[237] https://www.kreftregisteret.no/en/The-Registries/Cancer-Statistics/
[238] https://www.kreftregisteret.no/en/The-Registries/Clinical-Registries/

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Armed Forces. The purpose of the registry is to evaluate what health risk military personnel is exposed to and to provide a basis for statistics and research towards bettering the health of military personnel. Due to the mandatory national service and health test before enrolment, this registry also includes health data from all young men (and since 2010 also most young women).

- Registry of the Norwegian Armed Forces Medical Services[239]. (in Norwegian)

Information on how to apply for access (in Norwegian)[240]

The National Department of Health and Care Services is responsible for the Norwegian Patient registry and the Municipal patient registry that gathers information on all patients that have been given treatment or are awaiting treatment in the secondary and primary healthcare systems, respectively. The primary purposes of these registries are to provide a basis for quality assessment and administration of healthcare services. With the development of the electronic prescription system, a registry was established to ensure secure and effective prescriptions and that information on what medications a patient is receiving is available to the relevant health personnel.

- Norwegian Patient registry[241] – information on how to get access to data[242] (in Norwegian)
- Norwegian Information System for the Nursing and Care Sector[243] – information on access to data[244]
- Prescription registry

The Norwegian National Archives governs the National Health archives which include health records from deceased persons. This includes both newer e-records, but also old archives from both primary and secondary healthcare.

- Norwegian health archives[245]

Norwegian Services for medical quality registries

Medical quality registries gather information regarding the examinations, treatments, follow-up and outcomes of patients with defined diseases. The aim is to measure the quality of the treatment and improve the health services provided to specific patient groups and harmonize treatment and treatment quality at the various hospitals. The quality registries also contribute to clinical and epidemiological research. The registries are spread among the regional health authorities but are all combined under the National Services for Medical Quality Registries. It is possible to get access to data from these registries through the Helsedata-portal, and much of the data is available in English. Some of the data (aggregated) is freely accessible, while the greater part is only accessible by application. This is well indicated and described in the portal.

- Helsedata[246]
- National Service for Medical quality registries (in Norwegian)[247]

[239] https://www.forsvaret.no/forskning/forsvarets-helseregister-ime
[240] https://www.forsvaret.no/forskning/forsvarets-helseregister-ime/forskning-og-data
[241] https://helsedata.no/en/forvaltere/norwegian-directorate-of-health/norwegian-patient-registry-npr/
[242] https://www.helsedirektoratet.no/tema/statistikk-registre-og-rapporter/helsedata-og-helseregistre/norsk-pasientregister-npr/sok-om-data-fra-npr
[243] https://www.helsedirektoratet.no/tema/statistikk-registre-og-rapporter/helsedata-og-helseregistre/iplos-registeret
[244] https://www.helsedirektoratet.no/tema/statistikk-registre-og-rapporter/helsedata-og-helseregistre/iplos-registeret/sok-om-iplos-data
[245] https://www.arkivverket.no/om-oss/norsk-helsearkiv
[246] https://helsedata.no/en/

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10. Poland

10.1. Healthcare system

The Polish healthcare system is based on the insurance model. The compulsory health insurance contribution is paid by the Social Insurance Company (ZUS in Polish)[248] to the National Health Fund (NFZ in Polish)[249] and amounts to 9 percent of earnings. The National Health Fund finances health services provided to the insured and reimburses drugs. Part of health insurance contributions, including for: students, farmers and their household members (KRUS in Polish[250]) is financed from the state budget and special funds. Contributions for unemployed persons are financed by employment offices. Social welfare centres are assigned to persons not working, not registered with employment offices, who meet the income criterion, and the state budget - for clergy. People insured in the National Health Fund, apart from the insurance premium, do not incur any other costs of treatment. The exceptions include medicines, some of which are available for a lump sum or partial payment: sanatorium care, and adult dental care, some of which are paid for by the patient.

Pursuant to Article 68 of the Constitution of the Republic of Poland, everyone has the right to health protection. Each insured person may take advantage of, among others, medical examinations and consultations, if necessary, also at home, outpatient and inpatient treatment, medical rehabilitation, and health prophylaxis. Access to such health services is available, among others, to: children up to 18 years of age, students, unemployed persons registered with the Labour Office, women during pregnancy, childbirth and the postpartum period. Parents or legal guardians of children under the age of 18 or those in education up to the age of 26 are required to register the charges for insurance at the workplace. An unemployed person is subject to compulsory health insurance, provided that he is not covered by another basis.

Healthcare services are provided by both public and private institutions, medical professionals, group medical practice or group practice of nurses and midwives, if they have concluded an agreement with the National Health Fund for the provision of healthcare services in a given area. There are both public and private entities in the healthcare services market. Services provided by doctors, clinics and private hospitals may also be free for patients. In this case, the payer is the National Health Fund, which operates on the basis of an agreement for the provision of healthcare services (the so-called contracts). The services are provided by healthcare institutions. They are divided into public (SPZOZ in Polish) and non-public (NZOZ in Polish), there are medical, medical and dental practices, nursing, midwives and pharmacies.

The first level, i.e. primary healthcare

Basic health care (POZ in Polish) is primarily a family doctor to whom people report in the event of illness, periodic examinations and vaccinations. Patients receive assistance in an outpatient clinic and, in medically justified cases, also at home (also in a nursing home). If illness prevents the patient from getting to the clinic, the patient can arrange a home visit by a doctor, nurse or

[247] https://www.kvalitetsregistre.no/registeroversikt?f%5B0%5D=kategori%3A39
[248] https://lang.zus.pl/
[249] https://www.nfz.gov.pl/
[250] https://www.krus.gov.pl/

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midwife. Primary healthcare also includes preventive care for children and youth, which is provided by a nurse / hygienist at school or kindergarten.

As part of primary care, patients can choose:

- Doctor
- Nurse
- Midwife

The selection is made by submitting a written declaration at the clinic of their choice. It can also be done via the Patient's Online Account.

Second level: specialist treatment, i.e. outpatient specialist care

If GPs decide that a patient needs specialist treatment, they will refer the patient to a specialist. He will then be placed in outpatient specialist care. The patient has the right to choose any specialist clinic from among those with whom the National Health Fund has signed a contract. However, a referral only entitles patients to enrol in one clinic. Patients can sign up by phone, e-mail or in person without a referral, but this document must be delivered within 14 days of the appointment.

Third level: hospital

Both GPs and specialists can refer the patient to the hospital. He has the right to choose any hospital in Poland, provided that it has an agreement with the National Health Fund. In a situation where it is necessary due to the state of health, a doctor who does not have a contract with the National Health Fund can refer a hospital, and the patient does not have to pay for hospital treatment. Such a patient, however, does not have the right to free tests or consultations with a specialist on the basis of a referral from a private doctor - only a doctor who has a contract with the National Health Fund or works in a facility with such a contract can refer them. A referral for hospital treatment is important until an appointment is made for the patient to be admitted. Patients can also go to the hospital on their own, without a referral, in cases such as: accident, poisoning, trauma, childbirth has started, or life-threatening. The hospital does not have to admit the patient to the hospital ward immediately - it depends on the state of health and the possibility of admission at the moment. This rule does not apply in the event of a sudden threat to life or health. In such a situation, the hospital must see immediately to save life and health. If this is not possible (e.g. because it does not have the appropriate equipment, there is no department dealing with a given health problem in its structure), it must be ensured that the patient is transported by appropriate medical transport to the appropriate hospital.

10.2. Health databases and registries

The current list of medical registers created and maintained or created and commissioned to be kept by the minister responsible for health on the basis of the Act of 28 April 2011 on the information system in healthcare (Journal of Laws of 2020, item 702, as amended) d.):

- **National Register of Patients with COVID-19**

Regulation of the Minister of Health of April 7, 2020 on the National Register of Patients with COVID-19 (Journal of Laws of 2020, item 625);

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- **Family Hypercholesterolaemia Registry**

Regulation of the Minister of Health of 8 January 2020 on the Family Hypercholesterolaemia Register (Journal of Laws of 2020, item 83)

- **Register of Vascular Operations**

Regulation of the Minister of Health of 8 January 2020 on the Register of Vascular Operations (Journal of Laws of 2020, item 84)

- **Register of arthroplasty**

Regulation of the Minister of Health of 3 December 2019 on the register of endoprostheses (Journal of Laws 2019, item 2409)

- **Register of Transvascular Electrode Extraction**

Regulation of the Minister of Health of October 21, 2019 on the National Register of Endovascular Electrode Extraction (Journal of Laws of 2019, item 2191)

- **Infectious Endocarditis Registry**

Regulation of the Minister of Health of October 21, 2019 on the National Register of Infectious Endocarditis (Journal of Laws of 2019, item 2131)

- **Mechanical Circulation Support Register**

Regulation of the Minister of Health of October 16, 2019 on the National Register of Mechanical Circulation Support (Journal of Laws of 2019, item 2190)

- **National Register of Arrhythmia Ground Ablation**

Regulation of the Minister of Health of October 16, 2019 on the National Register of Arrhythmia Substrate Ablation (Journal of Laws of 2019, item 2098)

- **Polish Register of Congenital Developmental Defects**

Regulation of the Minister of Health of June 12, 2018 on the Polish Register of Congenital Developmental Defects (Journal of Laws 2018, item 1196)

- **Registry of Benign Neoplasms of Large Salivary Glands**

Regulation of the Minister of Health of June 12, 2018 on the Register of Benign Neoplasms of Large Salivary Glands (Journal of Laws of 2018, item 1181)

- **National Register of Cardiac Surgery**

Regulation of the Minister of Health of 30 May 2018 on the National Register of Cardiac Surgery (Journal of Laws 2018, item 1093)

- **National Register of Sharp Coronary Teams**

Regulation of the Minister of Health of 24 May 2018 on the National Register of Acute Coronary Syndromes (Journal of Laws of 2018, item 1063)

- **Register of Medically Assisted Procreation**

Regulation of the Minister of Health of August 16, 2018 on the Register of Medically Assisted Procreation (Journal of Laws of 2018, item 1598)

- **National Cancer Registry**

Regulation of the Minister of Health of 14 June 2018 on the National Cancer Register (Journal of Laws 2018, item 1197)

- **National cardiology and cardiac surgery registry of transcatheter treatment of heart valves "POL-TaVALVE"**

Regulation of the Minister of Health of September 28, 2021 on the nationwide cardiological and cardiac surgery register of transcatheter treatment of heart valves "POL-TaVALVE".

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10.3. Access to data

Medical data used for research and teaching purposes should be anonymised. Anonymization makes medical data lose the nature of personal data and cease to be protected. The GDPR applies to the processing of personal data in a fully or partially automated manner and to the otherwise processing of data that are or are to be part of a collection. It is worth remembering that the legal protection does not cover anonymous data, but only those which have the value of personal data. Personal data should be understood as any information relating to an identified or identifiable person. Therefore, if the notes concern clinical cases, without disclosing patient identification data, such as name and surname, PESEL number, address or photo of the face, they will not have the value of personal data. Then, they will not be protected even if the physician creates a clinical data set from them. Anonymous data collections can therefore be freely created and used for the purposes of research and teaching activities without fear of violating the law. With one caveat: be wary of extremely distinctive physical, physiological or psychological features or very rare medical conditions that may indirectly reveal the patient's identity.

The principle of anonymization also applies to the use of medical records for scientific and didactic purposes. The Patient Rights Act provides that medical records may be made available to a university or research institute for research purposes, without disclosing the name and other data enabling the identification of the person to whom the documentation relates. The authors would like to point out that the use of medical documentation for scientific purposes should be done through the university or institute. The hospital should not make the documentation available for research purposes directly to the doctor, and the doctor should not use it arbitrarily without the consent of the hospital.

11. Portugal

11.1. Healthcare system

Currently the Portuguese Health System is characterized by three coexisting, overlapping systems: 1) the universal tax-financed National Health System (Serviço Nacional de Saúde, SNS[251]), created in 1979 by which the State, assures the right to health protection, in the terms established by the Portuguese Constitution; 2) special social health insurance schemes for certain professions (health subsystems) that are occupation-based schemes used in the public or private sector of certain professions such as police, military, and banking that are normally financed through employer and employee contribution, covering 16% of the population (more information here[252]); 3) voluntary private health insurance, approximately 10% of the population, was covered by private health insurance in 2006[253], nevertheless, the number of people insured raised significantly since early 90's. There is the possibility of double or even triple coverage, that is, patients who benefit from the NHS, a health subsystem from their job and a private health insurance.

[251] https://www.sns.gov.pt/
[252] https://www.euro.who.int/__data/assets/pdf_file/0007/337471/HiT-Portugal.pdf
[253] https://apps.who.int/iris/bitstream/handle/10665/107844/HiT-9-5-2007-eng.pdf?sequence=7&isAllowed=y

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The Portuguese Ministry of Health (Ministério de Saúde)[254] is in charge of managing the Portuguese NHS. It is free, however, some fees are charged, not in order to finance the system but serving mainly to moderate and filter unnecessary access to the services. NHS is available to all residents in Portugal, although presently it still only covers all of mainland Portugal; the regions of Azores and Madeira have their own healthcare systems. The system covers both primary and secondary healthcare services. A central administration (Ministry of Health and its institutions) manages this while five regional health administrations (North, Central, Lisbon and Tagus Valley, Alentejo, and Algarve) deliver it.

Shared Services of the Ministry of Health, EPE (SPMS)[255] is a public enterprise created in 2010 under the guardianship of the Ministries of Health and Finance. Its aim is to provide shared services – in the areas of purchasing and logistics, financial services, human resources and information systems and technologies – to organizations operating specifically in the area of health, in order to "centralise, optimise and rationalise" the procurement of goods and services within the NHS.

SPMS is responsible for ensuring the operability and security of the Ministry of Health's technological infrastructures and information systems, promoting the definition and use of standards, methodologies and requirements that ensure the interoperability and interconnection of health information systems between itself, and with the information systems transversal to the Public Administration, aiming to develop and protect the health of the citizens.

Portugal has made considerable progress in the digital transformation of the NHS during the last decades. Currently, the country has a Digital National Health Service (e-NHS) that coexists with the traditional NHS made of healthcare provider institutions (hospitals, primary care units, continuity of care networks) and central agencies. The Portugues *e*NHS is composed by a network of multiple telehealth services and health information systems that collect and communicate data on people´s health and healthcare delivery. It can be divided in 6 main areas:

1. Administrative and Patient Management[256]
2. Clinical[257]
3. Financial[258]
4. Management and Planning[259]
5. Informative[260]
6. Information and Communication Technologies[261]

Which include more than 80 national health information systems that support the daily activity of 134 thousand health professionals, in about 2000 units providing health care in the NHS, 24 hours a day, 365 days a year. These systems guarantee the processing and availability of information at the different management levels of the NHS entities, at a local, regional and national level. Data

[254] https://www.sns.gov.pt/institucional/ministerio-da-saude/
[255] https://www.spms.min-saude.pt/
[256] https://www.spms.min-saude.pt/administrativo-e-gestao-de-doentes/
[257] https://www.spms.min-saude.pt/clinico/
[258] https://www.spms.min-saude.pt/financeiro/
[259] https://www.spms.min-saude.pt/gestao-e-planeamento/
[260] https://www.spms.min-saude.pt/centradonoutente/
[261] https://www.spms.min-saude.pt/tecnologias-de-informacao-e-comunicacao/

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stored in the *e*NHS support diverse range of healthcare functions, from clinical management (primary and secondary care) and medical prescription to public health surveillance and is a unique source of value for Portugal and for health protection of the population.

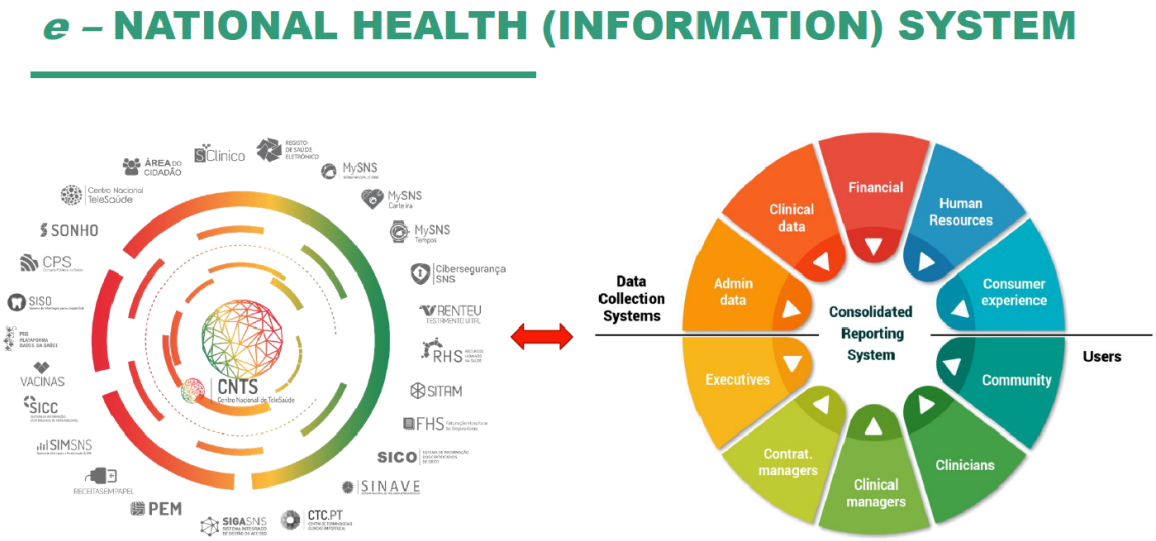

Figure 2: National landscape of digital National Health Service (e-NHS)

11.2. Health databases and registries

The Portuguese *e*NHS ecosystem has several independent databases such as:

- **RSE | Electronic Health Record**[262] **–** gather the clinical data collected electronically for each Citizen and produced by entities that provide health care. Allows the recording and sharing of clinical information between the user, health professionals and health service providers, in accordance with the requirements of the National Data Protection Commission (Authorization No. 940/2013). It comprises a Personal Area, a Professional Area and an Institutional Area.
- **RSE SIGA | Integrated Access Management System**[263] **-** which integrates the various health institutions, in practice, it is possible for CSPs and Hospital Centers to refer users with a discharge note for health care, so that they are followed up, after discharge, by the family doctor.
- **SINAVE | National Epidemiological Surveillance System**[264] **-** intended to dematerialize the notification process of notifiable diseases, including those resistant to antimicrobials. It also provides surveillance and statistical information to the Directorate-General for Health (DGS) and is integrated with the European Epidemiological Surveillance System under the responsibility of the ECDC (European Center for Disease Prevention and Control).

[262] https://www.spms.min-saude.pt/2020/07/registo-de-saude-eletronico/
[263] https://www.spms.min-saude.pt/2021/01/rse-siga/
[264] https://www.spms.min-saude.pt/2020/07/sinave-2/

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- **Trace COVID-19 platform**[265] – detailed records of specific information about the cases, the respective contract tracing, surveillance and clinical follow-up to patients with suspected or confirmed COVID-19.
- **SClinical | Hospital Health Care and SClinical | Primary Health Care**[266] **–** provides for the standardization of clinical record procedures, in order to guarantee the standardization of information. Access to the patient's varied clinical information, the use and sharing of data with health professionals from different areas and their systematization, allowing the homogenization of practices.
- **PEM | Electronic Medical Prescription**[267] **-** used in almost the entire NHS, responsible for more than 70% of the total prescriptions registered daily in Portugal.
- **Paperless Exams**[268] **-** to dematerialize the processes of requisition, execution and billing of Complementary Diagnostic and Therapeutic Means (MCDT).
- **SIVIDA | Information system HIV/AIDS**[269] **–** Information system that allows the monitoring and follow-up of users with HIV/AIDS, recording all the activity carried out within the scope of the provision of this care.
- **SIGLIC | Integrated Surgery Subscriber Management System**[270] **-** provides information on the list of candidates for surgery in the NHS, in order to have statistical data and indicators that allow for the control of the management of the programmed surgical activity, in view of the needs of users.
- **SISO | Oral Health Information System**[271] **-** provides statistics monitoring indicators, allows carrying out epidemiological studies, which include the collection of data on oral health and audit of procedures performed and recorded by dentists adhering to the program.

National registries

The national registers in Portugal are initiatives of the responsibility of institutions under supervision of the Ministry of Health such as SPMS, Instituto Nacional de Saúde Doutor Ricardo Jorge (INSA) or initiatives related to the various national scientific societies.

- National Registry of Living Wills (RENTEV)[272] - allows the collection, maintenance and management of access to the Living Wills of citizens who intend to grant a document of advance directives of will. This system is supported by a nationwide database, which centralizes and keeps the Living Wills and Health Care Attorneys up to date, guaranteeing citizens to consult them (and the respective health care attorney, if any), as well as as well as the doctors responsible for the provision of health care.
- National Register of Professionals (RNP)[273] - centralized collection of data from health professionals registered in professional associations: Nurses, Pharmacists, Dentists, Doctors, Nutritionists and Psychologists.

[265] https://www.spms.min-saude.pt/2019/05/trace-covid-19/
[266] https://www.spms.min-saude.pt/2020/07/sclinico-hospitalar/
[267] https://www.spms.min-saude.pt/2020/07/pem/
[268] https://www.spms.min-saude.pt/2019/07/exames-sem-papel/
[269] https://www.spms.min-saude.pt/2015/10/si-vida/
[270] https://www.spms.min-saude.pt/2015/10/siglic/
[271] https://www.spms.min-saude.pt/2015/06/siso/
[272] https://www.spms.min-saude.pt/2015/06/rentev-2/
[273] https://www.spms.min-saude.pt/2015/10/rnp/

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- National User Registry[274] - the reference database for the identification of Users of the National Health Service, at the level of a Master Patient Index (through the User number).
- National Registry of Congenital Anomalies (RENAC)[275] – is a population-based nosological registry, operating in Portugal since 1997, that aims to provide information on the epidemiology of congenital anomalies in Portugal, maintain a surveillance system that allows the detection of new teratogenic exposures, assess the effectiveness of primary prevention measures, assess the impact of prenatal diagnosis, maintain a database of data for research and to integrate the network of European registries of congenital anomalies (EUROCAT).
- EVITA system (Epidemiology and Surveillance of Trauma and Accidents)[276] - created in 2000 is a system for collecting and analysing data on Domestic and Leisure Accidents that involved resorting to emergencies of health units of the NH.
- National Cancer Registry (RON)[277] – created and regulated by the Law No. 53/2017 is a centralized registry based on a single electronic platform, which aims to collect and analyse data on all cancer patients diagnosed and/or treated in Mainland Portugal and in the autonomous regions, allowing for the monitoring of the activity performed by the institutions, the effectiveness of organized screening and therapeutic effectiveness, epidemiological surveillance, research and, in conjunction with INFARMED - National Authority of Medicines and Health Products, I. P. (INFARMED, I. P.), the monitoring of the effectiveness of medicines and medical devices.
- National Registry for Clinical Studies (RNEC)[278] - is a tool for registry and publication of all clinical studies undergoing in Portugal and that involve human beings, namely, clinical trials and other studies of clinical nature involving investigational products, medicines, medical devices and cosmetic products, allowing for a better interaction with all the stakeholders.

With the digitalisation of health data and the objective of providing a true picture of the Portuguese patients seen in clinical practice, practically all national scientific societies have created their own national registers. These data are used to acquire better knowledge of the diseases, for the development of national educational programmes based on the deficits captured, to allow for the comparison of different clinical practices and for the assessment of their compliance with International Recommendations and development of recommendations that actually meet the needs of patients and Health Professionals. Some examples of these registries related to the health are:

- Rheumatic Disease Portuguese Register[279]
- The National Centre for Cardiology Data Collection (CNCDC) is one initiative of the Portuguese Society of Cardiology with several national registries, such as:
    - National Registry of Heart Failure
    - National pilot register of Therapeutic Standards for Hypertension and Dyslipidemia
    - National Registry of Right Ventricular Arrythmogenic Myocardiopathy
    - National registry of X-Ray FA[280]
    - National register of Uncompacted Myocardiopathy[281]

[274] https://www.spms.min-saude.pt/2015/10/rnu/
[275] https://www.insa.min-saude.pt/category/areas-de-atuacao/epidemiologia/
[276] https://www.insa.min-saude.pt/category/areas-de-atuacao/epidemiologia/
[277] https://ron.min-saude.pt/pt
[278] https://www.rnec.pt/
[279] https://reuma.pt/enindex.html
[280] https://spc.pt/cncdc/#1572950135750-3d2d980a-73c1

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  - National register of interventional cardiology[282]
- The Portuguese Society of Transplants has several national registries, such as:
  - Renal Transplant Registry[283]
  - Pancreatic Transplant Registry[284]
- National Registry of Pneumonia in Internal Medicine Services[285]
- National Weight Control Register[286]

11.3. Access to data

National recommendations/policy documents

- SPMS launched at December 2019 the final version of the Portuguese Data Strategy for Next Generation National Health Service -From big data to smart health: putting data to work for the public´s health[287]. As part of the wider eHealth National strategy 2020-2022, *ENESIS 20|22 (National Strategy for the Health Information Ecosystem / Estratégia Nacional para o Ecosistema de Informação da Saúde 2020- 2022;*
- Guide published by SPMS on GDPR[288] - information privacy in the healthcare sector (document in Portuguese);
- National Law to complement the GDPR: Law n.º 58/2019 published on 8th August[289]. Article 31: "Personal data processing for public interest archiving, scientific research, historical or statistic purposes." (Document in Portuguese);
- INCoDe.2030 is the Portuguese initiative to foster digital skills guidance on *Artificial Intelligence Portugal 2030*[290]*,* launched on 4th June, 2019 that established a national strategy for *Artificial Intelligence*

Access for secondary use of NHS data

All the research projects using the non-integrated NHS data apply an ad hoc extraction process. It starts with a submission request of a scientific research protocol (including a data management plan and data security risks) to an SPMS Scientific Committee and at least one Ethical Committee. Since data were originally collected only for health purposes the secondary use pertinence and "purpose limitation" issues will be analysed. The National Ethics Committee (CEIC)[291] is the competent ethical board for clinical trials and interventional studies but also for national observational studies in the present COVID-19 context. The specific research objectives and public interest are under the scope of GDPR (nº1(b) of article 5; nº 4 of article 6, and nº1 (e) of article 23) and maybe not considered incompatible with the initial data collection purposes.

[281] https://spc.pt/cncdc/#1572950316528-a547dd3f-5432
[282] https://spc.pt/portfolio-item/registo-nacional-de-cardiologia-de-intervencao/
[283] http://www.spt.pt/site/desktop/webpage-58.php
[284] http://www.spt.pt/site/desktop/webpage-76.php
[285] https://www.spmi.pt/registo-nacional-pneumonias-servicos-medicina-interna/
[286] https://panosr.fmh.ulisboa.pt/rncp
[287] https://www.spms.min-saude.pt/wp-content/uploads/2020/07/Data-Strategy_VERSAOFINAL_07.01.2020.pdf
[288] https://spms.min-saude.pt/wp-content/uploads/2017/03/Guia-Privacidade-SMPS_RGPD_digital_20.03.172-v.2.pdf
[289] https://dre.pt/dre/detalhe/lei/58-2019-123815982
[290] https://www.incode2030.gov.pt/sites/default/files/julho_incode_brochura.pdf
[291] https://www.ceic.pt/normativo-internacional

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If the project is approved, before project initiation a written agreement between all parts involved will be put in place establishing among others, property issues, responsibility for safety issues, protective measures to avoid unforeseen usage and control of data access, duration of storage, destruction, research data dissemination and publication (may include exclusively aggregated and anonymised data). The data will be available /accessible for research for a duration period, but any subsequent studies will have to respect all the necessary ethical approvals.

Since data is scattered over multiple data sources there is no alternative to use subject identification to merge different datasets and ensure data quality. To deal with this issue, only Ministry of Health human resources (duly authorised SPMS staff) have access to identifiable data and are the only ones responsible for data extraction. Data protection is ensured by making use of legal, technical and operational measures already in place at the Ministry of Health for data management of personal and health-related data. Non-aggregated national data will be encrypted and exported for the data analysis specified. The encryption key is stored in SPMS. Specific measures to ensure that it is not possible to identify directly or indirectly by means reasonably likely to be used, must be adopted and validated by SPMS and Data Protection Officers. Also, digital privacy measures apply to avoid unauthorized or corrupted access, following national and international laws and standards that govern data security measures. These measures include strong user authentication, back-up solutions and other measures as applicable to the different project tasks, safeguarding data breaches, protection of privacy and data integrity.

Data will be stored with metadata which includes information on the methodology used to collect the data, analytical and procedural information, and definitions of variables from each of the health information systems that will be used as data sources for the research project.

12.Slovakia

12.1. Healthcare system

The National Council of the Slovak Republic is the sole constitutional and legislative body of the Slovak Republic. The Committee on Healthcare (Výbor NR SR pre zdravotníctvo)[292] carries out supervisory activities in relation to the Slovak Government and individual central state-administration authorities. The Committee recommends to the National Council positions and opinions regarding bills, and international treaties, and discusses and takes opinions regarding reports on the health of the population of the Slovak Republic and healthcare conditions in Slovakia. The Committee discusses the state budget proposal and performance of the state budget and final state account concerning the Ministry of Health of the Slovak Republic (Ministerstvo zdravotníctva Slovenskej Republiky)[293]. The Ministry of Health of the Slovak Republic is the central authority for public services of healthcare, health protection, public health insurance, education for health professionals, natural healing baths, resources and mineral springs, politics about prices of products, services and administration in health, establish non-

[292] https://www.nrsr.sk/web/Default.aspx?sid=vybory/vybor&ID=161
[293] https://www.health.gov.sk/Index.aspx

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profit-organizations, state-owned enterprises etc. The Public Health Authority of the Slovak republic (Úrad verejného zdravotníctva Slovenskej Republiky)[294] and the State Institute for Drug Control (Štátny ústav pre kontrolu liečiv, ŠÚKL)[295] and regional health authorities are subordinate to the Ministry of Health.

In Slovakia, healthcare is provided on the basis of public health insurance. Each employed citizen has to pay healthcare contributions. Currently, the citizens can freely choose from three health insurance companies in the Slovak Republic (Všeobecná zdravotná poisťovňa, Dôvera, Union). Generally, the insured citizens have universal accessibility to healthcare and they have the right to healthcare provision free of charge (Act No. 577/2004 Coll. on the scope of healthcare reimbursed on the basis of public health insurance and on reimbursements for services related to the provision of healthcare). In some special cases, the patient pays for part or all of the healthcare (for example dentistry). The Slovak healthcare system is operated by public and private healthcare providers, which have contracts with health insurance companies.

National Health Information Centre (NHIC) (Národné centrum zdravotníckych informácií NCZI)[296]

The National Health Information Centre is a state-funded organization founded by the Ministry of Health. NHIC covers electronic healthcare (e-Health), standardization of health informatics, statistics in the health system, national registries (national health registries and national health administrative registries) and Slovak medical library. Statistics in this information system review collecting data in annual, quarterly and monthly reports. It brings needed outputs about the health status of the population, but also reflects healthcare providers and the economy of health service. In 2015 the e-Health project was launched through special information and communication technologies that facilitate daily healthcare and processing of data. It supports collaboration with WHO, OECD, EUROSTAT and EMCDDA. Therefore, NHIC is an important tool for medical scientists and this informatization in health service multiplies participation in international clinical trials.

12.2. Health databases and registries

The National Health Information Centre in Slovak Republic administers, collects and processes data stored in the following registries according to Act No.153/2013 (Act no. 153/2013 Coll. on the National Health Information System and on Amendments and Additions to Certain Laws):

- National Registry of Electronic Health Records (Národný register elektronických zdravotných knižiek)[297]. Citizen's Electronic Health Book sharing current and complete data on the patient's health status. Recording of health data is signed by healthcare professionals after login. The key benefit is a comprehensive summary of patient's medical records.
- National Cancer Registry (Národný onkologický register)[298]
- National Diabetes Mellitus Registry (Národný register diabetes mellitus)[299]
- National Congenital Disease Registry (Národný register vrodených chýb)[300]

[294] https://www.uvzsr.sk/en/
[295] https://www.sukl.sk/hlavna-stranka/english-version?page_id=256
[296] https://www.nczisk.sk/en/Pages/default.aspx
[297] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-elektronickych-zdravotnych-kniziek.aspx
[298] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Narodny_onkologicky_register/Pages/default.aspx
[299] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-s-diabetes-mellitus.aspx

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- National Cardiovascular Registry (Národný register chorôb obehovej sústavy)[301]
- National Registry of Neurological Disorders (Národný register neurologických chorôb)[302]
- National Registry of Chronic Pulmonary Diseases (Národný register chronických pľúcnych chorôb)[303]
- National Registry of Persons with Injury Requiring Inpatient Healthcare (Národný register úrazov vyžadujúcich poskytnutie ústavnej zdravotnej starostlivosti)[304]
- National Registry of Persons Suspected of Being Neglected, Abused and on Victims of Violence (Národný register osôb s podozrením na ich zanedbávanie, týranie, zneužívanie a osôb, na ktorých bolo páchané násilie)[305]
- National Registry of Patients with Inflammatory Rheumatic Diseases (Národný register zápalových reumatických chorôb)[306]
- National Tuberculosis Registry (Národný register tuberkulózy)[307]
- National Arthroplasty Registry (Národný artroplastický register)[308]
- National Registry of Assisted Reproduction (Národný register asistovanej reprodukcie)[309]
- National Registry of Health Workers (Národný register zdravotníckych pracovníkov)[310]
- National Registry of Health Care Providers (Národný register poskytovateľov zdravotnej starostlivosti)[311]
- National Registry of Drug Handling Organizations (Národný register organizácií s osobitnými úlohami v zdravotníctve)[312]

National health registries analyse data about incidence, prevalence, mortality of diseases occurring on a large-scale or those which are socially significant in the population of the Slovak Republic. This data monitoring has an important impact on health politics, economic and social sphere. Collection, processing and analysis of these data are important in the field of taking measures in health, economic as well as social area.

12.3. Access to data

The personal data protection in Slovak republic edit Act No. 18/2018 on personal data protection and amending and supplementing certain Acts[313] with continuity on GDPR[314]. NHIC standard

[300] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-s-vrodenou-vyvojovou-chybou.aspx
[301] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-so-srdcovocievnym-ochorenim.aspx
[302] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-s-neurologickym-ochorenim.aspx
[303] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-s-chronickym-ochorenim-pluc.aspx
[304] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-osob-s-urazom-vyzadujucim-poskytnutie-ustavnej-zdravotnej-starostlivosti.aspx
[305] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-osob-s-podozrenim-na-ich-zanedbavanie-tyranie-zneuzivanie-a-osob-na-ktorych-bolo-pachane-nasilie.aspx
[306] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-so-zapalovym-reumatickym-ochorenim.aspx
[307] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-pacientov-s-tuberkulozou.aspx
[308] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-artroplasticky-register.aspx
[309] https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-asistovanej-reprodukcie.aspx
[310] https://www.nczisk.sk/Registre/Narodne-administrativne-registre/Narodny-register-zdravotnickych-pracovnikov/Pages/default.aspx
[311] https://www.nczisk.sk/Registre/Narodne-administrativne-registre/Narodny-register-poskytovatelov-zdravotnej-starostlivosti/Pages/default.aspx
[312] https://www.nczisk.sk/Registre/Narodne-administrativne-registre/Narodny_register_organizacii_zaobchadzajucich_s_liekmi/Pages/default.aspx

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summary statistic outputs of population are published on the official NHIC website[315] and in publications. The individual collected data stored by NHIC are not publicly available. The specific reports from registries are target for Ministry of Health and professionals[316].

Access to Citizen's Electronic Health Book is possible only for the patient, general practice and specialist (Act No.153/2013 Coll. on the National Health Information System and on Amendments and Additions to Certain Laws). Accessible data for scientific research started on endpoint level (never individual information about patient). Access to more statistic outputs for research purpose is based on request to NHIC, which is preparing them according to price list (Act 618/2003 Coll. on Copyright and Rights Related to Copyright - Copyright Act) or in case research project is necessary to apply NHIC as participating organization in the project.

13.Spain

13.1. Healthcare system

The Spanish health system is characterized by three statutory subsystems that coexist: the universal national health system (Sistema Nacional de Salud, SNS), Mutual Funds catering for civil servants, the Armed Forces and the judiciary (MUFACE, MUGEJU and ISFAS), and the Mutualities focused on assistance for Accidents and Occupational Diseases. It is a national health system based on the principles of universality, free access, equity and fairness of financing, and is mainly funded by taxes. It is organized at two levels – national and regional – mirroring the administrative division of the country. Health competencies are transferred to the 17 Autonomous Communities. Provision is free of charge at the point of delivery, with the exception of outpatient pharmaceutical prescriptions and specific orthosis and orthopaedic prosthesis.

The National Health System is structured into two healthcare levels, primary care and specialist care. Primary healthcare services are located within the community, they also deal with health promotion and disease prevention. The National Ministry of Health[317] receives support from four specialized agencies: the Agency for Medicines and Medical Devices[318], the National Transplants Organization[319]; the Agency for Consumer Affairs, Food Safety and Nutrition, and the Institute for Health Carlos III (Instituto de Salud Carlos III, ISCIII)[320], that combines health technology assessment, research centres, public health services and biomedical research coordination and financing.

More detailed information on the Spanish healthcare system can be obtained through the links:

- https://www.mscbs.gob.es/organizacion/sns/docs/sns2012/SNS012__Ingles.pdf

[313] https://dataprotection.gov.sk/uoou/sites/default/files/2019_10_03_act_18_2018_on_personal_data_protection_and_amending_and_supplementing_certain_acts.pdf#overlay-context=sk/content/182018
[314] https://www.justice.gov.sk/OSBR/Stranky/Ochrana-osobnych-udajov.aspx
[315] http://www.nczisk.sk/Statisticke_vystupy/Tematicke_statisticke_vystupy/Pages/default.aspx
[316] http://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Pristup-k-udajom-z-narodnych-zdravotnych-registrov-pre-zdravotnickych-pracovnikov.aspx
[317] https://www.sanidad.gob.es/
[318] https://www.aemps.gob.es/
[319] http://www.ont.es/Paginas/Home.aspx
[320] https://www.isciii.es/Paginas/Inicio.aspx

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- https://www.euro.who.int/__data/assets/pdf_file/0008/378620/hit-spain-eng.pdf

13.2. Health databases and registries

- **Aporta Initiative**

The main goal of the Aporta initiative, a key element in the Spanish government's open data policy, is to harmonize and efficiently take advantage of the synergies between ongoing open data projects. It seeks to always drive and coordinate actions being carried out by different levels of the administration, the private sector and the academic field, according to an integrating governance model. It does all of this in order to promote new products and services from the private sector and civil society to benefit society as a whole.

The data catalogue contains 22 categories, which include "Science and Technology" (1,735 datasets) and "Healthcare" (3,756 datasets) (Assessed June 2021).

Access to the data for research purposes:

Each dataset has a different format, but the user can access them publicly and no specific access request is required.

Information and data accessible here: https://datos.gob.es/en/about-aporta-initiative

- **INCLASNS Spanish National Key Indicators**

Prioritized set of information which gathers the most relevant aspects of health and the Spanish healthcare system, the database includes 16 health indicators.

Access to the data for research purposes: No specific access request is required.

Information and data accessible here: http://inclasns.msssi.es/?show=true

- **Data bank (Banco de Datos)**

The database contains the statistical publications of the Ministry of Health, Social Services and Equality. Accessible at:

https://www.sanidad.gob.es/estadEstudios/estadisticas/bancoDatos.htm

Free access to anonymized microdata files:

- Health Barometer
- National Catalogue of Hospitals
- NHS Primary Healthcare Centres Catalogue
- European Health Survey in Spain
- Spanish National Health Survey
- Statistics on Health Establishments providing In-Patient Care

Request for access and extraction of data

An access request form is needed; the data could be given over only to publicly owned welfare centres, public healthcare administrations and public research centres.

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824087.

- National Death Index[321]
- CMBD Discharges Record on Hospitalization and Specialized Out-Patient Care[322]

- **National Statistics Institute**

The National Statistics Institute plays an important role in public statistic activity, expressly placing it in charge of large-scale statistical operations (demographic and economic censuses, national accounts, demographic and social statistics, economic and social indicators, coordination and maintenance of company directories Electoral Census training...).

More information can be provided here:

https://www.ine.es/dyngs/INEbase/en/operacion.htm?c=Estadistica_C&cid=1254736176784&menu=ultiDatos&idp=1254735573175

Society-Health category includes the following subcategories[323]:

- Hospital morbidity surveys
- Death statistics according to cause of death
- European Survey of Health in Spain
- National Health Survey
- The employment of persons with disabilities
- The Wages of Persons with Disabilities
- Weekly death estimates (EDeS) during the COVID-19 outbreak
- Affiliated Health Professionals Statistics

Access to the above for research purposes does not require access request.

- **Information System for Research in Primary Care - SIDIAP**

The main aim of SIDIAP is to make available a great information system with data from the clinical work station of primary care (ECAP) of the Catalan Institute of Health and other complementary sources which allow access to valid and trustworthy information to achieve new knowledge and to support Primary Care research.

It can be accessed through the following link:

https://www.sidiap.org/index.php/en/

In more detail in SIDIAP can be found:

- Information originated from the medical records of the Catalonian Primary Care System-ECAP: All registered data since the programme started are available. More precisely, for each person SIDIAP has:
  - Demographic data: Date of birth, gender, nationality, allocated PCT and professionals, MEDEA index
  - Visits to Primary Care Service: Date, type and professional in charge
  - Health Problems: ICD-10 code, date of diagnosis and expiry date. Available for acute and chronic health problems

[321] https://www.sanidad.gob.es/estadEstudios/estadisticas/estadisticas/estMinisterio/IND_TipoDifusion.htm
[322] https://www.sanidad.gob.es/estadEstudios/estadisticas/estadisticas/estMinisterio/SolicitudCMBD.htm
[323] https://www.ine.es/dyngs/INEbase/en/categoria.htm?c=Estadistica_P&cid=1254735573175

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824087.

  - Clinical variables: Date and measurement. Clinical variables available are, for instance, blood pressure, smoking habit and BMI
  - Immunisations: Vaccine administered and date
  - Referrals: Date and department of referral
  - Death: Date of death
  - Prescriptions
  - Sick leave: Date and ICD-10 diagnosis

- Information on laboratory results: Since 2006, information is available on the results of laboratory analysis requested by PCT of the Catalan Institute of Health. This information is obtained directly from the databases of the laboratories and therefore does not depend on the manual register of the professionals in the PCT. Validation and standardization of protocols to guarantee data quality.
- Information on medication dispensed in pharmacies: Since 2005, information is available on all pharmaceutical products with a prescription of the national health system signed by a professional of the Catalan Institute of Health and dispensed in pharmacies. This information is directly obtained from the joint database of CatSalut with Catalan pharmacies.
- Other external sources: In addition and according to the needs of each project, SIDIAP allows linking with other databases of Catalonia at an individual level through a mechanism that guarantees the confidentiality of the clinical data. Some of these databases are:
  - CMBD-AH (CatSalut): Dates and diagnostics and procedures (ICD-9 Codes) linked to admissions in every hospital of Catalonia.
  - Mortality (Health Department): Date and causes of death of all residents of Catalonia.
  - Other: Population registers of cancer, arthroplasty, renal transplant, dialysis, etc.

Access to the data for research purposes: Investigators of research groups from other public research institutions can also apply to obtain data from the SIDIAP. A signed agreement is needed. The procedure is available here (including the relevant application form):

https://www.sidiap.org/index.php/en/solicituds-2

Schematically, the data access procedure for SIDIAP data is the following:

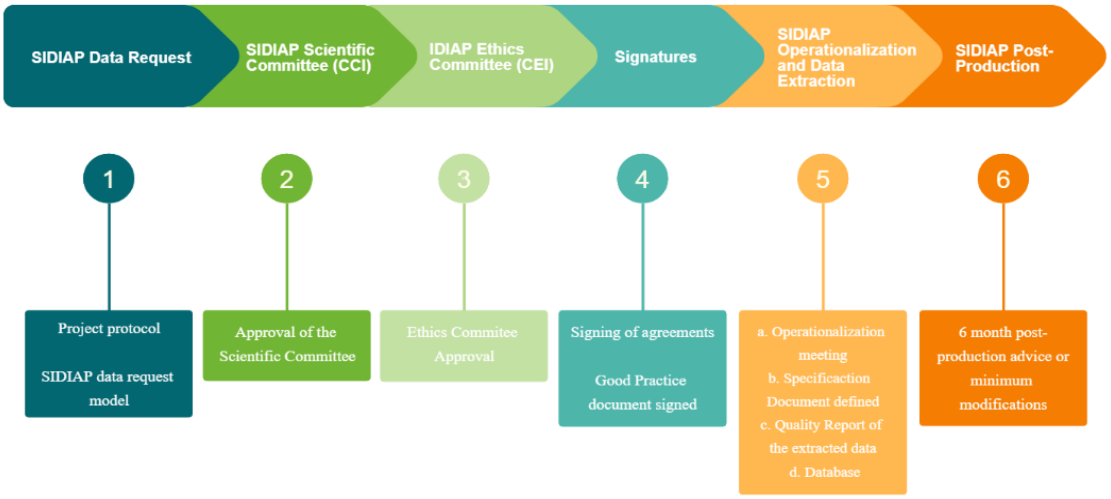

Figure 3: SIDIAP data request circuit

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- **BIFAP database**

BIFAP is a computerized database of Primary Care medical records for conducting pharmacoepidemiologic studies, belonging to the Spanish Agency for Medicines and Health Products (AEMPS), and has the collaboration of Autonomous Communities and the support of the main scientific societies involved. It can be accessed at: http://bifap.aemps.es/

Extraction and processing of data:

The responsible person of electronic health records at each Autonomous Community uploads the model, so that it can be exploited health data into the BIFAP database on a periodic basis. As datasets have different structures and technical specifications in each Autonomous Community, all the information is then harmonized and integrated into the common BIFAP afterwards. Information is always pseudonymised before being uploaded into the system.

Access to data for research purposes can be obtained through:

https://herramientas2bifap.aemps.es/ServiciosBifap/jsp/definiciones/signIn.xhtml

The applicant must be a Primary Care physician of the Health National System of the participating autonomous communities, staff of the participating administrations or work in a Spanish public research or health care body.

14.Sweden

14.1. Healthcare system

The Swedish health system provides universal health coverage for all residents, regardless of nationality, while emergency coverage is provided to all patients from the EU/EEA and via bilateral agreements. In Sweden there are three independent governmental levels, which are elected every four years - the national government (Riksdag), the county councils (Landsting) and the municipalities (Kommuner) - and all three are involved in healthcare. Thus, Sweden's healthcare system is organized and managed on three levels: national, regional and local. At the national level, the Ministry of Health and Social Affairs is responsible for overall healthcare policy and regulation and sets budgets for government agencies and grants to regions, working in concert with 8 national government agencies. At the regional level, 21 county councils are responsible for financing and delivering health services to residents. At the local level, 290 municipalities are responsible for the care of the elderly and the disabled, including long-term care. The councils and the municipalities have considerable freedom in planning for the delivery of care, which is one explanation for regional variations. On the national level, they are represented by the Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Regioner, SKR)[324].

In 2016, the government developed a vision of Sweden as a world leader in e-health by 2025[325]. Patients aged 16 or older can increasingly access their electronic medical records to view personal

[324] https://skr.se/skr.25.html
[325] https://www.government.se/information-material/2016/08/vision-for-ehealth-2025/

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health data, read physician's notes, schedule appointments, and refill prescriptions. This is possible thanks to a national patient portal (1177.se)[326] and a national Health Information Exchange (HIE) platform.

14.2. Health databases and registries

National quality registries (Nationella kvalitetsregister)

In Sweden there are more than 100 national quality registries that have been created within specific areas of the healthcare system in order to develop and ensure the quality of care in a systematic and continuous way. The registers contain personal data on healthcare in specific areas (examples of data are diagnosis, treatment, and treatment outcome) and are used to improve and follow up healthcare outcomes as well as research.

Most quality registries have been initiated by health professionals, which constitute the majority of the members of the registries' steering groups. The quality registries receive logistic and economic support from two sources: the Swedish government and the SKR. The registries vary in size and are differently established, therefore are differently suited for research purposes. Early contact with the registry holder, or another representative of the registry's steering group, is therefore recommended to researchers interested in accessing data. The office for National Quality Registries within the SKR has developed the website Kvalitetsregister.se[327] that provides information about all National quality registries, contact details, name of the registry holder, information about certification levels and link to the registry website.

The following is a list of the National Quality Registries with links to their description and website:

- National Quality Registry for Amputation and Prostheses (SwedAmp) – Description[328], Website[329]
- National Quality Registry for Assisted Reproduction (Q IVF) – Description[330], Website[331]
- National Quality Registry for Childhood Cancer – Description[332], Website[333]
- National Quality Registry for Childhood Epilepsy (BEPQ) – Description[334], Website[335]
- National Quality Registry for Childhood Obesity (BORIS) – Description[336], Website[337]
- National Quality Registry for Child and Adolescent Psychiatry (Q-bup) – Description[338], Website[339]
- National Quality Registry for Catheter Ablation – Description[340], Website[341]

[326] https://www.1177.se/
[327] https://skr.se/kvalitetsregister.32864.html
[328] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/amputationochprotes.44126.html
[329] https://swedeamp.com/
[330] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/assisteradbefruktning.44155.html
[331] https://www.medscinet.com/qivf/
[332] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/barncancer.44156.html
[333] https://sbcr.se/
[334] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/barnepilepsi.44157.html
[335] https://bepq.se/
[336] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/barnfetma.44169.html
[337] http://www.e-boris.se/
[338] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/barnochungdomspsykiatri.44171.html
[339] https://qbup.registercentrum.se/
[340] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/behandlingaravhjartrytmrubbningar.44172.html
[341] https://www.ucr.uu.se/kateterablation/

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- National Quality Registry for Dependency – Description[342], Website[343]
- National Quality Registry for Better Management of Patients with Osteoarthritis (BOA) – Description[344], Website[345]
- National Quality Register for Bipolar Affective Disorder (BipoläR) – Description[346], Website[347]
- National Quality Registry for Breast Cancer (NKBC) – Description[348], Website[349]
- National Quality Registry for Breast Implants – Description[350], Website[351]
- National Quality Registry for Pancreatic and Periampullary Cancer – Description[352], Website[353]
- National Quality Registry for Follow-up of Persons with Cerebral Palsy (CPUP) – Description[354], Website[355]
- National Quality Registry for Cystic Fibrosis (CF-registret) – Description[356], Website[357]
- National Quality Registry for Behavioural and Psychological Symptoms of Dementia (BPSD) – Description[358], Website[359]
- National Quality Registry for Dementia (SveDem) – Description[360], Website[361]
- National Quality Registry for Diabetes (NDR) with SWEDIABKIDS – Description[362], Website[363]
- National Quality Registry for Electroconvulsive therapy (ECT) – Description[364], Website[365]
- National Quality Registry for Endovascular Treatment of Ischemic Stroke (EVAS) – Description[366], Website[367]
- National Quality register for foot and ankle surgery – Description[368], Website[369]
- National Quality Registry for Ankle Surgery – Description[370], Website[371]
- National Quality Registry for Fractures (SFR) – Description[372], Website[373]
- National Quality Registry for Atrial Fibrillation (AuriculA) – Description[374], Website[375]

[342] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/beroendevard.44173.html
[343] https://battreberoendevard.registercentrum.se/
[344] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/artros.44154.html
[345] https://boa.registercentrum.se/
[346] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/bipolarsjukdom.44174.html
[347] https://bipolar.registercentrum.se/
[348] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/brostcancer.44178.html
[349] https://cancercentrum.se/samverkan/cancerdiagnoser/brost/kvalitetsregister
[350] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/brostimplantat.44179.html
[351] https://brimp.registercentrum.se/
[352] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/canceribukspottskorteln.44181.html
[353] https://cancercentrum.se/samverkan/cancerdiagnoser/bukspottkortel/kvalitetsregister/
[354] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/cerebralparescp.44184.html
[355] https://cpup.se/
[356] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/cystiskfibros.44185.html
[357] https://cf-registret.se/
[358] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/demensmedbeteendemassigaochpsykiskasymptom.44186.html
[359] https://bpsd.se/
[360] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/demenssjukdomar.44187.html
[361] https://www.ucr.uu.se/svedem/
[362] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/diabetes.44188.html
[363] https://www.ndr.nu/#/
[364] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/elbehandlingvidpsykiatriskasjukdomar.44221.html
[365] https://ect.registercentrum.se/
[366] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/endovaskularbehandlingavstroke.44190.html
[367] https://evas-registret.se/en/new-englishpage/
[368] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/fotochfotledskirurgi.44191.html
[369] https://fot.registercentrum.se/
[370] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/fotledskirurgi.44192.html
[371] http://swedankle.se/
[372] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/fraktur.44193.html
[373] https://sfr.registercentrum.se/
[374] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/formaksflimmer.44194.html

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824087.

- National Quality Registry for Gallstone Surgery (GallRiks) – Description[376], Website[377]
- National Quality Registry for Pregnancy – Description[378], Website[379]
- National Quality Registry for Cataracts – Description[380], Website[381]
- National Quality Registry for Gynaecological Surgery (GynOp) – Description[382], Website[383]
- National Quality Registry for Gynaecological Oncology – Description[384], Website[385]
- National Quality Registry for Hand Surgery (HAKIR) – Description[386], Website[387]
- National Quality Registry for Hepatitis (InfCare Hepatit) – Description[388], Website[389]
- National Quality Registry for HIV (InfCare HIV) – Description[390], Website[391]
- National Quality Registry for Brain Tumours – Description[392], Website[393]
- National Quality Registry for Enhancement and Development of Evidence-Based Care in Heart Disease (SWEDEHEART) – Description[394], Website[395]
- National Quality Registry for Heart Failure (RiksSvikt) – Description[396], Website[397]
- National Quality Registry for Corneal Transplant – Description[398], Website[399]
- Swedish Head and Neck Cancer Register (SweHNCR) – Description[400], Website[401]
- The Swedish Pituitary Register – Description[402], Website[403]
- National Quality Registry for Hip Fracture (RIKSHÖFT) – Description[404], Website[405]
- National Quality Registry for Infectious Diseases – Description[406], Website[407]
- National Quality Registry for Inflammatory Bowel Disease (SWIBREG) – Description[408], Website[409]

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[375] https://www.ucr.uu.se/auricula/
[376] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/gallstenskirurgi.44195.html
[377] https://www.ucr.uu.se/gallriks/
[378] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/graviditet.44196.html
[379] https://www.medscinet.com/gr/default.aspx
[380] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/grastarr.44197.html
[381] http://kataraktreg.se/
[382] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/gynekologiskaoperationer.44199.html
[383] https://www.gynop.se/
[384] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/gynekologiskcancer.44200.html
[385] https://cancercentrum.se/samverkan/cancerdiagnoser/gynekologi/kvalitetsregister
[386] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/handkirurgi.44202.html
[387] https://hakir.se/
[388] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hepatit.44203.html
[389] https://qrcstockholm.se/register/anslutna-register/infcarehiv-och-infcarehepatit/
[390] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hiv.44204.html
[391] https://infcarehiv.se/about-infcarehiv
[392] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hjarntumor.44205.html
[393] https://cancercentrum.se/samverkan/cancerdiagnoser/hjarna-ryggmarg-och-hypofys/hjarna-och-ryggmarg/kvalitetsregister/
[394] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hjartinfarkt.44206.html
[395] https://www.ucr.uu.se/swedeheart/
[396] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hjartsvikt.44208.html
[397] https://www.ucr.uu.se/rikssvikt/
[398] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hornhinnetransplantation.44209.html
[399] http://www.cornea.nu/
[400] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/huvudochhalscancer.44210.html
[401] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hornhinnetransplantation.44209.html
[402] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hypofyssjukdomar.44211.html
[403] https://cancercentrum.se/samverkan/cancerdiagnoser/hjarna-ryggmarg-och-hypofys/hypofys/kvalitetsregister-for-hypofystumorer/
[404] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hoftfraktur.44212.html
[405] https://www.xn--rikshft-e1a.se/
[406] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/infektionssjukdomar.44213.html
[407] https://infektionsregistret.se/
[408] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/inflammatoriskatarmsjukdomar.44214.html
[409] https://www.swibreg.se/

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- National Quality Registry for Intensive Care (SIR) – Description[410], Website[411]
- National Quality Registry for Internet-Based Psychological Treatment (SibeR) – Description[412], Website[413]
- National Quality Registry for Caries and Periodontitis (SKaPa) – Description[414], Website[415]
- The Swedish National Airway Register – SNAR – Description[416], Website[417]
- National Quality Registry for Cruciate Ligament Injuries – Description[418], Website[419]
- National Quality Registry for Leukemia – Description[420], Website[421]
- National Quality Registry for Pulmonary Arterial Hypertension (SPAHR) – Description[422], Website[423]
- National Quality Registry for Haemophilia – Description[424], Website[425]
- National Quality Registry for Oesophageal and Stomach Cancer (NREV) – Description[426], Website[427]
- National Quality Registry of Urinary Bladder Cancer – Description[428], Website[429]
- National Quality Registry for Vascular Surgery (Swedvasc) – Description[430], Website[431]
- National Quality Registry for Gender Dysphoria – Description[432], Website[433]
- National Quality Registry for Paediatric Rheumatology – Description[434], Website[435]
- National Quality Registry for Hip Arthroplasty – Description[436], Website[437]
- National Quality Registry for Liver, Bile Duct and Gallbladder Cancer (SweLiv) – Description[438], Website[439]
- National Quality Registry for Cardiopulmonary Resuscitation – Description[440], Website[441]
- National Quality Registry for Cervical Cancer Prevention – Description[442], Website[443]

[410] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/intensivvard.44215.html
[411] https://www.icuregswe.org/
[412] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/internetbaseradpsykologiskbehandling.44216.html
[413] https://siber.registercentrum.se/
[414] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/kariesochparodontit.44217.html
[415] http://www.skapareg.se/
[416] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/kolochastma.44219.html
[417] https://lvr.registercentrum.se/
[418] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/korsbandsskada.44220.html
[419] https://www.aclregister.nu/
[420] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/blodcancer.44175.html
[421] https://cancercentrum.se/samverkan/cancerdiagnoser/blod-lymfom-myelom
[422] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/blodtryck.44176.html
[423] https://www.ucr.uu.se/spahr/
[424] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/blodarsjuka.44177.html
[425] https://svenskahemofiliregistret.se/
[426] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/cancerimatstrupeochmagsack.44182.html
[427] https://cancercentrum.se/samverkan/cancerdiagnoser/matstrupe-och-magsack/kvalitetsregister
[428] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/canceriurinblasan.44183.html
[429] https://cancercentrum.se/samverkan/cancerdiagnoser/urinblasa-urinvagar/kvalitetsregister/
[430] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/karlkirurgi.44222.html
[431] https://www.ucr.uu.se/swedvasc/
[432] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/konsdysfori.44223.html
[433] https://konsdysforiregistret.se/
[434] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/ledgangsreumatismhosbarnochungdom.44224.html
[435] https://childreg.carmona.se/
[436] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/ledprotes.44225.html
[437] https://slr.registercentrum.se/
[438] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/leverochgallcancer.44226.html
[439] https://cancercentrum.se/vast/cancerdiagnoser/lever-och-galla/kvalitetsregister
[440] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hjartstopp.44207.html
[441] https://shlr.registercentrum.se/
[442] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/livmoderhalscancer.44227.html

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- National Quality Registry for Inguinal Hernia Surgery – Description[444], Website[445]
- National Quality Registry for Lung Cancer – Description[446], Website[447]
- National Quality Registry for Macula – Description[448], Website[449]
- National Quality Registry for Mammography Screening – Description[450], Website[451]
- National Quality Registry for Congenital Heart Disease (SWEDCON) – Description[452], Website[453]
- National Quality Registry for Congenital Metabolic Diseases – Description[454], Website[455]
- National Quality Registry for Cleft Lip and Palate – Description[456], Website[457]
- National Quality Registry for Neurological Care – Description[458], Website[459]
- National Quality Registry for Kidney Cancer – Description[460], Website[461]
- National Quality Registry for Paediatric Kidney Disease – Description[462], Website[463]
- National Quality Registry for Renal Failure (SNR) – Description[464], Website[465]
- National Quality Registry for Obesity Surgery (SOReg) – Description[466], Website[467]
- National Quality Registry for Paediatric Orthopaedic Conditions (SPOQ) – Description[468], Website[469]
- National Quality Registry for Penile Cancer – Description[470], Website[471]
- National Quality Registry for Primary Immunodeficiency (PIDcare) – Description[472], Website[473]
- National Prostate Cancer Registry (NPCR) – Description[474], Website[475]
- National Register for systemic treatment of Psoriasis (PsoReg) – Description[476], Website[477]

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[443] https://cancercentrum.se/vast/vara-uppdrag/prevention-och-tidig-upptackt/gynekologisk-cellprovskontroll/kvalitetsregister/cytburken
[444] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/ljumskbrack.44228.html
[445] https://www.svensktbrackregister.se/en/
[446] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/lungcancer.44229.html
[447] https://cancercentrum.se/samverkan/cancerdiagnoser/lunga-och-lungsack/kvalitetsregister
[448] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/makula.44198.html
[449] http://makulareg.se/
[450] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/mammografi.44230.html
[451] https://cancercentrum.se/samverkan/vara-uppdrag/prevention-och-tidig-upptackt/mammografiscreening
[452] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/medfoddahjartsjukdomar.44231.html
[453] https://www.ucr.uu.se/swedcon/
[454] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/medfoddametabolasjukdomar.44232.html
[455] https://rmms.se/
[456] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/lappkakochgomspaltlkg.44233.html
[457] http://lkg-registret.se/
[458] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/neurologiskasjukdomar.44234.html
[459] https://www.neuroreg.se/
[460] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/njurcancer.44236.html
[461] https://cancercentrum.se/samverkan/cancerdiagnoser/njure/kvalitetsregister
[462] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/njursjukdomhosbarn.44237.html
[463] https://barnnjurregistret.se/
[464] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/njursvikt.44238.html
[465] https://www.medscinet.net/snr/
[466] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/operationervidfetma.44239.html
[467] https://www.ucr.uu.se/soreg/
[468] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/ortopedibarn.44240.html
[469] https://spoq.registercentrum.se/
[470] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/peniscancer.44241.html
[471] https://cancercentrum.se/samverkan/cancerdiagnoser/penis/kvalitetsregister
[472] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/primarimmunbrist.44242.html
[473] https://www.pidcare.se/
[474] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/prostatacancer.44544.html
[475] https://npcr.se/
[476] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/psoriasis.44545.html
[477] https://www.psoreg.se/

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824087.

- National Quality Registry for Psychosis Care (PsykosR) – Description[478], Website[479]
- National Quality Registry for Rehabilitation Medicine (WebRehab Sweden) – Description[480], Website[481]
- National Quality Registry for Rehabilitation for Visual Impairment (SKRS) – Description[482], Website[483]
- National Quality Registry for Rheumatic Diseases (SRQ) – Description[484], Website[485]
- National Quality Registry for Spine Surgery (Swespine) – Description[486], Website[487]
- National Quality Registry for Spinal Dysraphism and Hydrocephalus (MMCUP) – Description[488], Website[489]
- National Quality Registry for Forensic Psychiatry (RättspsyK) – Description[490], Website[491]
- National Quality Registry for Shoulder and Elbow Arthroplasty – Description[492], Website[493]
- National Quality Registry for Thyroid, Parathyroid and Adrenal Surgery (SQRTPA) – Description[494], Website[495]
- National Quality Registry for Thyroid Cancer – Description[496], Website[497]
- National Quality Registry for Pain Rehabilitation (NRS) – Description[498], Website[499]
- The Swedish Stroke Register (Riksstroke) – Description[500], Website[501]
- Swedish Melanoma Registry (SweMR) – Description[502], Website[503]
- National Quality Registry for Sleep Apnoea (SESAR) – Description[504], Website[505]
- Swedish Neonatal Quality Register (SNQ) – Description[506], Website[507]
- Swedish Perioperative Registry (SPOR) – Description[508], Website[509]
- National Quality Registry for Ulcer Treatment (RiksSår) – Description[510], Website[511]

[478] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/psykossjukdomar.44546.html
[479] https://www.psykosr.se/
[480] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/rehabilitering.44547.html
[481] https://svereh.registercentrum.se/
[482] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/rehabiliteringvidsynnedsattning.44548.html
[483] https://rcsyd.se/skrs/
[484] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/reumatism.44549.html
[485] https://srq.nu/en/welcome/
[486] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/ryggkirurgi.44550.html
[487] https://www.swespine.se/
[488] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/ryggmargsbrack.44551.html
[489] https://mmcup.se/
[490] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/rattspsykiatri.44552.html
[491] https://rattspsyk.registercentrum.se/
[492] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/skuldrorocharmbagskirurgi.44553.html
[493] http://www.ssas.se/axel/
[494] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/endokrinkirurgi.44554.html
[495] https://sqrtpa.se/
[496] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/skoldskortelcancer.44555.html
[497] https://cancercentrum.se/samverkan/cancerdiagnoser/skoldkortel/kvalitetsregister
[498] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/smartrehabilitering.44556.html
[499] https://www.ucr.uu.se/nrs/
[500] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/stroke.44557.html
[501] https://www.riksstroke.org/sve/
[502] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/hudmelanom.44558.html
[503] https://cancercentrum.se/samverkan/cancerdiagnoser/hud-och-melanom/malignt-melanom/kvalitetsregister
[504] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/somnapne.44559.html
[505] https://sesar.registercentrum.se/
[506] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/neonatalasjukdomar.44560.html
[507] https://www.medscinet.com/pnq/
[508] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/operation.44561.html
[509] https://spor.se/
[510] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/svarlaktasar.44562.html

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- National Quality Registry for Respiratory Failure (Swedevox) – Description[512], Website[513]
- National Quality Registry for Testicular Cancer (SWENOTECA) – Description[514], Website[515]
- Swedish Colorectal Cancer Registry (SCRCR) – Description[516], Website[517]
- National Quality Registry for Trauma – Description[518], Website[519]
- National Quality Registry for Palliative Care – Description[520], Website[521]
- National Quality Registry for Preventative Care (Senior alert) – Description[522], Website[523]
- National Quality Registers for ear, nose and throat – Description[524], Website[525]

Registries of the National Board of Health and Welfare

The National Board of Health and Welfare (Socialstyrelsen)[526] is the central national authority for social services, public health, infectious diseases prevention and health services. The Board manages the following health registries (whose data are based on social security numbers):

- **The Cancer Registry**

In Sweden, approximately 60,000 malignant cancer cases are reported each year to the cancer registry. The number refers to reported tumours and not the number of people. It contains, among other things, information such as social security number, gender, domicile at diagnosis, reporting hospital and clinic, date of diagnosis, clinical and morphological diagnosis and tumour spread at the time of diagnosis. Information on the date of death and the underlying cause is also obtained from the cause of death registry, and information on possible migration and information on whether the person is still registered in the country are obtained from the Register of the Total Population (RTB)[527] at Statistics Sweden (SCB)[528]. Different statistics on cancer can be produced using the database[529].

- **The registry of initiatives in municipal health and medical care**

The registry provides a basis for the official statistics on municipal health and medical care initiatives in Sweden. The data in the register are also used for research. The registry covers about 400,000 people per year. Different statistics on municipal health and medical care can be produced using the database[530].

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[511] https://www.rikssar.se/
[512] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/andningssvikt.44563.html
[513] https://www.ucr.uu.se/swedevox/
[514] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/testikelcancer.44564.html
[515] https://cancercentrum.se/samverkan/cancerdiagnoser/testikel/kvalitetsregister
[516] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/tjockochandtarmscancer.44565.html
[517] https://cancercentrum.se/samverkan/cancerdiagnoser/tjocktarm-andtarm-och-anal/tjock--och-andtarm/kvalitetsregister
[518] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/trauma.44566.html
[519] https://rcsyd.se/swetrau/
[520] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/vardilivetsslutskede.44567.html
[521] https://palliativregistret.se/
[522] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/vardpreventionforaldre.44568.html
[523] https://www.senioralert.se/
[524] https://skr.se/en/kvalitetsregister/hittaregister/registerarkiv/oronnasaochhals.44570.html
[525] https://orl.registercentrum.se/
[526] https://www.socialstyrelsen.se/
[527] https://www.scb.se/vara-tjanster/bestalla-mikrodata/vilka-mikrodata-finns/individregister/registret-over-totalbefolkningen-rtb/
[528] https://www.scb.se/en/
[529] https://sdb.socialstyrelsen.se/if_can/val.aspx
[530] https://sdb.socialstyrelsen.se/if_hsl/

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- **The Medicines Registry**

The purpose of the Medicines Registry is to increase patient safety in the field of medicines. The registry is used by researchers, journalists, investigators within county councils and authorities as well as by representatives from the pharmaceutical industry.

The registry contains information about:

- the patient (gender, age, place of registration)
- the product (e.g. ATC code, drug name, strength, pack size)
- the prescription (for example, the prescribed quantity, the date of the prescription and the date when the goods were picked up)
- costs (county council cost and deductible)
- characteristics of the workplace where the prescription took place (for example, business orientation) and what profession and specialist training the prescriber has.

Different statistics with regards to medicinal products can be produced using the database[531].

- **Medical birth registry**

The purpose of the registry is to be able to describe events and outcomes for women and children during pregnancy, childbirth and the neonatal period. The information includes the woman's previous pregnancies, smoking, maternity clinic, length of pregnancy, pain relief, method of delivery, diagnoses in mother and child, operations, the child's gender, weight, height and head circumference and the baby's condition at birth. Linked to the medical birth registry is the registry monitoring of birth defects and chromosomal abnormalities[532]. Different statistics on pregnancies, births and newborns can be produced using the database[533].

- **Patient registry**

The patient registry provides data for statistics on diseases and treatments in Swedish specialist care. The registry contains:

- All completed care sessions in inpatient care since 1964 (comprehensive from 1987).
- Data on patients treated by physicians in specialized outpatient care since 2001.
- Data on patients who have been cared for in psychiatric compulsory care according to the Compulsory Psychiatric Care Act (LPT) or the Swedish Psychiatric Care Act (LRV) since 2010.
- Information on emergency waiting times and emergency operations since 2016.

The patient registry does not contain:

- Information on primary care
- Information on patients treated by health care professionals other than doctors

The following statistical areas are based on the patient register:

- Diseases and symptoms[534]
- Surgery and treatments[535]

[531] https://sdb.socialstyrelsen.se/if_lak/val.aspx
[532] https://www.socialstyrelsen.se/statistik-och-data/register/alla-register/medicinska-fodelseregistret/overvakning-av-fosterskador/
[533] https://sdb.socialstyrelsen.se/if_mfr_004/val.aspx
[534] https://www.socialstyrelsen.se/statistik-och-data/statistik/statistikamnen/sjukdomar-och-symtom/
[535] https://www.socialstyrelsen.se/statistik-och-data/statistik/alla-statistikamnen/operationer-och-behandlingar/

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- Injuries and poisonings[536]
- Waiting times at emergency hospitals[537]
- Heart attacks[538]
- Stroke[539]

- **The dental health registry**

The dental health registry contains all permits and measures that have been submitted to and approved by the Swedish Social Insurance Agency within the framework of the state dental care support and two of the support within dental care for health and medical care fees. It is dental care for people with certain long-term illnesses and disabilities as well as necessary dental care. The dental health registry does not include the dental care provided free of charge to children and young people between the ages of 0 and 23, maxillofacial surgery or dental care as part of short-term medical treatment. Different statistics on dental health can be produced using the database[540].

The National Board of Health and Welfare holds other registries such as: The registry of financial assistance[541], The Compulsory care of addicts registry[542], The registry of interventions for children and young people[543], The registry of initiatives for the elderly and people with disabilities[544], The cause of death registry[545], The healthcare professionals registry[546], Medical Birth Registry[547].

14.3. Access to data

A summary of the process for accessing data from Swedish Quality Registers is provided below:

1. Establish contact with the registry:

- Contact the registrar or a member of the steering committee to confirm if it is possible to use the quality registry data for your research.
- Obtain the required application forms and contacts.

2. Contact the National Board of Health and Welfare (national registry service) to:

- Discuss whether or not it would be possible to use their registries for comparison to the national registry data.
- Obtain information on how to apply for data extraction (if not provided by the registry).

3. Apply to the Regional Ethical Review Board (EPN):

- Apply for permission to carry out your research with the EPN.

[536] https://www.socialstyrelsen.se/statistik-och-data/statistik/alla-statistikamnen/skador-och-forgiftningar/
[537] https://www.socialstyrelsen.se/statistik-och-data/statistik/alla-statistikamnen/vantetider-och-besok-vid-sjukhusbundna-akutmottagningar/
[538] https://www.socialstyrelsen.se/statistik-och-data/statistik/alla-statistikamnen/hjartinfarkter/
[539] https://www.socialstyrelsen.se/statistik-och-data/statistik/alla-statistikamnen/stroke/
[540] https://sdb.socialstyrelsen.se/if_tandhalsa/val.aspx
[541] https://www.socialstyrelsen.se/statistik-och-data/register/ekonomiskt-bistand/
[542] https://www.socialstyrelsen.se/statistik-och-data/register/tvangsvard-av-missbrukare/
[543] https://www.socialstyrelsen.se/statistik-och-data/register/barn-och-unga/
[544] https://www.socialstyrelsen.se/statistik-och-data/register/aldre-och-personer-med-funktionsnedsattning/
[545] https://www.socialstyrelsen.se/statistik-och-data/register/dodsorsaksregistret/
[546] https://www.socialstyrelsen.se/statistik-och-data/register/halso-och-sjukvardspersonal/
[547] https://www.socialstyrelsen.se/statistik-och-data/register/medicinska-fodelseregistret/

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- Clearly define in the application what data may be used and how it will be processed.
- Ensure that patient information and consent form is available for the project.
- If biobank samples will be included in the research project this needs to be part of the application.

4. Apply to the registry for data extraction:

- Apply for permission to have the data released from the quality registry using the form provided by the registry and/or its personal data holding authority (CPUA).
- If no form is available, use the "Application for registry Data from the Quality Registry for Research Purposes" form available on the Registry Centre Organisation's website.
- If data will be obtained from several registries, separate applications must be submitted.

5. Processing of the application:

- Application is reviewed by a designated representative for CPUA (County council personal data controller). This is typically the registrar and the registry steering committee/research council.

6. Disclosure approval and agreement drafted:

- A decision on disclosure is made.
- If "Yes" an agreement is drafted which covers terms such as; costs for extraction, what variables will be disclosed, access time, results reporting, archiving and destruction of copies and publications.

7. Disclosure of data:

- Data release according to agreed terms.

Access to data from quality registers is mainly regulated by these laws:

- Act concerning the Ethical Review of Research Involving Humans (2003:460) (in Swedish)[548]
- General Data Protection Regulation (GDPR)[549]
- Publicity and Secrecy Act (2009: 400) determine how the information can be disclosed. (in Swedish)
- The Patient Data Act (2008: 355)[550] (in Swedish)

The Swedish Research Council has been commissioned by the government to improve the accessibility to and facilitate the use of registry data for research purposes, and to assist researchers with information about registries and relevant legislation. As such, it has developed the website Registerforskning.se[551], which is primarily aimed at researchers who wish to use registry data in their research. Registerforskning.se contains information about registries, how to request data for research, and current laws and ordinances. Another part of this project is the development of the Register Utiliser Tool (RUT)[552]. RUT utilises detailed information about the available registries and variables (metadata) but no actual individual data (microdata). Using RUT,

[548] https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460
[549] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=SV
[550] https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/offentlighets--och-sekretesslag-2009400_sfs-2009-400
[551] https://www.registerforskning.se/en/
[552] https://rut.registerforskning.se/

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it is possible to create a record of variables that are relevant to a research question, which can make up part of the foundation for the ethical review as well as for a data request.

15.Switzerland

15.1. Healthcare system

The Swiss healthcare system is universal and regulated by the Swiss Federal Law on Health Insurance[553]. There are no free state-provided health services, but private health insurance is compulsory for all persons residing in Switzerland. Swiss private insurers are required to offer basic coverage to everyone, regardless of age or medical history. Health insurance covers the costs of medical treatment and hospitalisation of the insured. However, the insured person pays part of the cost of treatment. This is done (a) by means of an annual deductible (called the *franchise*), and (b) by a charge of 10% of the costs over and above the excess up to a stop-loss amount.

Healthcare in Switzerland is largely organised by the individual cantons. The health ministers from all cantons form the Swiss Conference of the Cantonal Ministers of Public Health (GDK). This aims to promote cooperation and implement common policies between cantons. It is overseen by the Federal Office of Public Health (FOPH)[554].

Unlike many of the state-supported European models of universal coverage, the Swiss system relies heavily, although not exclusively, on the private sector. At the same time, however, the 26 cantonal governments provide important subsidies to hospitals, and the federal government plays a key role in regulating the industry and influencing premiums and medical costs.

15.2. Health databases

Health data in Switzerland usually remain where they were generated and are used exclusively for the purpose originally specified. For example, anyone planning a study on the side effects of a new drug must precisely determine the fate of their test subjects in advance for their informed consent. Multiple use of data or their use in unforeseen questions is not provided for by law unless the person has given his general consent at hospital admission.

For current developments in data-driven medicine, a comprehensive assessment is provided by a working group of the Federal Office for Public Health (FOPH):

https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/biomedizinische-forschung-und-technologie/masterplan-zur-staerkung-der-biomedizinischen-forschung-und-technologie/personalisierte-medizin.html

[553] https://www.bag.admin.ch/bag/de/home/gesetze-und-bewilligungen/gesetzgebung/gesetzgebung-versicherungen/gesetzgebung-krankenversicherung/kvg.html
[554] https://www.bag.admin.ch/bag/en/home.html

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15.3. Registries

There are many health registries in Switzerland, an overview is given here: FMH national medical register overview[555].

Some specific as examples are listed below:

- National register for rare diseases[556] currently under construction
- National organ donor register[557]
- National DMD and SMA register[558]
- National Cancer Registry[559]

Recommendations for the establishment and operation of health-related registers

In order to contribute to quality assurance, the organisations ANQ (Swiss National Association for Quality Development in Hospitals and Clinics)[560], FMH (Swiss Medical Association)[561], H+ (Swiss Hospitals)[562], SAMS (Swiss Academy of Medical Sciences)[563] and unimedsuisse[564] have jointly published recommendations for the establishment and operation of health-related registers. These contain minimum standards, among others on data protection and data quality.

- https://www.anq.ch/de/medienmitteilungen/gemeinsame-empfehlungen-fuer-gesundheitsregister-publiziert/
- Recommendations : https://www.anq.ch/wp-content/uploads/2017/12/Register_Empfehlungen.pdf
- Register Checklist: https://www.anq.ch/wp-content/uploads/2017/12/Register_Checkliste.xlsx
- Register Infographic: https://www.anq.ch/wp-content/uploads/2020/04/Register_Infografik.pdf

15.4. Access to data

Legal basis for health research, research involving

Switzerland's legislation on research involving humans:

[555] https://www.fmh.ch/themen/qualitaet-saqm/register/medizinische-register.cfm#results
[556] https://www.kosekschweiz.ch/daten-und-register/nationales-register
[557] https://www.swisstransplant.org/de/
[558] https://www.muskelgesellschaft.ch/
[559] https://www.nkrs.ch/
[560] https://www.anq.ch/en/
[561] https://www.fmh.ch/fr/index.cfm
[562] https://www.hplus.ch/fr/
[563] https://www.samw.ch/en.html
[564] https://www.unimedsuisse.ch/fr

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https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/forschung-am-menschen/entstehung-humanforschungsgesetz.html

Data sharing

To date, data sharing in Switzerland is still in its infancy, there are working groups that deal with the ethical, legal and social implications of data sharing and establish guidelines, e.g.:

- the SPHN ELSI group (https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1558)
- SCTO Biostatistics platform (Data sharing statement: https://www.preprints.org/manuscript/202006.0344/v1)

Access to and process for obtaining access to data

Access to data and its process is governed by the place where data are generated, usually there is a Data Access Committee installed that defines the process for obtaining data, e.g.:

- https://dkf.unibas.ch/de/services/data-science/data-access-committee/

Conclusions

The digitization of healthcare brings new opportunities to complement and enhance the data traditionally utilized in regulatory decision-making. The hope is that in the near future we will be able to foster the enormous potential presented by the use of routinely collected RWD (e.g. electronic health records, medical claims, insurance data) to improve the timeliness, accuracy, and relevance of decisions across the medical product lifecycle. The exact conditions for RWE acceptability and applicability by regulatory authorities around the globe remain to be clarified with many of them (including the FDA in U.S., the EMA in Europe, the PMDA in Japan etc.) issuing guidance over the past 3 years on how to use RWD to provide RWE.

Despite the strong movement towards the use of RWD, several challenges still remain, at least in Europe. These include operational, technical, methodological and ethical, legal and societal issues. Reusing RWD in Europe for research purposes and especially in a cross-border manner is hampered by the fact that health databases and registries are not easily discoverable (e.g. due to lack of standardised records, unavailability of information available in English etc.), and even when they are, understanding what data they contain and their suitability for addressing a specific research question remains not trivial due to the lack of detailed, high quality, standardised, interoperable data catalogues implementing the FAIR principles [8,9]. The requirements for accessing the data of such databases for research are also quite different, as a result of them being subject to different governance and sustainability models and depending on the applicable local rules and legislations (which can be national, regional or even institutional).

The present report is entitled "*D4.5 Public database inventorying the national health databases and registries and describing their access procedures for reuse for research purposes*". As the title indicates, the report delivered an inventory of national health databases and registries covering

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15 European countries: Austria, Czech Republic, France, Germany, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovakia, Spain, Sweden, Switzerland. The authors looked into the healthcare systems of each country in order to provide better insights of the context in which the data in national databases have been generated. Then, a list of relevant databases and registries is provided together with descriptions (or links to descriptions) of what they contain and guidance on how to access the data for research purposes. Although D4.5 was initially foreseen in the Description of Work as a "website" database, it was commonly decided in WP4 that building such a database would be an unnecessary duplication of efforts as currently the European Health Information Portal[565] plays this role. This document will thus instead be made publicly available on Zenodo beyond the life-time of the EOSC-Life project and it will be disseminated to other EC projects working on similar aspects (e.g. HealthyCloud[566], TEHDAS[567]), including the actors behind the European Health Information Portal.

Based on our research we can safely conclude that the picture across Europe is diverse and at times patchy; some countries have definitions of EHR and registries in their legislation, while others have not. Also in terms of obtaining access to the data we observe different mechanisms: some data are available via commercial routes, others via academic collaborations and others only via direct collaboration with the data source holders themselves. In most cases, getting in contact directly with the database/registry is seen as a necessary step to obtain clarifications and prepare appropriately the data access request. This is especially true as the current European legal landscape is a "moving target" with new national/European laws governing health data sharing being currently "in the making" (including the European Health Data Space Regulation, expected to be a "game changer" in the sharing of health data in Europe). Across Europe, there are currently no uniform definitions of "pseudonymisation", "anonymization" and "de-identification" which in practice results in conditions of use and negotiations on a case by case basis.

Although the challenges above mirror the difficulties in discovering and accessing the data, which is the main scope of this report, the authors would also like to highlight concerns about the actual usefulness of accessing these data for research purposes. A number of significant challenges complicate the use of large healthcare databases. For example, the data can be both structured and unstructured and exist in many different formats and terminologies, which more often than not are not interoperable with the standards used in clinical research. The reader is referred to previous EOSC-Life WP4 work (D4.4) for an extensive analysis of the data standards used in research and healthcare and their interoperability gaps[568]. In addition, the content of health databases and registries is variable with time, and the quality and completeness of those sources are sometimes unknown.

As a study by the EMA Observational data (Real World Data) subgroup concluded, Europe has shown significant progress over the last few decades in digitalising healthcare and towards health data sharing but additional work is needed to turn these databases to suitable RWD sources for regulatory purposes and establish a sustainable network of distributed datasets to mirror that of

[565] https://www.healthinformationportal.eu/
[566] https://healthycloud.eu/
[567] https://tehdas.eu/
[568] https://zenodo.org/record/5810612#.Yy3ApOzMITW

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Sentinel[569], CNODES[570] and MidNet[571]. The ongoing work around the development of the European Health Data Space is expected to contribute considerably towards this direction.

The reader is referred to the Health Systems in Transition (HiT) series of the European Observatory on Health Systems and Policies[572] if interested in obtaining more details on the healthcare systems in each country. If the reader wants to know more about the legal framework applicable in each country a useful reference is the recent "Assessment of the EU Member States rules on health data in the light of GDPR"[573] published by the EC. Especially interesting are the country fiches[574].

Last but not least, the authors would like to highlight that they have described in this report the national landscape to the best of their capacities, but by no means claim that this is an exhaustive inventory of the national data sources. In addition, there has been no intention to evaluate the quality of the data sources and "recommend" one over another for research.

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Abbreviations

AEMPS	Spanish Agency for Medicines and Health Products
AIFA	Italian Medicines Agency
ALL	Adult Acute Lymphoblastic Leukaemia
AMF	Anonymised Microdata File
ANQ	Swiss National Association for Quality Development in Hospitals and Clinics
ASL	Local Health Unit (Italy)
ATIH	Technical Agency for Information on Hospitalisation (France)
BBMRI	Biobanking and Biomolecular Resources Research Infrastructure
BfArM	Federal Institute for Drugs and Medical Devices (Germany)
BIFAP	Pharmacoepidemiological Research Database for Public Health Systems (Spain)
BMBF	Federal Ministry of Education and Research (Germany)
BMI	Body Mass Index
CBS	Statistics Netherlands
CEIC	National Ethics Committee (Portugal)
CNIL	National Commission for Data Protection and Liberties (France)
CPUA	Personal Data Holding Authority (Sweden)
CSO	Central Statistics Office (Ireland)
DAC	Data Access Committee
DHD	Dutch Hospital Data
DoH	Department of Health (Ireland)
DPC	Data Protection Commission (Ireland)
DTL	Dutch Techcentre for Life Sciences
EATRIS	European Infrastructure for Translational Medicine
ECRIN	European Clinical Infrastructure Network
EEA	European Economic Area
EESZT	National eHealth Infrastructure (Hungary)
EHDS	European Health Data Space
EHIC	European Health Insurance Card
EHR	Electronic Health Records
ELSI	Ethical, Legal, and Social Issues
ELGA	Electronic Health Records Act (Austria)
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EOI	Extensions of Indication
EOSC	European Open Science Cloud
EPN	Regional Ethical Review Board (Sweden)
ERA	European Research Area
ESFRI	European Strategy Forum for Research Infrastructures
ESRI	Economic and Social Research Institute (Ireland)
EU	European Union

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FAIR	Findability, Accessibility, Interoperability, and Reusability
FDA	Food and Drug Administration (U.S.A.)
FDZ	Research Data Center (Germany)
FMH	Swiss Medical Association
FOG	Research Organisation Act (Austria)
FOPH	Federal Office of Public Health (Switzerland)
GDK	Swiss Conference of the Cantonal Ministers of Public Health
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GEKID	Association of Population-Based Cancer Registries in Germany
GHGA	German Human Genome-Phenome Archive
GIS	Geographical Information System (Ireland)
GP	General Practitioner
GTelG	Health Telematics Act (Austria)
G-BA	Federal Joint Committee (Germany)
HDH	Health Data Hub (France)
HIE	Health Information Exchange
HIPE	Hospital In-Patient Enquiry (Ireland)
HIQA	Health Information and Quality Authority (Ireland)
HPO	Healthcare Pricing Office (Ireland)
HPSC	Health Protection Surveillance Center (Ireland)
HRB	Health Research Board (Ireland)
HRCDC	Health Research Consent Declaration Committee (Ireland)
HSE	Health Service Executive (Ireland)
H+	Swiss Hospitals
IARC	International Agency for Research on Cancer
INCLASNS	Key Indicators of the National Health System (Spain)
ISCIII	Institute for Health Carlos III
ISSDA	Irish Social Science Data Archive
ICMRA	International Coalition of Medicines Regulatory Authorities
IKNL	The Netherlands Comprehensive Cancer Organisation
INSEE	National Institute of Statistics and Economic Studies (France)
LBZ	the National Registration of Hospital Care (the Netherlands)
LEA	Essential Levels of Assistance
LS RI	Life Science Research Infrastructure
MAA	Marketing Authorisation Application
MII	Medical Informatics Initiative (Germany)
NAKO	German National Cohort
NAPKON	National Pandemic Cohort Network (Germany)
NCR	The Netherlands Cancer Registry
NCRI	National Cancer Registry Ireland
NEAK	National Health Insurance Fund Management (Hungary)
NFDI4Health	National Research Data Infrastructure for Personal Health Data (Germany)
NFU	The Netherlands Federation of University Medical Centres
NHIC	National Health Information Centre (Slovak Republic) or NCZI (in Slovak)
NHIS	National Health Information System (Czech Republic)
NIMS	National Incident Management System (Ireland)

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NIPH	Norwegian Institute of Public Health (FHI in Norwegian)
NIVEL	the Netherlands Institute for Health Services Research
NIZ	Dutch Hospital Association
NMPA	National Medical Products Administration (China)
NNSC	National Nosocomial Surveillance (Hungary)
NOCA	National Office of Clinical Audit (Ireland)
NTR	The Netherlands Twin Registry
OECD	Organisation for Economic Cooperation and Development
OSI	Ordinance Survey Ireland
OKFŐ	National Healthcare Service Centre (Hungary)
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMSI	Programme for the Medicalisation of Information Systems (France)
POZ	Primary Healthcare (Poland)
PRN	The Netherlands Perinatal Registry
PTR	Patient Treatment Register (Ireland)
RCT	Randomised Control Trial
RD	Rare Diseases
RDGB	Research Data Governance Board (Ireland)
RIVM	National Institute for Public Health and the Environment (the Netherlands)
RMF	Research Microdata File
RTB	Register of the Total Population (Sweden)
RUT	Register Utiliser Tool (Sweden)
RWD	Real World Data
RWE	Real World Evidence
SAMS	Swiss Academy of Medical Sciences
SCB	Statistics Sweden
SCTO	Swiss Clinical Trial Organisation
SFK	The Dutch Foundation for Pharmaceutical statistics
SKR	Swedish Association of Local Authorities and Regions
SIDIAP	Information System for Research in Primary Care (Spain)
SNDS	National Health Data System (France)
SNS	National Health System (Portugal)
SNS	National Health System (Spain)
SPE	Secure Processing Environment
SPHN	Swiss Personalised Health Network
SPMS	Shared Services of the Ministry of Health (Portugal)
SSN	National Health Service (Italy)
ŠÚKL	State Institute for Drug Control (Slovak Republic)
UN	United Nations
VWS	Ministry of Health, Welfare, and Sport (the Netherlands)
WHO	World Health Organisation
ZfKD	Center for Cancer Registry Data (Germany)
ZFZ	National Health Fund (Poland)
ZIN	National Health Care Institute (the Netherlands)
ZSKI	Center for Rare Diseases Innsbruck (Austria)
ZUS	Social Insurance Company (Poland)

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Delivery and Schedule

"D4.5 – Public database inventorying the national health databases and registries and describing their access procedures for reuse for research purposes" has been delayed. The deliverable was initially due in month 30 (August 2021) and was finally submitted in month 44 (October 2022).

This is due to several factors:

- The complex nature of this deliverable, requiring close collaboration between the EOSC-Life partners and national experts in order to provide a detailed overview of the landscape in each country.
- This report is written by people involved directly or indirectly in clinical research and healthcare. As such their availability and priorities during the COVID-19 outbreak shifted towards prioritizing COVID-19 related work to help tackle the pandemic.
- The European and international health data sharing landscape is constantly changing and a lot of new initiatives have emerged (and are still emerging), making it difficult for the authors to adequately "capture" the information and frequent revisions of previously collected content were necessary to try to keep this document as up-to-date as possible.
- This deliverable was initially "conceived" in the format of a public website but it was a common decision within WP4 to change its format to a report reviewing the situation in each country. This decision was mainly driven by the fact that the European Health Information Portal[575] already fulfils this role. Instead, the present deliverable will be publicly available in Zenodo and disseminated to relevant stakeholders.

[575] mailto:https://www.healthinformationportal.eu/

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