



MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR ET DE LA RECHERCHE

*Liberté
Égalité
Fraternité*



Strasbourg, 3.5.2022
COM(2022) 197 final

2022/0140 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

EUROPEAN HEALTH DATA SPACE

[Volker Beckmann](#)

French Ministry for Higher Education and Research (MESR)

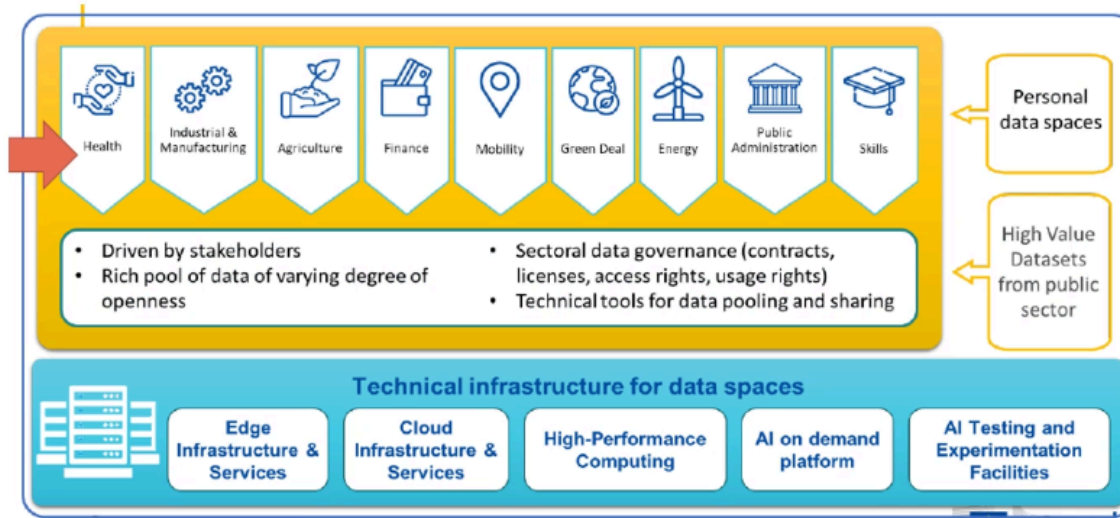


European Health Data Space (EHDS) in context

The European Data Spaces are part of [Europe's strategy for data](#) focuses on putting people first in developing technology and defending and promoting European values and rights in the digital world.

Part of this strategy are the [Data Governance Act](#) and the [Data Act](#). Common European data spaces will ensure that more data becomes available for use in the economy and society, while keeping the companies and individuals who generate the data in control.

Premier espace européen de données sectoriel



European Health Data Space (EHDS)

The [European Health Data Space](#) (EHDS) is the first of 9 data spaces foreseen to be implemented. Its two main objectives are:

1. The general objective of the EHDS is to ensure that EU individuals have increased control over their health data ([primary use of data](#)).
2. providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities ([secondary use of data](#))

“The general objective is to ensure that natural persons in the EU have increased control in practise over their electronic health data. It also aims to ensure a legal framework consisting of trusted EU and Member State governance mechanisms and a secure processing environment. This would allow researchers, innovators, policy-makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well- informed policies. It also aims to contribute to a genuine single market for digital health products and services, by harmonising rules, and so boost healthcare system efficiencies.” ([EHDS draft proposal](#), page 1)

“When providing a framework for the secondary use of electronic health data, the EHDS **builds upon the proposed Data Governance Act** and the proposed **Data Act**.” ([EHDS draft proposal](#), page 4)

Directorates involved on the European Commission side: DG SANTE and DG-CNECT

European Health Data Space (EHDS)

Table of contents of the [proposal for a regulation of the European parliament and of the council on the EHDS](#) (version May 3, 2022):

- Chapter I (**page 45 ff**) defines the subject matter and the scope of the regulation, sets out the definitions used throughout the instrument as well as its relationship with other Union's instruments.
- Chapter II (**page 49 ff.**) develops the additional rights and mechanisms designed to complement the individual's rights provided by the Regulation (EU) 2016/679 in relation to the their personal health data.
- Chapter III (**page 59 ff.**) is solely focused on implementing a mandatory certification scheme for electronic health record systems where such system must comply with essential requirements related to interoperability and security.
- Chapter IV (**page 69 ff.**) facilitates the **re-use of health data for research**, innovation, policy making and regulatory purpose. It defines a set of data types that can be re-used for defined purposes. Some purposes such as commercial advertising are specifically prohibited. Member States will have to set up competent body charged with monitoring such re-use of personal (?) health data and ensure that personal (?) health data is made available by data providers for data users.
- Chapter V (**page 89 ff.**) aims to put forward other measures to promote capacity building by the Member States in order to accompany the development of the European health data space, such as exchange of information on digital public services, funding, etc.
- Chapter VI (**page 91 ff.**) creates a formal expert group (the 'European Digital and Health Data') which will facilitate the cooperation between the competent authorities in particular the relation between primary and secondary use of electronic health data. Dedicated sub-groups such as sub-groups on primary use of heath data and on secondary use of health data will be created to focus on specific issues or process.
- Chapter VII (**page 92**) allows the Commission to adopt delegated acts concerning the European health data space.
- Chapter IX (**page 95**) contains provisions regarding cooperation, penalties and provides for final provisions.
- **Estimated Financial Impact of the Proposal** : page 108 ff.

Preferred* implementation option

Option 2 and 2+: Intervention with medium intensity: It would strengthen the rights of individuals to control digitally their health data and provide an **EU framework for re-use of health data**. The governance would rely on national bodies (for primary and secondary use of data) that would implement the policies nationally and, at EU level, would support the development of appropriate requirements. A **digital infrastructure would support cross border sharing and re-use of health data**. Implementation would be supported by a certification for EHR systems and a voluntary label for wellness applications, thus ensuring transparency for authorities, procurers and users.

Preferred option 2 / 2+ : overall costs for the preferred option are expected to be between **EUR 0.7-2.5 billion** above the baseline over 10 years

*preferred by the EC, see [EHDS draft proposal](#), page 13 ff.

EOSC and EHDS : EOSC Opinion Paper (09/2022)

1. Ensure that the regulation for the European Health Data Space is coherent and develops synergetically with the EOSC initiative, exploiting and strengthening the relevant existing public data infrastructures and services.
2. Raise awareness for the overarching role of EOSC as a transverse European Data Space.

EOSC-SB agreed on recommendations to slightly modify the text of the regulation in Chapter IV and Chapter VI

Input to inter-ministerial discussions about the EHDS regulation

Progress report on regulation (01/12/2022)

During the Czech Presidency, 15 meetings of the Working Party on Public Health have been held, and the first examination of the proposal has been concluded. Detailed discussions have also taken place on the interlinkage with other legislation, in particular with the GDPR, on the legal basis, and the proposed European governance structure of the EHDS.

The Presidency asked the Council Legal Service to provide a written opinion on the legal basis of the text, [...]

Pending the Council Legal Service's written opinion and based on the discussions in the meetings and the written comments from delegations, the Presidency tabled a revised text for Chapters II and III of the proposal [...]

Main comments on Chapter II + III (primary use of data)

On the remainder of the proposal, the Presidency considers that other outstanding issues are: the list of minimum categories for secondary use of data; the tasks of health data access bodies (HDAB); HDABs' reporting duties and the fees charged by HDABs; some aspects of the issuance of data permits; joint controllership of secondary use of data and responsibilities; third countries' participation in HealthData@EU; data quality and utility labels; and the governance structure.

We are not done yet :

The Council is invited to take note of the progress achieved so far, confirm that the Presidency's suggestions provide a good basis for future discussions, and invite the incoming Presidency to build on the progress made so far.

Progress on regulation

- Conference on “EHDS - Opportunity for Innovation and Economic Growth - Vision or Reality”, November 15 (Prague)
- Recording of the conference : <https://www.komora.cz/eu-ehds/>

Remaining issues (?)

- “The governance would rely on national bodies for primary and secondary use of electronic health data that would implement the policies nationally and, at EU level, support the development of appropriate requirements. Two digital infrastructures would support cross border sharing and secondary use of electronic health data” —> cross border sharing often between hospitals (clinical trials) and not transverse national bodies / data hubs.
- Interoperability, missing standards
- *This implies the development of ad hoc repositories, equipped with processing tools (statistics, interoperability and integration, AI, anonymisation etc), and complex procedures for storing and accessing data. Europe will therefore be unattractive and uncompetitive in this area of sharing and secondary use, and the extra costs inherent in this complexity should be borne by the EU rather than by potential users.*

European Health Data Space

- strong focus on primary use of data (patient rights)
- secondary use of data (i.e. health data for research) often seen as a menace and risk rather than an opportunity
- European Data Spaces need be constructed in a coordinated way
- Avoid duplication of effort
- Recognise EOSC as a transverse European Data Space
- Continue to follow evolution of regulation and identify other data spaces where intervention might be useful



volker.beckmann@recherche.gouv.fr