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Health data space

Using data to improve healthcare in Europe

Dear Readers,

With the idea of creating a European Health Data Space (EHDS), the European Union (EU) started a major project in May this year. All EU citizens should be able to use their health data in future when they are in another country, for example on holiday or on a business trip. A doctor in Spain could then view the medical history, medication or various examination results of patients from another country with just a few clicks – and in their own language. This waives new examinations, for example X-rays. This protects patients and also saves costs.

But that is not all. Once health data has been collected, it should also be made usable for science, industry, public institutions and politics. Important data could thus be used across borders in the development of drugs for rare diseases or medical devices. But also politics should benefit from this and be able to make better decisions on a broad data basis, for example during a pandemic.

The EHDS can certainly improve medical care for people in the EU. However, our health data is particularly worthy of protection. Therefore, the highest requirements must be placed on the security and protection of data. Patients must be allowed to retain control over their data and be able to determine for themselves what information is included in their patient record and what they disclose.

The original goal of getting the project up and running by 2025 can certainly not be met. Even though it already partly builds on existing cooperation and project structures, there are many practical challenges to be overcome. Among other things, the very different digitisation infrastructures in the Member States must be brought to a common level and subordinated to a common data governance. But different understandings of data use and data protection must also be reconciled.

How the European Parliament and the Member States will overcome these hurdles in the course of the legislative process will be seen in the coming months. In our current magazine ed*, we would like to take a look at the EHDS now and show you what challenges lie ahead for the Member States and for us as social insurance institutions.

We wish you an interesting read.

Yours sincerely, Ilka Wölfle

Collecting and exchanging health data

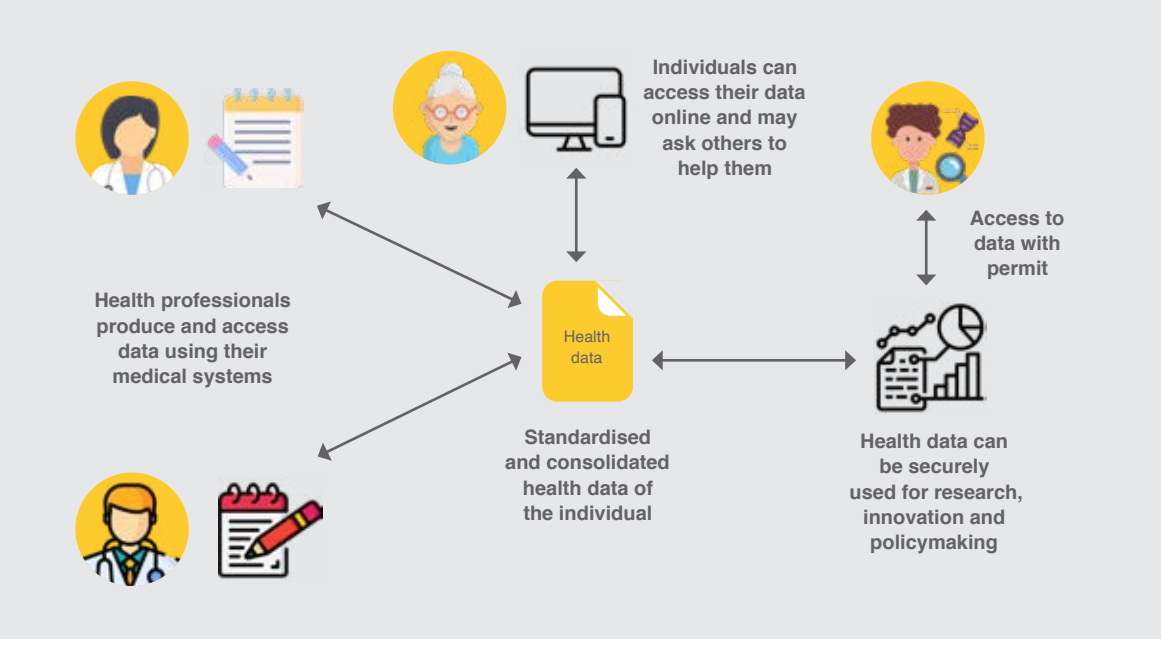
Opportunities for Europe

The main features of the EHDS

"Data is the new gold". This saying is increasingly associated with the digital age when it comes to collecting and using data. The European Commission already realised a long time ago that enormous added value can be derived from data. According to its estimates, The volume of data worldwide will increase by 530 per cent in 2025 compared to 2018.[1] And it wants to tap into this continuously growing treasure trove of data. How it would like to implement this, the European Commission explained in its European Data Strategy in February 2020. The aim is to create a single European and cross-border market for data, based on European rules and values. In the course of this, nine sector-specific data spaces are to be created, among other things, in the areas of health, mobility, energy, finance or industry.

[1] European Commission (2022). Fact sheet "The European Data Strategy", 19.02.2020, https://ec.europa.eu/commission/presscorner/detail/en/fs_20_283

Primary and secondary data use



Source: European Commission (2022). Communication on the establishment of a European Health Data Space (COM(2022)196 final), p. 11 (Icons: Flaticon.com)

In May 2022, the European Commission presented the EHDS.

Legislative context

The EHDS is linked to many legal regulations at European level:

- The EHDS builds on the Directive on **patients' rights in cross-border healthcare**.
- The EHDS wants to close the loopholes that the **General Data Protection Regulation (GDPR)** leaves the Member States when dealing with health data.
- The **Data Governance Act** establishes rules for "data intermediaries" and voluntary "data donations".
- The **EU Data Act** lays the foundations for the conditions of data exchange both in the private and public sectors.
- Based on the **Artificial Intelligence** (AI) **Act**, AI systems are to be trained with data from the EHDS.
- Interfaces with the **Medical Devices Regulation** exist in terms of safety and interoperability when data from medical devices are to be transferred to the patient records.
- Patients should be able to use the recognised authentication and identification mechanisms according to the **eIDAS Regulation**.

It starts with the healthcare sector and the idea of building an EHDS that regulates exactly when, how and for what data can be collected and exchanged. Citizens should be given access to their data. The aim is to improve healthcare in the EU.

On 3 May 2022, the European Commission presented its idea for an EHDS. The aim is to bring together health data in a meaningful way and to use it across borders for research, innovation, policy-making and healthcare.

In order to make this possible, some challenges have to be overcome. Thus, the EHDS must it well into the already existing national health and social structures. These differ greatly in the Member States, for example in the level of digitisation, the technical governance structures and the data protection conventions. While in Germany, for example, the ePrescription (eRezept) will only be introduced gradually from September, it has already been used in Finland for 15 years. European harmonisation of these national structures and standards is costly.

Two regulatory areas under one roof

With its draft regulation, the European Commission places two different regulatory areas under one legislative initiative and distinguishes between primary and secondary data use.

Access to treatment data

In a first step, patients should have the right to access their treatment data electronically anywhere in the EU and make it available to their attending physicians. This can have great advantages for patients. For example, a doctor in the Czech Republic treating a Portuguese patient should be able to access his or her basic health information. A German patient posted in Helsinki should also be able to obtain his or her prescription medication from a Finnish pharmacy. Prescriptions should be digitally retrievable and redeemable throughout Europe. This harmonisation should not only reduce the costs of health data traffic in the EU, but also strengthen cross-border mobility in Europe and, above all, improve the quality of healthcare for citizens.

For this purpose, patients are to be given access to their electronic health data. Service providers, such as doctors or hospitals, must be connected to an interoperable data

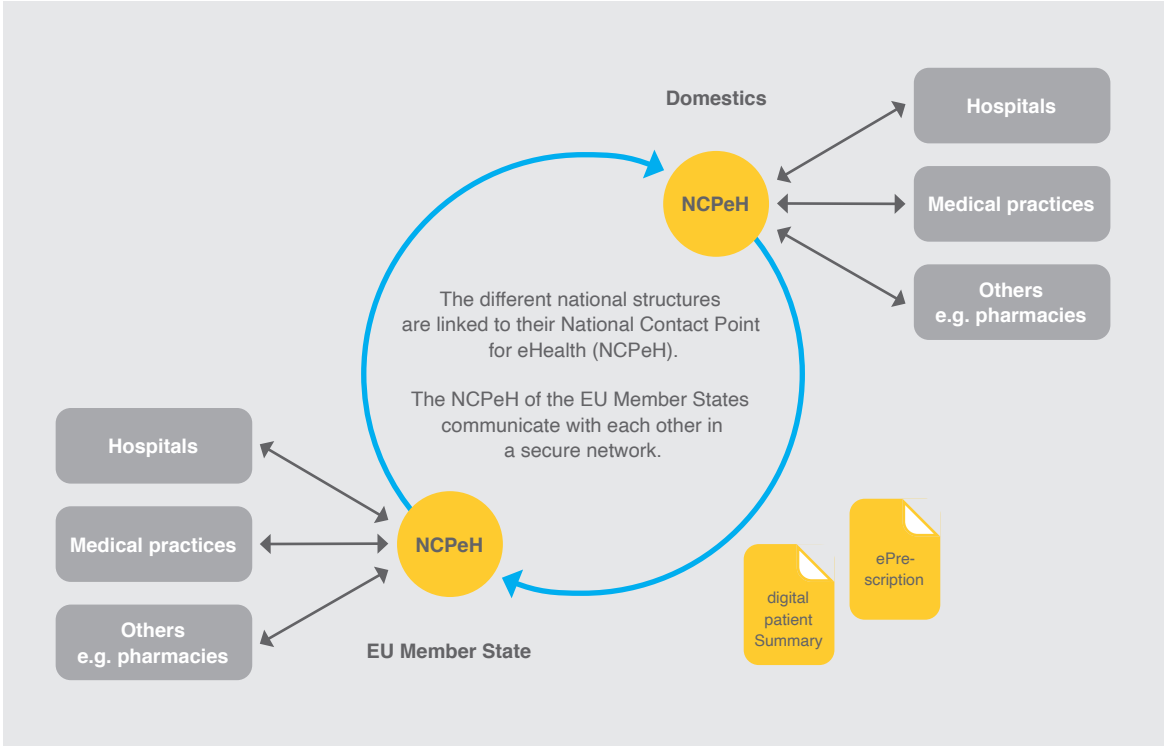
infrastructure, be able to read data in their national language and add data records. When filling ePrescriptions, patients must be able to identify themselves and pharmacy staff must be able to read prescriptions issued abroad.The interoperable data structure already exists, in principle in the MyHealth@EU project. It has also been tested by some Member States, so the EHDS can build on this structure. The voluntary exchange of data via MyHealth@EU is to become mandatory for all Member States with the EHDS.

Data exchange via MyHealth@EU – What is behind it?

For over seven years now, a number of Member States have been working voluntarily to establish the basis for the exchange of medical information in the EU. The MyHealth@EU data infrastructure was launched in 2015, at that time still under the name eHealth Digital Service Infrastructure (eHDSI). Via MyHealth@EU, personal health data is exchanged securely and efficiently within the EU. The interfaces with the respective national systems are formed by national contact points for electronic health services (NCPeH); in Germany, this is the German Liaison Agency Health Insurance – International which is a part of the organisational structure of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband).

Ten Member States are now actively participating in the exchange of ePrescriptions and digital patient summaries via MyHealth@EU. With the digital ePrescription, insured persons can not only benefit on a national level, but also already the prescribed medicines within the neighbouring country at the pharmacy. The digital patient summaries – not to be confused with the

MyHealth@EU data infrastructure



Source: own illustration

By 2025, all Member States should be connected to MyHealth@EU.

complete e-health record[2] – contains all emergency-relevant information of an insured person, for example information on previous illnesses or allergies. The first exchange of an electronic prescription took place between Estonia and Finland in January 2019. Seven years after the start of the project, there are still differences in the intensity of the exchange. At present, not all participating Member States can send and receive ePrescriptions and digital patient summaries abroad in the same way. In addition, the number of pharmacies and hospitals already integrated into the data infrastructure varies.[3] So far, a total of around 66,700 ePrescriptions and 1,800 digital patient summaries have been exchanged in the EU. Germany would like to be able to exchange at least digital patient summaries in 2023.

With the EHDS, all Member States are to be connected to the MyHealth@EU data infrastructure by 2025. In addition, further data is to be exchanged in the future, such as laboratory results, medical images and discharge reports. To this end, the EHDS lays down uniform rules on standardisation and interoperability.

The European Health Record is at the centre

The central instrument for primary data exchange is the European Health Record (EHR). By 2025, the European Commission wants all citizens in the EU to have access to their EHR and to be able to make their health data available across borders. For this purpose, a uniform exchange format ismandatory within the framework of the EHDS. Through a self-certification system, EHR systems should prove that they meet the requirements for interoperability and security in order to avoid fragmentation and inequalities in access to eHealth services and data transmission. If the European Commission has its way, it will also be possible in future to feed data from wellness applications, such as fitness wristbands, into health records.

The impact this has on data quality is debated. Doctors use EHR data for their treatment decisions and must be sure that the data is valid. Wellness apps are not regulated to the same extent as medical devices. There is a great potential for error when recording data.

The eHealth Network

Cooperation in cross-border electronic data exchange has so far been coordinated in the **eHealth Network (eHN)**. The network is controlled by the respective authorities of the Member States responsible for eHealth, in Germany the Federal Ministry of Health. So far, the cooperation has been voluntary; with the EHDS, it is institutionalised in a new body, the EHDS Committee.

The eHN has also facilitated the development of the digital **COVID-19 certificate** by agreeing on technical specifications to ensure the interoperability of vaccination, testing and recovery certificates. The COVID-19 certificate has subsequently become a successful product. Over 45 third countries have joined the EU-COVID-certification-scheme.

[2] The electronic health record is the central and comprehensive repository of health data. In addition to the emergency data from the patient summary, insured persons can save medication plans, medical reports, lab results or X-ray images. They can also store their own data in their ePA, such as a diary of blood glucose measurements.

[3] Interactive dashboard on the implementation status of eHDSI, https://webgate.ec.europa.eu/santegis/eHDSI/

Harmonisation of European and national infrastructures a must

The EHDS will strongly influence the ongoing implementation of the national health records as well as the further development and expansion of the national telematics infrastructures. The approach of the European Commission to make the entire primary documentation of all service providers as well as the data of the health insurance funds available in the patient file is very extensive.

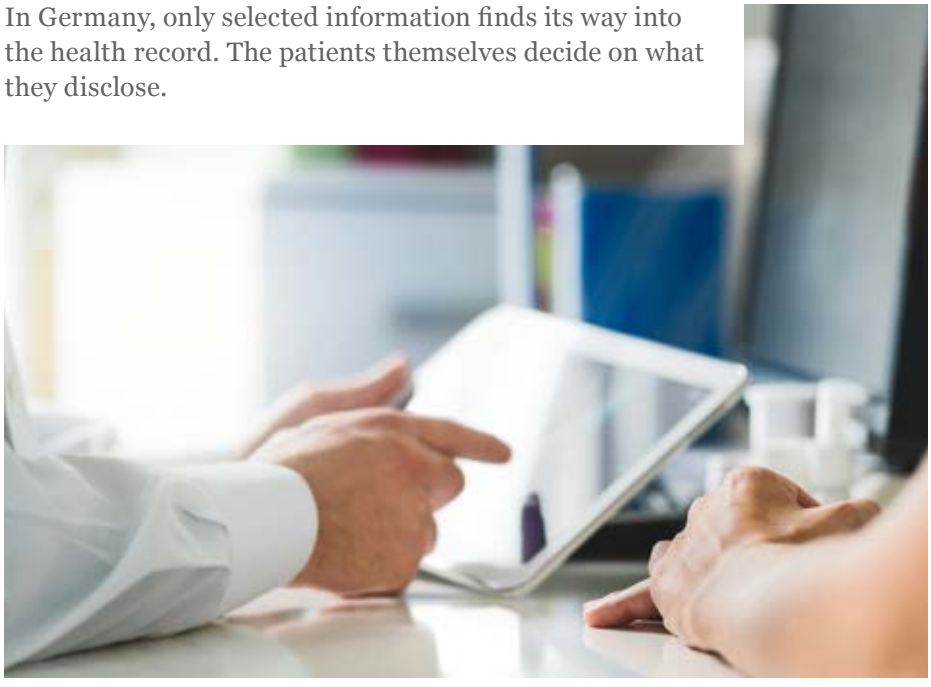
It is in contrast to the procedure in Germany, where only select information is to be included in the patient record. In addition, the patients decide themselves as to what they disclose. A specific opt-out option and thus, the possibility to object to the use of data is not provided for in the draft regulation.

Furthermore, it is problematic to transfer the data for claiming benefits – these are especially ePrescriptions – to the primary data use. This raises national regulations to the European level. However, since specific national features insurance cannot be taken into account at EU level, there is a risk that care in the Member States will be impaired by forcing adjustments in benefit law.

In addition, the proposals of the European Commission also raise questions regarding the usability of investments made so far, the adaptation of technology, processes, formats and standards – also in relation to national telematics infrastructure. In view of such areas needing improvement, it must be assumed that the path to a political agreement on the EHDS will be accompanied by protracted and difficult negotiations.

The path to a political agreement on the EHDS is likely to be long and difficult.

In Germany, only selected information finds its way into the health record. The patients themselves decide on what they disclose.



The collection of large amounts of data should enable medical advancement.

Use of national health data

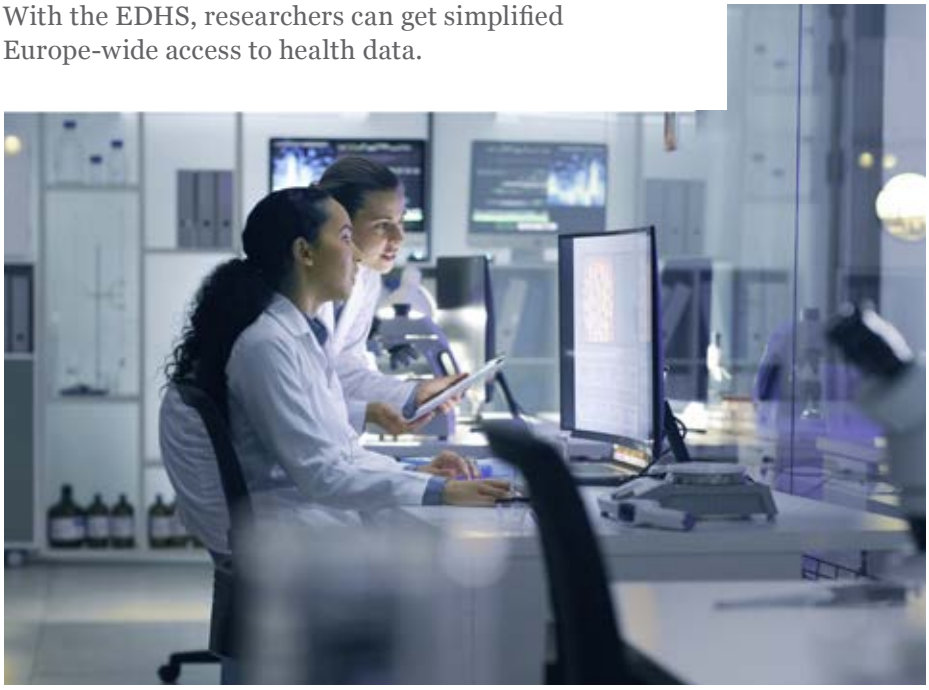
The second major area to be regulated by the EHDS is the secondary use of health data. Member States – and under certain conditions also third-countries – are to make their health data electronically available throughout the EU for research, innovation, political decisions, the development of AI and personalised medicine.

In practice, this means that researchers and policy-makers can get simplified Europe-wide access to health data. The EHDS shall regulate the health data they can access, where and in what quality. The pooling of large data volumes should also make important medical advances possible for the treatment of diseases.

The exchange of secondary data takes place via HealthData@EU

Among other things, the contents of electronic patient records, data on claims and service invoices, data from population-wide health registers and clinical studies as well as data on the use of medicines and medical devices are to be made available. Member States shall establish national access points to ensure the exchange of data on the HealthData@EU infrastructure. They publish catalogues of the available datasets, authorise data use on request and charge fees.

With the EDHS, researchers can get simplified Europe-wide access to health data.



Different data infrastructures

For cross-border data exchange, the existing national infrastructures must be linked via the European data infrastructure HealthData@EU. But these structures differ in the Member States, sometimes considerably. This concerns, among other things, data quality and formats as well as official responsibilities. In addition to the GDPR, various national regulations on health and research data must also be observed from a legal perspective. In Germany, these include regulations on social data protection under SGB V (Fünftes Sozialgesetzbuch) or the data protection regulations in the state hospital laws.

Unlike in Finland or France, German social insurance data is held decentralised. It is also specified who may use the data. There is only a small circle of users. Commercial use is not intended.

In the area of statutory health insurance, personal data such as age, gender, place of residence, as well as all cost and benefit data are compiled for each insured person. The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) acts as a data collection point and transmits the data in pseudonymised form to the Health Research Data Centre (FDZ Gesundheit) at the Federal Institute for Drugs and Medical Devices (BfArM). The FDZ Gesundheit compiles datasets that are made available to authorised users upon request. In addition, the Federal Joint Committee makes the data from quality assurance in hospitals available for research purposes.

The datasets of the statutory pension insurance are fed by the data of the statistical reporting system. The pension insurance institutions jointly maintain a data centre at the German Federal Pension Insurance Association (Deutsche Rentenversicherung Bund – DRV Bund). The social data – mainly on salaries, pensions, rehabilitation benefits – are stored according to strict conditions under the supervision of the Federal Ministry of Labour and Social Affairs. Access to health-related data is limited to case-by-case processing. The Research Data Centre for Pension Insurance (FDZ-RV) is an institution of the DRV Bund and has been providing information to science and research since 2004 Microdata records are made available in anonymised form according to transparent and standardised rules. These are relevant for science, since the datasets refer to the totality of all insured persons and are of high informa-

Finland

In Finland, the establishment of FinData 2019 created the central national authority for managing and issuing data. It is the central access point for social and health data. Aggregated statistical datasets can be queried. Personal pseudonymised data is made available digitally with personalised access in a secure cloud infrastructure for a fixed period of use. Private companies are also entitled to use it.

The Netherlands

In the Netherlands, in contrast, health data is managed in more than 200 registers and organisations. Requests for data use must be made directly to the respective organisations. The organisations and registries may define modalities of use beyond the general rights of application. Access to health data is correspondingly bureaucratic.

France

France has also enabled centralised access to health data since 2019 with the French Health Data Hub (HDH). It is still being set up, but in future it is to include all the data of the national health data system. Datasets are compiled and made available in a cloud. Research results based on data from the HDH should be freely accessible.

tive value. They also enable differentiated findings for questions that only relate to small groups of people.

The SGB VII (Siebtes Sozialgesetzbuch) describes the framework for social data in the area of statutory accident insurance. The accident insurance institutions may collect and store the social data necessary for the fulfilment of their statutory tasks.

Health data in the narrower sense, this is mainly data on insured persons, benefits and invoicing as well as reimbursement and compensation claims. In addition, the accident insurance has a pool of preventive information that includes data on the prevention of insured events, the prevention of work-related health hazards, and risks and health hazards for insured persons. This also includes research data on combating occupational diseases.

The umbrella organisation of the accident insurance institutions, the German Association of Occupational Accident Insurance (DGUV), alone has three scientific institutes; the Institute for Occupational Safety and Health (IfA), the Institute for Work and Health (IAG) and the Institute for Prevention and Occupational Medicine (IPA). In addition, there are other research institutes at some of the German employer's liability insurance associations. While the research centres in the area of pension insurance and health insurance process social and health data in order to make it available to science and research, the SGB VII does not provide for the accident insurance data to be systematically made available to other interested parties. Nevertheless, the DGUV also provides data on request. It should be noted that even within one country, the handling of social and health data can be quite different due to legal requirements.

Data catalogues must be created for secondary data use.

The more countries are included, the more colourful the picture becomes. Even the few examples from Finland, the Netherlands and France show that the task of making datasets available across Europe is a major challenge. Catalogues of datasets whose specifications, standards and formats enable data exchange will have to be created for secondary data use.

The development of the EHDS for the use of secondary data is likely to be a long process, in which the existing health data in the Member States are successively made accessible across borders. This requires a roadmap that shows how this process can be shaped together, in terms of both content and timing. Cooperation networks such as the Joint Action “Towards the European Health Data Space, THEDAS” should provide assistance.

The diversity of Europe – also with regard to the different data infrastructures and resources – will require a great deal of detailed coordination when setting up the EHDS. The expense is justified by the expected high benefit that large data volumes and high data availability promise.

However, the framework conditions that allow commercial use of health data of the social insurers must be clarified. The actual scope of data for secondary data use will also have to be discussed. In the draft regulation on the EHDS, the European Commission worded maximum ideas that even include administrative data, information on reimbursements and also data from wellness applications. The further legislative process must set limits here. The further design the EHDS should continue to take into account meaningful national differences in the Member States.

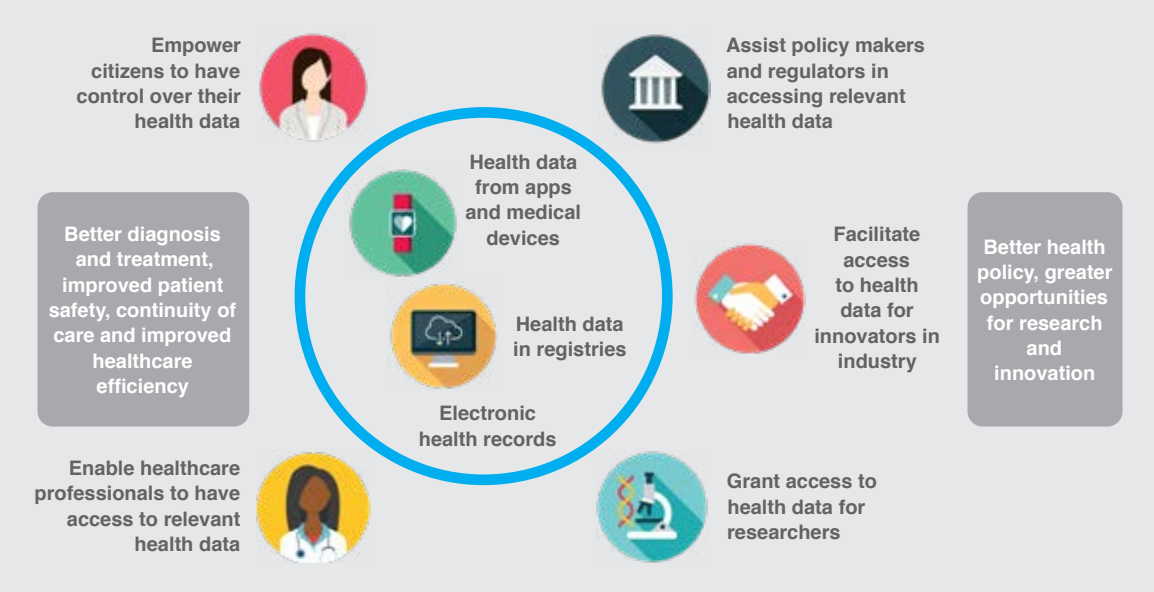
THEDAS

THEDAS brings together 25 European countries in developing a common understanding for the secondary use of health data across Europe. Technical hurdles must be overcome and legal issues must be clarified. Also the Interpretation of the GDPR must be clarified. On the German side, the BfArM, the gematik and the Research Data Centre of the Federal Statistical Office are involved. The project completion date is August 2023. This is followed by the practical test.

EHDS2 pilot project

In the EHDS2 pilot project, led by the French Health Data Hub, 16 cooperation partners from ten EU Member States will share their infrastructure with each other. Further implementation is to be tested using specific case studies from medical research. The German FDZ Gesundheit is also a project partner here.

Advantages for the users of the EHDS



Source: European Commission (2022). Communication on the establishment of a European Health Data Space (COM(2022)196 final), p. 16

Outlook

The EHDS is a prestige project. It can be a great success if it adds real value to the care of patients in the EU.

The implementation of the EHDS may exert a high pressure on the Member States to adapt and may be associated with high costs. It is problematic that many decisions – from the scope of data to technical specifications – are to be made in implementing acts. Such acts lay down detailed rules on aspects which are often very technical but essential for the implementation of that basic act (implementing decisions). Implementing acts are usually adopted by the European Commission under the monitoring of committees composed of representatives of the Member States. Here, the Member States should be more involved and have the right to review.

The approaches to primary and secondary data use are very different. With the use of primary data, cross-border healthcare, in particular should also receive a boost. The use of secondary data, on the contrary, aims at the exploitation of national data resources. The current legislative process will show whether the decision to bring the two approaches under one roof was planned with foresight.

The social insurance institutions generate, process and use health data to optimise care. From the point of view of the social security system, it is important that the Member States have sufficient co-determination rights in the EHDS. This is because the national circumstances of the health and social systems cannot be applied to other countries, neither in terms of the content nor the depth of the regulations EU level should be fully taken into account.

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