WHITE PAPER

AI FOR HEALTH

How to Make the European Health Data Space an Asset for France ?

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AI for Health Summit

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Executive Summary

Key points of the white paper summarized here

Adopted in April 2024, the European Health Data Space (EHDS) is a key initiative of the European strategy for health data. It aims to create a harmonized framework enabling secure access to health data while respecting citizens' rights and supporting research, innovation and public policy.

The EHDS is based on two main uses that reflect the ambition to leverage health data:

- **Primary use:** Facilitating cross-border access to electronic medical records (EMRs) to improve patient care across Europe (MyHealth@EU).
- **Secondary use:** Reuse data for research, innovation and public policy design within a strictly regulated framework (HealthData@EU).

Context and Challenges

EEDS responds to several challenges hampering the optimal use of data:

- **Legal fragmentation and national silos**, complicating data sharing and limiting interoperability.
- **Administrative complexity**, slowing down data access for researchers and innovators.
- **Concerns about data security and confidentiality**, fuelling public distrust.

Priority Actions for the Optimal Deployment of the EHDS

During our workshop, several strategic priority actions were identified:

- **Build a solid governance framework:** Include trusted third parties such as patient associations in strategic discussions with organizations responsible for data access, to guarantee transparency and raise awareness among all stakeholders.
- **Adopt a collaborative approach by disease:** Mobilize stakeholders around specific diseases to demonstrate the value of shared data and the effectiveness of targeted collaborations.
- **Train healthcare professionals and researchers:** Acculturate them to interoperability standards, pseudonymization and secondary use of data.
- **Create transparency portals:** Give citizens the means to track the use of their data and identify the holders of their data, strengthening their trust through transparency.
- **Strengthen partnerships:** Establish a framework of trust for data access, guaranteeing transparency in terms of access and use via dedicated contracts.
- **Establish reference frameworks:** Help research and innovation players in their data re-use projects, and provide them with greater legal certainty and predictability, if possible on a European scale.

Keys to a Successful Acculturation Strategy Based on Common Understanding

The EHDS must be accompanied by an awareness-raising strategy to ensure stakeholder buy-in:

- **Communicate clearly:** Explain the benefits to citizens and reassure them about data security.
- **Adapt messages:** Use social networks to run awareness campaigns and illustrate positive impacts through concrete use cases.
- **Involve citizens:** Multiply points of view by setting up citizen committees and explaining key notions such as public interest.

The EHDS offers a unique opportunity to transform health data into a lever for innovation, while guaranteeing EU sovereignty and the protection of citizens' data and rights. With inclusive governance, strong partnerships and an effective acculturation strategy, it can become a pioneering model at the service of all.

OVERVIEW

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Introduction

Health data plays a fundamental role in the transformation of healthcare systems, enabling advances in research, innovation, and the improvement of care. However, their optimal use remains hindered by challenges such as the fragmentation of legal frameworks, the lack of interoperability, and concerns related to data privacy. To address these issues, the European Union (EU) has adopted an ambitious initiative: **the European Health Data Space (EHDS)**.

This initiative is **part of the European strategy for data**, which aims to strengthen digital sovereignty and establish a single market for data within the EU. Adopted in April 2024, the EHDS seeks to transform the way health data is used and shared, while respecting citizens' rights, and supporting research and innovation.

An Ambitious Vision for Europe

The EHDS is the first of eleven sectoral data spaces defined by the European strategy, marking a key step in building a digital Europe. It is based on two complementary pillars:

- **Primary Use of Data:** The program MyHealth@EU aims to improve cross-border patient care through secure access to electronic medical records (EMRs), including information such as prescriptions or medical imaging.
- **Secondary Use of Data:** The program HealthData@EU allows for the reuse of health data for purposes of research, innovation, and the development of public policies, within a strictly regulated framework.

These two pillars illustrate the ambition of the EHDS: to create a harmonized European ecosystem where data can be accessed securely and efficiently among public and private actors, while respecting citizens' rights and their privacy.

Keys Stages of Implementation

The EHDS has already passed and will pass several decisive stages. The current phase is crucial: Member States must transpose the provisions of the regulation into their national frameworks, harmonize their technical infrastructures, and engage stakeholders.

April 2024

Vote in plenary session at the European Parliament

May-November 2024

Work of the legal linguists (so-called corrigendum procedure)

December 2024 - January 2025

Formal adoption of the revised version by the European Parliament and the Council

January-February 2025

Promulgation (publication in the Official Journal of the European Union)

Next steps

Entry into force: 21 days after publication in the Official Journal of the European Union

Entry into application: staggered between 2 and 10 years after the date of entry into force

A Transformation in the Use of Health Data

The EHDS proposes a profound change from the current situation. Today, health data often remains siloed within national boundaries, limiting its potential for secondary uses. Researchers, industry players, and public authorities face significant obstacles in accessing this data, including administrative delays and regulatory inconsistencies. With the EHDS, the EU aims to provide solutions and impact a variety of stakeholders.

Patients and Citizens

- **Facilitate patient care** on a European scale by enabling secure sharing of data between healthcare professionals.
- **Restore control to citizens over their data**, with better access, the right to object to certain processing, the ability to restrict access to specific information, and the option to complete their medical records.
- **Ensure citizens benefit from scientific advances in research** and innovation while respecting the confidentiality of their data.

Professionnals

- **Healthcare Professionals:** Simplified access to electronic medical records (EMRs), even for patients treated abroad.
- **Researchers:** Extended and rapid access to diverse health data, centralized and sourced from multiple origins.
- **Industry Players:** Easier access to the European market for medical software publishers and leveraging secondary use of data for innovation purposes.
- **Digital Health Companies:** Increased opportunities in the European market for medical solution providers, with access to data to develop innovations.
- **Public Authorities:** Develop public health policies and produce reliable statistics using harmonized and accessible data.

A Strict Framework for the Ethical Use of Health Data

To ensure these transformations respect fundamental rights, the EHDS strictly regulates secondary uses of data. Only purposes such as scientific research, the development of public policies, or health innovation are permitted. Furthermore, sensitive data must be pseudonymized or anonymized, and access occurs through secure environments.

By strengthening transparency and introducing mechanisms like the opt-out right for citizens, the EHDS seeks to strike a balance between innovation and ethical standards.

An Opportunity for Research and Innovation

The EHDS embodies a vision for Europe: making health data a driver of innovation and progress while respecting citizens' data protection rights. Its successful implementation will depend on collaboration between Member States and private actors, guided by a spirit of shared responsibility.

During the collective intelligence workshop organized at the **AI for Health Summit 2024** , discussions highlighted the potential of the EHDS for France and Europe. Participants emphasized the need for an ambitious implementation, combining sovereignty, security, and interoperability. This deliverable aims to summarize these exchanges, outlining priority actions to be implemented and strategies for fostering awareness and adoption of this major initiative.

Priority Actions
for the Implementation of the EHDS

The implementation of the EHDS relies on strategic actions aimed at strengthening trust, establishing inclusive governance, and engaging stakeholders.

These priorities reflect key axes identified to ensure successful and sustainable adoption.

1. Trust, Governance and Inclusion of Trusted Third Parties

Building a robust and inclusive governance framework with health data authorities is essential to establish trust among stakeholders. The **inclusion of trusted third parties**, such as associations or civil society representatives, is crucial from the outset of discussions. These third parties can:

- **Raise awareness among citizens and stakeholders** about the issues and benefits of the EHDS.
- **Act as information intermediaries**, ensuring that all voices, including those of patients and civil society, are heard.

This participatory approach helps build a framework that inspires trust and reflects the concerns of all relevant stakeholders.

2. Partnerships and Data Access Contracts

A partnership-based approach is essential to ensure transparency and shared acceptability of data access modalities. The data access contract serves as a key tool to:

- **Build trust among various stakeholders** whether academic, industrial, administrative, or medical.
- **Establish clear and balanced rules** that address the needs of each stakeholder while protecting the interests of citizens.

Finding a compromise between these different interests without making the contractual framework overly burdensome remains a challenge, but it is essential for ensuring effective and sustainable implementation of the EHDS. Reference frameworks can be useful in helping structure, draft, and implement partnerships around data.

3. Training and Education of Healthcare Professionals

Healthcare professionals play a central role in the successful deployment of the EHDS and in fully realizing its benefits. They must be educated on fundamental concepts such as pseudonymization, anonymization, and data transparency. This education will enable them to:

- **Explain to patients the purposes of data usage**, including their contribution to European research or innovation projects.
- **Foster transparency from the point of data collection**, thereby strengthening citizens' trust in the system.

4. Pathology-Based Approach and Consortia

An effective strategy to illustrate the added value of the EHDS is to focus efforts on a specific pathology. This would allow for:

- **The creation of consortia bringing together all stakeholders**, including patients, around a given disease (e.g., cancers, rare diseases, etc.). Since several consortia already exist, the idea would also be to engage them and encourage their involvement in the EHDS initiative.
- Demonstrating the concrete benefits of collaboration by using shared data to accelerate research and improve treatments.

5. Acculturation of the Research Community

The research community must be made aware of and prepared for the EHDS requirements regarding interoperability and common standards. This will enable:

- **The establishment of a clear framework** for the effective use of harmonized data.
- **Positioning French research among the leaders** by ensuring optimal preparation from the early phases of implementation.

6. Raising Awarennes at the European Level

Awareness-raising efforts must transcend national borders to reflect the pan-European nature of the EHDS. This involves:

- **Campaigns tailored to diverse audiences**, using social media to reach younger demographics.
- **Visual content that incorporates a strong European identity**, such as multilingual videos or testimonials from different Member States.

This approach will strengthen unity and understanding around the EHDS across all European countries.

7. Promoting a Culture of Secondary Use of Health Data

To maximize the benefits of the EHDS, it is essential to consider the secondary use of data from the design phase of systems and projects. This will allow for:

- The integration of a **reuse logic for research, public policies, and solidarity initiatives** from the early stages of development.
- **Avoiding complex or costly adaptations** later on, while ensuring an ethical and secure framework.

8. Transparency Portal and Identification of Data Holders

Transparency is a key lever for building durable trust. The creation of transparency portals will enable citizens to:

- **Track the use of their data** and understand the benefits generated by the EHDS.
- **Identify data holders** and their various responsibilities.

In parallel, data holders must be made aware of their roles and supported in meeting transparency requirements and ensuring data quality.

9. Legal Clarification and Specific Use Cases

A number of legal questions arise, particularly regarding data categories and their intended uses, which may require clarification. Relying on **concrete use cases** will help to:

- **Establish a shared and understandable doctrine** for all stakeholders.
- **Define clear rules and reference frameworks**, reducing ambiguities and reassuring both data holders and users.

10. Public Interest Concept and Ethics

The concept of public interest, central to the EHDS, must be made accessible to avoid it being perceived as abstract or reserved for a select group of experts. It is necessary to:

- **Explain this concept in a clear and accessible manner**, making it understandable to everyone.
- **Ensure that it remains at the heart of decisions related to the EHDS**, to guarantee that the initiative truly serves the common good.

Key Messages & Acculturation Strategy Around The EHDS

For the EHDS to achieve its objectives, it is essential to develop **a clear and targeted acculturation strategy**. This strategy must enable citizens, healthcare professionals, researchers and political decision-makers to understand the issues, benefits and fundamental principles of the EHDS, while responding to their expectations and concerns.

1. Explaining the EHDS: a Concise, Shared Definition

Defining the EHDS for different audiences
The level of understanding and expectations varies according to the players involved in the EHDS (technical, legal, regulatory). It is therefore crucial to adopt an approach tailored to each audience to clearly define what the EHDS is:

- A framework that facilitates **secure access to healthcare data**, not its transfer or circulation.
- An initiative to **improve care, research and innovation** while respecting citizens' rights and member states' sovereignty.

The definition should be accompanied by concrete examples to illustrate the positive impact of the EHDS. For example, show how access to data can enable advances in disease research.

2. Building Trust through Clear Access Procedures

Accessing data vs. data circulation
Clear communication is essential to dispel misunderstandings. The term "data circulation" can raise concerns about loss of control or the risk of massive transfers. The emphasis should be on:

- The **provision of data**, in secure environments.
- The **interoperability** as a key condition for effective use of data without compromising its security.

Guaranteeing sovereignty and security
The EHDS relies on robust safeguards and techniques, such as pseudonymization and anonymization, to protect sensitive information. In addition, compliance with European regulatory frameworks ensures that data remains under the control of member states, reinforcing digital sovereignty.

3. Raising Awareness Among the General Public and Stakeholders

Adapting communication channels
To reach a wide audience, it's crucial to simplify the technical discourse and use educational aids:

- **Explanatory videos** showing how the EHDS improves care and supports research, with concrete examples such as the treatment of rare forms of cancer.
- **Understandable diagrams** illustrating the steps involved in securing data and its use.

Reassurance about data security
Fear of cyber-attacks is a major barrier to adoption. It is imperative to communicate clearly about the security mechanisms adopted.

4. Involving Citizens and Healthcare Professionals

Citizen participation
The EHDS must include citizens in its governance to ensure that their concerns are taken into account. The **establishment of citizen committees** would:

- **Give a voice** to the end users of the data.
- **Multiply points of view** to enrich thinking and avoid blind spots.

Training healthcare professionals
Health professionals play a key role in raising patient awareness. They must be trained to:

- **Popularize the purposes of data use** with citizens, particularly on a European scale.
- **Integrate the issues** of transparency, if necessary consent and security, right from the data collection stage.

5. Mobilizing Political Decision-Makers and Researchers

Involving political decision-makers
Political leaders need to be made aware of the strategic benefits of the EHDS, particularly in terms of :

- **Research and innovation**, positioning Europe as a world leader.
- **Efficiency of healthcare systems**, with better use of available resources.

Acculturating researchers to interoperability
To maximize the impact of EEDS, researchers need to be supported in adopting common standards and interoperable practices, in order to take full advantage of harmonized databases.

Conclusion

Optimal capitalization on the EHDS relies on well-defined priority actions aligned with its objectives of transparency, inclusivity and efficiency. By **strengthening governance**, by **fostering partnerships** and by **mobilizing all stakeholders** - citizens, professionals, researchers and policymakers -, **Europe can create a pioneering framework for the use of health data**.

These initiatives must be accompanied by clear **communication, appropriate training and practical tools to overcome** technical, legal and cultural obstacles, particularly by taking into account the differences in people's approach to digital, which vary from one European country to another, especially in terms of the level of trust expressed. It is only by combining these efforts that the EHDS will be able to realize its ambition of transforming health data into a lever for innovation and progress at the service of all, particularly in France. We wish to widely disseminate these reflections and contribute to the spread of knowledge around the contributions of the EHDS, with the **will to continue working with all stakeholders** towards a common understanding and joint work.

Glossary

Acculturation: The process by which stakeholders acquire an understanding and acceptance of the issues and opportunities related to the use of health data, in this case.

Anonymization of data: The process of transforming personal data irreversibly so that it is no longer possible to directly or indirectly identify a person, even by combining the information with other data.

Data access contract: A formal agreement between a data requester and a data holder to regulate the use of data in accordance with legal and ethical rules.

Consortia: A temporary grouping of actors collaborating on a common project, often in the field of research or innovation.

Health data holders: Entities (hospitals, laboratories, industry players, insurers, administrations) responsible for collecting, storing, and managing health data.

Electronic medical record (EMR): A centralized digital system that allows for the secure collection, storage, and sharing of a patient’s medical information to improve care coordination and quality.

Right to opt-out: The right allowing a person to refuse or object to the use of their personal data, while ensuring that this opposition is respected by the concerned entity.

Sectoral data spaces defined by the European strategy: Dedicated environments for data sharing in specific domains (health, agriculture, energy) to promote innovation and collaboration within the European Union.

Legal fragmentation and national silos: The diversity of legal frameworks and practices across countries, which hinders the sharing and use of health data at the European level.

Data governance: The set of rules, practices, and processes ensuring the ethical, legal, and secure use of data.

Health data technical infrastructure: Systems, platforms, and technological tools required to collect, store, secure, and share health data.

Public interest: A collective objective aimed at improving general well-being, such as public health, medical research, or health security.

Interoperability: The ability of different systems or databases to exchange and use information consistently.

Pan-European: Refers to what pertains to all of Europe or encompasses all European countries, often from a perspective of political, cultural, or economic unity.

Stakeholders: All actors involved in a project or initiative (healthcare professionals, researchers, institutions, patients, businesses).

Pseudonymization of data: The process of transforming personal data so that a person can no longer be directly identified, while allowing re-identification under strict conditions.

Transposition of EU regulation provisions into national frameworks: The adaptation and integration of European regulations into national laws to ensure harmonized implementation in each Member State.

Primary and secondary use of health data:

- Primary Use : Direct use of data to treat a patient (diagnosis, treatment).
- Secondary Use : Use of data for purposes such as research, public health, or improving healthcare systems.

Methodology

The methodological process followed to produce this deliverable was structured in several key stages:

1. **Introduction**

An introduction was made to set the scene for the workshop and explain the objectives relating to the EHDS

2. **Presentation of the EHDS principles**

A presentation detailed the fundamentals of the EHDS, providing a common basis of understanding for participants before moving on to collaborative activities.

3. **Group work: creating messages and pedagogical tools**

Participants were divided into groups to design key messages and develop adapted pedagogical tools, with the aim of raising awareness and mobilizing different audiences around the EHDS.

4. **Group feedback**

Each group presented its proposals, enabling a constructive exchange and confrontation of ideas.

5. **Identification of priority actions to support the EHDS in France and make it an asset**

Collective reflection, based on the **1-2-4-All** method, was conducted using design thinking methods to prioritize the actions to be implemented.

This approach enabled us to:

- **Create a common basis of understanding**: The principles of the EHDS were clarified from the outset, guaranteeing a shared vision.
- **Unite participants around collective thinking**: Group work and plenary exchanges strengthened collaboration and the emergence of innovative ideas.
- **Identify concrete, achievable priorities**: The workshop resulted in clear, directly applicable recommendations to support the EHDS in France and Europe.

Nota Bene

This white paper reflects the reflections and discussions from a two-hour workshop, which naturally limits the depth and level of technical detail covered. While we have identified key points and strategic issues, further analysis and clarification would be required to address certain complex aspects. We encourage readers to bear this in mind when interpreting the information presented here, and to consider this document as a basis for further discussion.

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If you would like to contribute to the reflections of this report, participate in our upcoming workshops, share your opinion or be part of our next Summit, please contact :

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