Questions and Answers on the European Health Data Space

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What is the EHDS proposal about?

Every second all over the EU, doctors, nurses, pharmacists, researchers and health regulators 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 is key to inform effective public health measures and respond to crises. The pandemic has also triggered a huge acceleration in the uptake of digital tools, but complex obstacles remain 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, digital 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.

Who benefits from the EHDS?

The European Health Data Space will empower individuals across the EU by giving them more control over their health data. People will be able to access and share this data more easily, while retaining greater control over them. This is fully in line with our overall EU approach to data protection and complements existing rules.

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 supporting 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 discovering which data is available and accessing it within a trusted and secure framework. Researchers will have access to larger amounts of high-quality, representative 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 more effective policy making and for a better functioning of healthcare systems, grounded in evidence. This will lead to better access to healthcare, reduced costs, increased efficiency, strengthened research and innovation and more resilient health systems.

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 by facilitating 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.

What kind of governance system will be introduced?

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

The EHDS extends the scope of the data categories exchanged for primary use and takes the next step by turning the existing voluntary cooperation among some Member States into an obligation for all Member States.

It will also establish a framework to regulate secondary use of health data (the re-use of health data originally collected for another purpose by entities such as 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, co-chaired by a Member State and the Commission, composed of representatives of the Member States for primary and secondary use of health data, the Commission and observers. It will contribute to a consistent application of the rules throughout the EU. It is complemented by a stakeholder forum gathering insights from entities such as patient organisations, researchers, and industry.

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) in dedicated steering groups.

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

Overall, the EHDS it is expected to save 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.

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 develop 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.**

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 **which 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** 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 be able to **access** to your health data only for specific purposes that benefit individuals and society;
- 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.

What if I don't want to participate?

For primary use, you will be able to restrict access to your data. In addition, there will be a possibility for Member States to provide for a full opt-out, enabling people who do not want to take part in the exchanges under the EHDS to revert to the previous style of exchanging medical records. This would mean for example having to manually provide earlier laboratory reports to your doctor.

Should you not want to take part in secondary use, you will have a right to opt-out specifically from secondary use, in an easy and reversible way. However, for certain important public interests and under strict safeguards, including transparency requirements, your data may still be used.

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

Example 1: A woman living in Portugal goes on holiday to France. Unfortunately, she falls ill in France and needs to see a local general practitioner. Thanks to the EHDS and MyHealth@EU, a doctor in France will see on their computer the medical history of this patient (facilitated by translation functions). As a result, 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. The prescription information can be shared as well, so it can be used back home in Portugal, or anywhere else in the Union.

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 previous patients. Through the EHDS, the company is able to efficiently and securely access a large number of medical images to train the AI algorithm, which in turn optimises 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 doctor in another hospital. Thanks to the EHDS, his doctor can see the medical image performed in the other hospital, thus avoiding a new, unnecessary test.

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, medical images and imaging reports, as well as laboratory results, 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.

How will the EHDS protect data privacy and security?

The EHDS builds on the **General Data Protection Regulation (GDPR)**, **Data Governance Act**, **Data Act** and **NIS2 Directive**. The EHDS complements these initiatives and provides additional tailor-made rules for the health sector where needed.

Trust is a key 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, treatment, research, statistics or for public interest.

Moreover, processing electronic health data for secondary use is only possible for specific **purposes** foreseen in the Regulation, based on a **permit** issued by a **data access body**. There are clear rules on what you can and cannot do with the data. For example, it will be **forbidden to use the data to take decisions detrimental to individuals**, or to use the data for marketing purposes.

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 at most access pseudonymised data, in case the purpose cannot be achieved with anonymised data. It is forbidden for the user to re-identify the data subjects, or even to try to. Strict measures are paramount given the sensitive nature of health data.

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 eleven Member States support the sharing of patient summaries and ePrescriptions via MyHealth@EU. There are however plans for almost all Member States to join MyHealth@EU by 2025. Exchanges under the EHDS are scheduled to begin in 2028 for all Member States, with additional data categories to be added in 2030. This leaves sufficient time for Member States and healthcare providers to prepare.

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, some Member States have 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 in Finland, the Health Data Hub in France, the German Forschungsdatenzentren, and others. The EHDS' rules on secondary use are scheduled to start applying in 2028, leaving sufficient time for Member States and health data holders to prepare. In 2030, additional data categories will start to be made available.

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

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 request access to data for secondary use and be granted a permit to access the data under the rules of the EHDS through the health data access bodies. Only the data necessary for that specific request would be made available, without revealing individuals' identities, and it can only be accessed in the secure processing environment for the duration of their project.

However, industry will have no access to the data exchanged in primary use, in the context of healthcare. Regarding primary use the EHDS only supports the access of health professionals to the data of their patients and patients to their own data.

For more information

Press release

Factsheet

Webpage

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Press contacts:

Stefan DE KEERSMAECKER (+32 2 298 46 80)
Anna Gray (+32 2 29 80873)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email