All you need to know about the European Health Data Space (EHDS)

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What changes should startups expect?

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EXECUTIVE SUMMARY

The European Health Data Space (EHDS) is a set of rules, processes and technical specifications to exchange health data across the EU for three main purposes:

- Facilitate patients’ access to care across borders (primary use of health data)
- Facilitate research, innovation, and public policy (secondary use of health data)
- Improve the functioning of the Single Market, in particular for the development, marketing, and use of digital health services and products.

Startups and scaleups providing software to manage Electronic Health Records (EHR) for the delivery of care (primary use) will have to abide by some new obligations: ensure interoperability with a European data exchange format, get a CE marking and allow patients to exercise rights over their data, including an opt-out. Wellness apps claiming interoperability with EHR systems, instead, will only have to display a label and register in the EU database.

Startups and scaleups requesting/providing access to health datasets to carry out research or develop innovative products (secondary use) will have to cooperate with a newly established Data Access Body. This body will manage inbound and outbound data access requests and related fees. Importantly, the EHDS procedure will not replace existing contracts and mechanisms to access health data for research and innovation. Patients will have the right to opt-out.

The EHDS will be supervised by four national authorities (Data Protection Authority, Digital Health Authorities, Market Surveillance Authorities, Data Access Bodies). Digital Health Authorities will coordinate at EU level via the EHDS Board. Technical aspects (standards, infrastructure) will be determined by the European Commission and Member State representatives, while industry will be represented in a Stakeholder Forum.

The EHDS will likely enter into force in autumn 2024 and apply two years later (2026).
What is the European Health Data Space (EHDS)?

The European Health Data Space (EHDS) is a set of rules, processes and technical specifications to exchange health data in the EU- it is not a repository of health data.

The goal of the EHDS is to "ensure the secure and free movement of electronic health data across the Union" for three main purposes:

- Facilitate patients’ access to care across borders (primary use of health data)
- Facilitate research, innovation, and public policy (secondary use of health data)
- Improve the functioning of the Single Market, in particular for the development, marketing, and use of digital health services and products.

How does the EHDS work?

Different rules and procedures apply depending on whether you deal with health data for the delivery of care (primary use) or for research & innovation purposes (secondary use).

Primary use: sharing data to enable access to care

The first goal of the EHDS is to facilitate patients’ access to care across the EU. Concretely, it means that if you are attached to the French social security system and break your leg during a trip to Greece, the Greek doctor visiting you will be able to access the history of your previous injuries and prescribe treatment accordingly. Same goes for prescriptions: if you suffer from a chronic illness and run out of your daily medicine while on holiday in Spain, you will be able to go to a Spanish pharmacy and get the drug with your French prescription.

To make this possible, the EHDS establishes that Electronic Health Records (EHR) of European patients have to be in a standardized format, at least for some categories of data, and have to be accessible across borders via the MyHealth@EU infrastructure orchestrated by national contact points.

If you develop software for Electronic Health Records (EHR) - or wellness apps that are interoperable with EHR systems - this chapter concerns you.

EHR systems are “appliances or software that allow to store, intermediate, export, import, convert, edit or view priority categories of personal electronic health data”.

The "priority categories of health data" concerned are patient summaries, electronic prescriptions, electronic dispensations, medical imaging studies and related imaging reports, medical test results, including laboratory and other diagnostic results and related reports, discharge reports. This list may be extended by Member States.

Patients will have several rights in relation to the primary categories of health data: they will be able to access, port and rectify their data, insert additional information in their EHR, obtain information on who, when and where accessed their data, restrict access and even opt-out from access of their primary data via an EHR. Member States, however, may allow health providers to override the opt-out if it is in the vital interest of the patient. At the same time, they may introduce additional safeguards to protect these data, like requiring that electronic health data for primary use is stored in the EU (art. 60a).
The “European EHR exchange format” shall be commonly used, machine-readable, applicable both to structured and unstructured data and interoperable across different software applications, devices and healthcare providers. The format will be established by the European Commission in cooperation with a Committee of Member State experts taking into account existing national terminologies.

If you develop an EHR system, you will have to comply with several obligations: ensure interoperability with the European EHR exchange format, draft technical documentation, provide an information sheet to users, fill in an EU declaration of conformity, obtain a CE marking, register in an EU database and allow for and track complaints.

While you cannot charge a fee to allow the primary use of health data, the procurement and reimbursement of EHR systems remains regulated by national law.

If you develop a wellness app and claim that it is interoperable with an EHR system, you have to put a label on it indicating (1) the categories of data for which there is interoperability (2) the common specifications you have adopted (3) the duration of the label (up to 3 years). Interoperability does not mean automatic transmission of data to the EHR system - you need to inform the user of this option and ask for their consent. You must also register the app in the EU database.

Secondary use: sharing data for research and innovation

The second goal of the EHDS is to facilitate research, innovation and public policy, including the delivery of care, public and occupational health, higher education and occupational training (secondary use). Concretely, it means that if you develop algorithms to predict heart failure and need to access patient data to train your artificial intelligence system, you may go through the EHDS procedure rather than contact hospitals individually to get access to the training data.

To make this possible, the EHDS establishes that data should be made available to companies, health professionals, researchers and public institutions for secondary use via a newly-established entity, the Health Data Access Body.

The Health Data Access Body will act as an intermediary between data users and data holders (like the Health Data Hub in France) but will not replace existing data access agreements and partnerships. The Body will decide on data access applications, issue data permits, prepare data (including pseudonymisation and anonymization if needed), protect Intellectual Property (IP) and trade secrets, contribute to the development of common standards and provide a secure processing environment for health data. It will also facilitate cross-border access to data via the HealthData@EU infrastructure that will have to be set up by the European Commission and Member States.

Public and private data holders will have to communicate to the Health Data Access body a description of the datasets they hold and update it at least once a year. This description should also indicate whether any datasets or parts thereof are protected by IP and/or trade secrets. The datasets will then be featured both in a national and in the EU catalogs to allow for their discoverability by data users.
To access such datasets, individuals (for example, a researcher), public entities (for example, the Ministry of Health), companies (for example, a startup) or other legitimate data users will have to fill in a data access application (or a data access request for anonymized data in statistical format) to the Data Access Body.

The Data Access Body will then establish if the application is legitimate. If IP and trade secrets are involved, the Body will also determine whether sufficient protective measures can be put in place or whether the data access should be denied. If the Body considers that it is safe to share the data, it will communicate the estimated fee to the data user.

Fees will be calculated by adding the costs incurred by the data holder to those incurred by the data access body to prepare and make the data available. This includes the pseudonymization or anonymization of the data, which may be carried out by the data holder or by the data access body. The fees should be non-discriminatory and may be reduced for some entities based in the EU like universities.

After seeing the estimate, the data user can decide whether to withdraw the application or pay the fee. In the first case, the data user only pays the costs incurred by the data holder and the Data Access Body up to that point. If instead they agree to pay the fee, the Data Access body will communicate the fee reflecting the real costs to the data user, who will make a payment to the Data Access Body, which will then transfer the relevant amount to the data holder. The data access body will then issue a data permit and the data holder will have up to 3 months to provide the data to the user.

The data user will access the data via the secure processing environment maintained by the Health Data Access Body (or download the data if in an anonymized and statistical format). If IP and trade secrets are involved, the Body will be responsible for their protection. The data user will then have up to 18 months to publish the results of their research in an anonymized version.

Importantly, patients will be allowed to opt out from the secondary use of their health data, although Member States may override this right with national law if certain cumulative conditions apply.

Who is concerned by these new rules?

The EHDS concerns several types of stakeholders: patients, health professionals, medical establishments, research institutions, public authorities, but also technology companies providing Electronic Health Record (EHR) systems and wellness apps or using health data to carry out research and/or develop new products and services.

A startup that asks a hospital for access to a dataset on radiology exams is a data user, whereas a startup that builds a dataset on heart failure based on the use of its pacemaker by patients is a data holder. A startup can also be a manufacturer if it provides technology for patients and/or medical professionals, for example, to manage prescriptions (EHR system), or an app to track sleep patterns (wellness app).

Startups can be any of these stakeholders, depending on their role in the value chain and the nature of their activity (product, service, subsidiary activities like research etc.). If you deal with health data on some level, the EHDS concerns you.
What are the authorities involved?

The respect of rules on the primary use of data will be entrusted to one or multiple national digital health authorities, which will coordinate at European level via the EHDS Board. These authorities will also handle complaints by natural and legal persons.

Obligations related to EHR systems and wellness apps, instead, will be the remit of national market surveillance authorities, while compliance with rules on secondary use of health data will be ensured by data access bodies. Lastly, national data protection authorities will oversee the respect of patients’ rights over their data.

When it comes to standards and infrastructure, they will be determined by the European Commission and Member States representatives within Steering Committees.

Industry will be represented in a Stakeholder Forum chaired by a representative of the Commission. Members will be appointed by the Commission after a transparent call for expression of interest with a balanced representation of large companies and startups.

Are there any fines?

In case of non-compliance of EHR systems, the competent market surveillance authority can restrict or prohibit the EHR system/ wellnes app from being placed on the market or ensure that it is recalled or withdrawn from the market.

Moreover, digital health authorities, data protection authorities and data access bodies may impose administrative fines. For companies, such fines may go up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.

When will the EHDS apply?

The European Parliament and Council reached an agreement on 22/3/24 and the text was approved by the Parliament’s plenary on 24/4/24. It will probably be published in the Official Journal in autumn 2024. The EHDS will enter into force 20 days after and will apply starting 2 years later (est. autumn 2026).

What has been the role of France Digitale?

France Digitale has advocated since the publication of the EHDS proposal in May 2022 with and for its members to improve the EHDS. We have worked in particular on clarifying definitions, setting the conditions for data permits, protecting trade secrets and intellectual property, introducing reasonable interoperability obligations, ensuring fair remuneration for startups and increasing their participation in decisions that affect them. We also advocated to enable patients to exercise their rights via the products and services provided by our members, including the right to opt-out.

The greatest victory for us is that the EHDS does not replace contractual or other mechanisms that you may already have in place to share health data to develop your product/service, it’s an additional procedure available to you. Moreover, we have succeeded in improving startups representation and ensured that the standards they already comply with at national level are taken into account.
Got a question?

Reach out to the team 🎈