



Questions and answers - EU Health: European Health Data Space (EHDS)

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1. What is the EHDS proposal about?

Every second, doctors, nurses, pharmacists, researchers and health regulators all over the EU generate and use large numbers of essential healthcare data that are critical to their lifesaving work. Health data are the blood running through the veins of our healthcare systems. The COVID-19 pandemic has shown that up-to-date health data are key to take well informed public health measures and to respond to crises. The pandemic has also triggered a huge acceleration in the uptake of digital tools. Unfortunately, there are still complex obstacles that make it difficult to reach the full potential of digital health and health data.

The European Health Data Space will overcome these obstacles. It is a health-specific data sharing framework establishing clear rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes.

2. Who benefits from the EHDS?

The European Health Data Space will empower **individuals** across the EU to fully exercise their rights over their health data. People will be able to easily access and share these data, while retaining greater control over them, fully in line with our overall EU approach to data protection.

At the same time, the work of **health professionals'** will be made easier and more effective. With improved interoperability, health professionals will be able to access a patient's medical history across borders, thus increasing the evidence base for decisions on treatment and diagnosis, including when the patients' data is in another EU country.

By strengthening interoperability to support data exchange between healthcare providers within countries and across borders, **healthcare providers** will avoid duplications of tests, with positive effects for patients and healthcare costs.

Researchers will also benefit from a more direct way of obtaining access to data within a trusted and secure framework. Researchers will have access to larger amounts of high-quality data. They will be able to access the data in a more efficient and less expensive way, through a data access body that guarantees the privacy of the patients.

Regulators and policymakers will also have easier access to health data for policy making and for a better functioning of healthcare systems. This will lead to better access to healthcare, reduced costs, increased efficiency, more resilient health systems, new research and innovation and enable more evidence-based policymaking.

Industry will benefit from an EU-wide market for electronic health record systems, with the same standards and specifications. Greater availability of electronic health data will improve people's health, facilitate the production of innovative medicinal products and devices that offer better and more personalised care. Industry will be also able to develop new devices that use artificial intelligence technology.

3. What kind of governance system will be introduced?

The EHDS will reinforce governance at national and EU level. It builds upon the current cooperation for the primary use of data in healthcare (the use of data for the patients themselves) within the eHealth Network, which showed its value during the COVID-19 pandemic.

The EHDS extends the scope of this primary use and will now also regulate secondary use of health data (the re-use of aggregated health data by for example researchers, policy makers, innovators and industry).

The EHDS rules on the re-use of health data build on the framework introduced by the Data Governance Act. A **new European Health Data Space Board** will be created, composed of the

representatives of digital health authorities and new health data access bodies from all the Member States, the Commission and observers. It will contribute to a consistent application of the rules throughout the EU, including by advising the European Commission, while cooperating with other EU bodies and stakeholders such as patient organisations.

Member States will also cooperate at EU level on two cross-border digital infrastructures to enable data sharing (one for primary uses of health data and another one for secondary uses of health data).

4. What are the benefits and costs of the EHDS and how will it be financed?

Overall, the EHDS it is expected to save for the EU around €11 billion over ten years: €5.5 billion will be saved from better access and exchange of health data in healthcare and another €5.4 billion will be saved from better use of health data for research, innovation and policy making.

To make the EHDS a reality, further digitalisation is needed at national level. At the same time, it is necessary to set up interoperable EU-wide infrastructures to enable the cross-border use of health data in the EU. Both the Member States and the Commission will therefore support the EHDS under different EU funds and instruments. For instance, **Member States** have budgeted €12 billion for investments in digital health under the **Recovery and Resilience Facility**. The **European Regional Development Fund** and **Invest EU** offer further opportunities for investment.

In addition, **the Commission will provide over €810 million** to support the EHDS. €280 million will be available under the EU4Health Programme and the rest will be financed by the Digital Europe Programme, the Connecting Europe Facility and Horizon Europe.

5. What is the expected impact on other initiatives of the European Health Union – cancer, pharma, HERA?

The EHDS is a central component of a strong European Health Union.

It will help to boost the work under **Europe's Beating Cancer Plan**. Pooling and sharing knowledge, experience and data helps developing practical solutions for cancer patients. The EHDS will also enable the development of innovative approaches to cancer registration, allowing for more timely and efficient collection of information on various types of cancers. This will help to provide a real-time state of play of cancers across the EU.

The EHDS will also allow health data to make a vital contribution to innovation, research and the development of new medicines, treatments, and medicinal products. As a result, it will strongly support the **Pharmaceutical Strategy for Europe** and the work of **HERA**.

6. What's in it for me?

The Health Data Space, together with GDPR rights, will give you **greater control over your health data**. You will in particular:

- have access to your health data in electronic form **immediately** and **without any cost**
- be able **to share** your data **with health professionals** within the EU and across borders
- be able **to add information, rectify errors, restrict access** and **obtain** information on **what health professional accessed your data**
- have certain categories of health data, such as **patient summaries, ePrescriptions, images and image reports, laboratory results and discharge reports** be issued and accepted in a **European electronic health record exchange format**.

Moreover, **your security and privacy will be ensured**:

- researchers, industry or public institutions will have **access** to your health data only for specific purposes that benefit individuals and society
- but they can only access data that do not **reveal your identity**
- the data can only be accessed and processed in **closed, secure environments** and only anonymised data can be downloaded.

7. Can you give concrete examples of how the EHDS will function?

Example 1: A woman living in Portugal is going on holidays to France. Unfortunately, she gets sick in France and therefore needs to see a local general practitioner. Thanks to the EHDS and MyHealth@EU, a doctor in France will see on his/her computer the medical history of this patient in French. The doctor can prescribe the necessary medicine based on the medical history of the patient, avoiding for instance products to which the patient is allergic.

Example 2: A health tech company is developing a new AI-based medical decision support tool that

assists doctors to make diagnostic and treatment decisions following a review of the patient's laboratory images. The AI compares the patient's images with those of many other previous patients. Through the EHDS, the company is able to have efficient and secure access to a large number of medical images to train the AI algorithm and optimise its accuracy and effectiveness before seeking market approval.

Example 3: A man has a medical image of his lungs, taken in the public hospital where he was brought in by the emergency team. Shortly after, he visits his regular pulmonologist in another hospital. Thanks to the EHDS, his pulmonologist can see the medical image performed in the other hospital, thus avoiding a new, unnecessary test.

8. What impact will the EHDS have on health professionals?

Electronic health data will become available more easily for health professionals both within and across borders. With this improved interoperability, health professionals can access a patient's medical history, thus increasing the evidence base for decisions on treatment and diagnosis.

Through easier and faster access to relevant health data, health professionals will be able to improve the continuity of care.

They will also be able to access health data from different sources more easily, reducing the administrative burden from having to manually copy records across different systems. This will also positively impact healthcare system efficiencies. If health professionals are involved in research, they will enjoy the benefits of easier access to health data for research and innovation.

9. How will the EHDS protect data privacy and security?

The EHDS builds on the [General Data Protection Regulation \(GDPR\)](#), [proposed Data Governance Act](#), [draft Data Act](#) and [NIS Directive](#). The EHDS complements these initiatives and provides more tailor-made rules for the health sector where needed.

Trust is an important element of the EHDS. The proposal introduces security criteria for interoperability and security of electronic health record systems and requires manufacturers to certify them. The EHDS also builds on the possibility offered by GDPR to put forward an EU law supporting the use of health data for diagnosis and treatment and for research, statistics or for public interest.

Moreover, processing electronic health data for secondary use of data is only possible for specific **purposes** foreseen in the Regulation, based on a **permit** issued by a **data access body**. It will be **forbidden to use the data to take decisions detrimental to individuals**, or to market health products towards health professionals or patients.

Data processing can only take place **in secure processing environments**, which need to comply with very high standards of privacy and (cyber)-security and no personal data can be downloaded from such environments. Moreover, the researcher, company or public institution can only access non-identifiable data (offering information about the disease, symptoms and medication, without revealing the identity of the individual). It is forbidden for the user to re-identify the data subjects. Strict measures are paramount given the sensitive nature of health data.

10. To what extent are Member States ready for the EHDS?

Member States have different maturity levels when it comes to digital health.

As regards **primary use of health data**: the use of health data for health service provision, as illustrated in different studies, some Member States have achieved high levels of digitalisation and interoperability within their borders, while others are in the process of taking the necessary steps. Patient summaries and e-prescription services exist in two-thirds of all Member States and are most frequently accessed via an online portal, but only in a few countries can they be sent or received across borders and 11 countries are still using paper printouts for prescriptions. Today, only ten Member States support the sharing of patient summaries and ePrescriptions via MyHealth@EU. There are however plans for all Member States to join MyHealth@EU by 2025.

As regards the **secondary use of health data** for research, innovation, policy making and regulatory purposes: studies which inform regulatory decisions are currently often performed in a small set of databases clustered in a few EU Member States, limiting their geographical and demographic sample sizes. To overcome this fragmentation and the over-reliance on consent, some Member States started to adopt national laws. For instance, 13 Member States have started to put forward more centralised national systems to provide access to data, but there is no link between them at EU level, the system remains fragmented and there are differences between tasks, even though they share many commonalities. Some Member States have created Health Data Access Bodies such as Findata, French Data Hub, German Forschungsdatenzentren, and others.

The EHDS is ambitious in the sense that the proposal wants to **advance digital health for all Member States** and to make the healthcare systems of the EU ready for the digital future.

11. Will the EHDS share health data with industry?

It is important that industry can use health data, to allow for innovation that will improve the prevention, diagnosis and treatment of diseases. The COVID-19 pandemic showed again the importance of such innovation to develop vaccines that helped saving millions of lives.

That is why industry will have the opportunity to make use of the health data access bodies, after they have been granted a permit for access to data. Only the data necessary for that specific research would be put at their disposal, without revealing individual's identity, and it can only be accessible in the secure processing environment for the duration of their project.

In the context of healthcare, the EHDS only supports the access of health professionals to the data of their patients. Industry will not have access to such data.

For More Information

[Communication: A European Health Data Space: Harnessing the power of health data for people, patients and innovation](#)

[Proposal for a Regulation on the European Health Data Space](#)

[Press Release](#)

[Factsheet](#)

[Data Strategy of 19 February 2020](#)

[Webpage](#)

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