



**MINISTÈRE  
DU TRAVAIL, DE LA SANTÉ,  
DES SOLIDARITÉS  
ET DES FAMILLES**

*Liberté  
Égalité  
Fraternité*

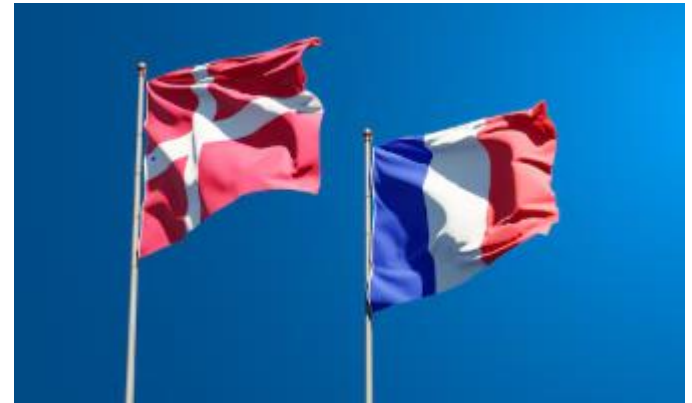
Délégation au numérique en santé

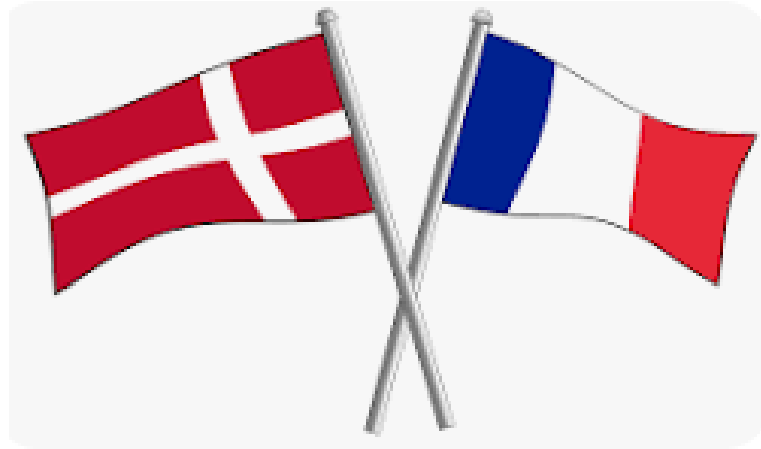
# **DIGITAL HEALTH & EHDS – PERSPECTIVES FROM FRANCE**

June 2<sup>nd</sup>, 2025

Digital Health Delegation (DNS)  
French Ministry of Health

**Louisa Stuwe**  
**Project Director**  
**Regulatory and European affairs unit**





**Tak for invitationen!  
Let us keep up our joint work in digital health between  
Denmark and France.**

# Overview

1. Who are we?

**The French Digital Health Delegation**

2. What do we do?

**France's digital health roadmap 2023-2027**

3. Health data

**National strategies**

**European Health Data Space (EHDS)**

# 1. Who are we?

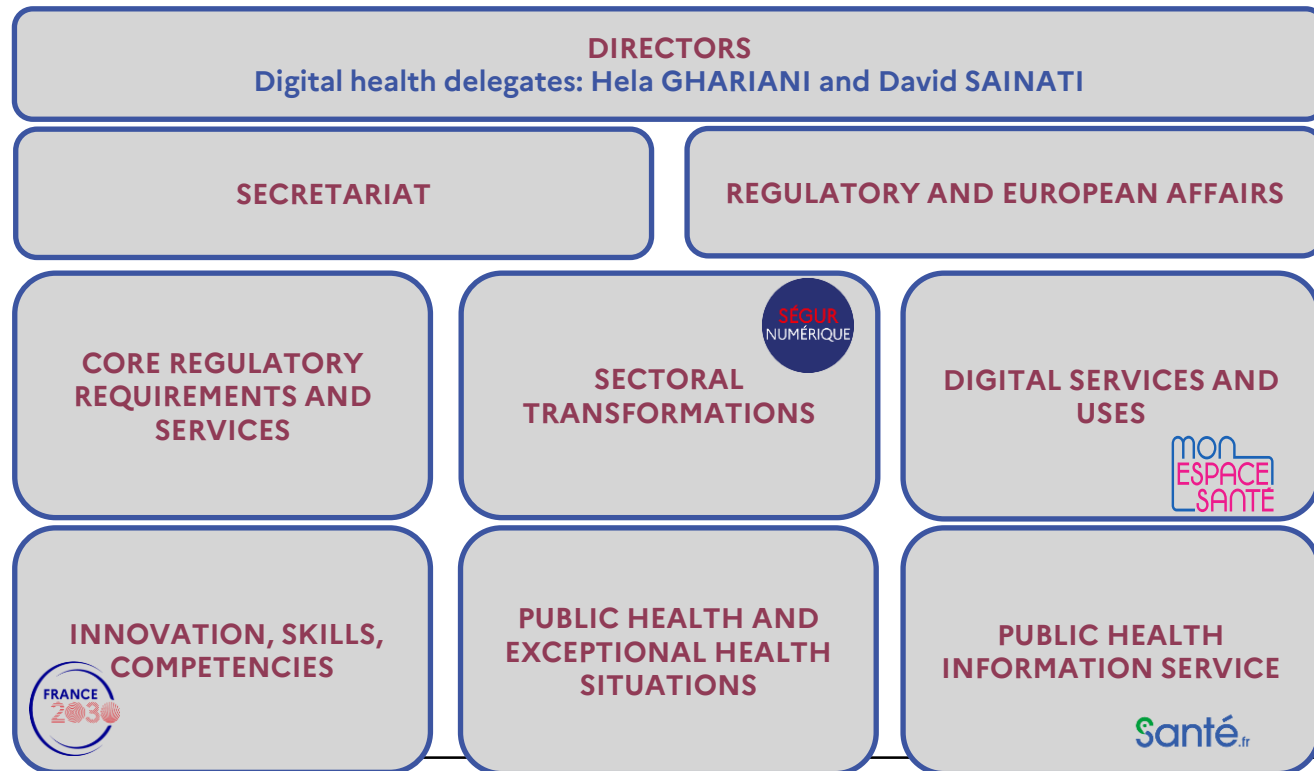
## The French Digital Health Delegation

# The French Digital Health Delegation (DNS)



**A team of 65 agents with a wide variety of profiles: engineers, healthcare professionals, researchers, designers, entrepreneurs...**

# Mission of the DNS : Digital health transformation, development and regulation in France.



- Officially created in December 2019
- A ministerial order published on May 15th, 2023



# Institutional actors around digital health in France



## Digital Health Delegation (DNS)

Oversees all **digital healthcare transformation projects** in France on the **national level**, based on three fundamental pillars: **ethics, security and interoperability**



Délégation au numérique en santé

## National Digital Health Agency (ANS)

The agency is **supervised by the DNS** and acts as its "operational arm". The ANS ensures the deployment and respect of **digital health standards and referentials**.



## National Health Insurance Fund (CNAM)

Defines the national **health insurance policy**. Its role is to monitor, coordinate and advise actions of primary health insurance funds (CPAMs) and the 5 general social security funds.



## Health Data Hub (HDH)

Unique gateway to facilitate **unified, transparent and secure access to health data** in order to improve the quality of care and support for patients.



## Health Innovation Agency (AIS)

The AIS has been created to steer interministerial work on innovation in healthcare and encourage the emergence, development and dissemination of these innovations.



AGENCE DE L'INNOVATION EN SANTÉ

## 15 Regional Support Groups for the Development of e-Health (GRaDeS)



Provides **digital health expertise for the regions** and support healthcare professionals in the digital transition of their profession.

## 18 Regional Health Agencies (ARS)

Provides **unified management** of health care in the regions



**Regional/ local actors:** hospitals, universities, healthcare professionals, actors of the digital health ecosystem

## 2. What do we do?

# France's Digital Health Roadmap 2023-2027





# Digital Health Roadmap 2023-2027

- 4 focus areas
- 18 priorities
- 65 objectives

# Digital Health Roadmap 2023-2027 :

4 focus areas, 18 priorities and 65 objectives

This roadmap is the result of several months of **consultation**, resulting from a **18-stage tour of French regions**.  
The roadmap is based on the values of **ethics, sovereignty** and **sustainability**.



## PREVENTION

Developing prevention and giving everyone an active role in their own health

5 priorities

20 objectives



## PATIENT CARE

Freeing up time for healthcare professionals and improving patient care thanks to digital technology

5 priorities

16 objectives



## ACCESS TO HEALTHCARE

Improving access to healthcare for people and the professionals who refer them

4 priorities

11 objectives



## SUPPORTIVE FRAMEWORK

Developing a framework that supports the development of solutions and digital innovation in healthcare

4 priorities

18 objectives



## Developing prevention and giving everyone an active role in their own healthcare



1. Using Mon espace santé in everyday life to manage your health
2. Developing personalised prevention
3. Giving everyone an active role in their healthcare and control of their health data
4. Helping all citizens to make use of digital health, especially those in the most vulnerable situations
5. Ensuring everyone benefits from digital health innovations



## Saving time for healthcare professionals and improving patient care thanks to digital technology



6. Enabling professionals to access the health history of the patients they treat
7. Improving the integration and ergonomics of core services in the tools that healthcare professionals use on a daily basis
8. Rolling out the services package for professionals, the e-prescription and secure identification means for healthcare professionals.
9. Simplifying the tools for local coordination of healthcare trajectories
10. Strengthening digital training and support for healthcare professionals, and medico-social care workers



## Improving access to healthcare for citizens and referring healthcare professionals



- 11.** Strengthening information for patients and professionals about health and healthcare provision across the territory
- 12.** Developing the use of telehealth within a regulated and ethical framework
- 13.** Promoting and interlinking digital platforms for medical regulation and emergency care
- 14.** Extensively promoting the Carte Vitale application and the national health identity (INS)



## Developing a framework that supports the use of digital health solutions and innovations



- 15.** Considerably improving cybersecurity in establishments, our sovereignty on hosting and our resilience to future health crises
- 16.** Generalising the co-construction of specifications framework, sector by sector, by ensuring the compliance of the solutions used by healthcare stakeholders.
- 17.** Attracting talents to the digital sector
- 18.** Developing digital health research and the secondary use of health data



All useful links  
are here!

Find out more about French digital health regulation and actors through G\_NIUS (FR/EN)



## Financing

Directory of public and  
European fundings

Get reimbursed:  
Telemonitoring,  
PECAN...



## Regulation

Everything you need  
to know about digital  
medical devices

Understand the  
regulatory  
requirements for your  
project



## E-health ecosystem

Who to contact?  
When?  
For what?

Deciphering e-health  
internationally



## National Programs

Discover the digital  
health roadmap

Understanding the  
Digital Health  
Acceleration Strategy



## Stay informed

Follow the news and  
participate in events

Listen to feedback  
from the ecosystem  
with our  
*100 Days to Succeed*  
podcast

Our partners:

# We are building a digital health system that is sovereign, civic and ethical by engaging citizens.

Public  
consultations

Biannual national digital  
health council

Citizen committees  
and conferences



A Citizen Committee played a key role in shaping France's stance on the EHDS Regulation. The committee, composed of 29 citizens from diverse backgrounds and regions, was convened over several weekends in 2024–2025 to deliberate on the challenges and opportunities presented by the EHDS. The Committee produced 52 recommendations aimed at strengthening citizen trust in digital health, enhancing transparency about data use, and ensuring patients have effective control over their health information.

# European Ethical Principles for Digital Health

These principles, adopted in January 2022 under the French Presidency of the EU Council, provide a human-centric framework to guide AI integration and data governance in healthcare.

These principles are structured around four core dimensions.

1. **Base Digital Health on humanistic values**
2. **Enable individuals to manage their Digital Health and data**
3. **Make Digital Health inclusive**
4. **Implement eco-responsible Digital Health**

Microsoft Word - 220128 European Ethical Principles for Digital Health\_FR\_ENG.docx



## PRINCIPES EUROPÉENS POUR L'ÉTHIQUE DU NUMÉRIQUE EN SANTÉ EUROPEAN ETHICAL PRINCIPLES FOR DIGITAL HEALTH

Inscrire le numérique en santé dans un cadre de valeurs humanistes Base Digital Health on humanistic values
1. Le numérique en santé complète et optimise les pratiques de santé en effectuant en priorité Digital Health complements and optimises best-practice healthcare
2. Les personnes sont informées des bénéfices et des limites du numérique en santé Individuals are informed about benefits and limits of Digital Health
3. Les personnes sont informées des modalités de fonctionnement des services numériques en santé et peuvent facilement paramétrer leurs interactions avec ces outils Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them
4. Lorsqu'une intelligence artificielle est mise en œuvre, le maximum a été fait pour qu'elle soit explicable et sans biais discriminatoire When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias
Donner le choix aux personnes sur le numérique et sur leurs données de santé Enable individuals to manage their Digital Health and data
5. Les personnes ont un rôle actif dans l'élaboration des cadres européens et nationaux du numérique et des données de santé Individuals are actively involved in shaping the European and national frameworks of Digital Health and data
6. Les personnes peuvent récupérer facilement et de manière fiable leurs données de santé dans un format couramment utilisé Individuals can easily and reliably retrieve their health data in a commonly used format
7. Les personnes peuvent facilement obtenir des informations sur la manière dont leurs données de santé ont été ou peuvent être consultées et dans quel but Individuals can easily get information on how their health data have been or may be accessed and for which purpose
8. Les personnes peuvent facilement et de manière fiable donner l'accès à leurs données de santé et exercer leurs droits, y compris leur droit d'opposition quand il est applicable Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable
Développer un numérique en santé inclusif Make Digital Health inclusive
9. Les services numériques en santé sont accessibles à tous, y compris à des personnes en situation de handicap ou avec un faible niveau de littératie Digital health services are accessible by all, including by people with disabilities or low levels of literacy
10. Les services du numérique en santé sont intuitifs et faciles à utiliser Digital health services are intuitive and easy to use
11. Les personnes ont accès à des formations sur le numérique en santé Individuals have access to Digital Health training
12. Les services numériques en santé proposent une assistance humaine lorsqu'elle est nécessaire Digital health services include support through human communication when needed
Mettre en œuvre un numérique en santé éco-responsable Implement eco-responsible Digital Health
13. Les impacts environnementaux du numérique en santé sont identifiés et mesurés Environmental impacts of Digital health are identified and measured
14. Les services numériques en santé sont développés dans le respect des bonnes pratiques d'éco-conception Digital health services are developed in compliance with eco-design best practices
15. La ré-utilisation et le recyclage des équipements informatiques en santé sont prévus Re-use and recycling of digital health equipment is ensured
16. Les acteurs du numérique en santé s'engagent à réduire leur empreinte écologique Digital health stakeholders are committed to reducing their ecological footprint

# 3. Health data

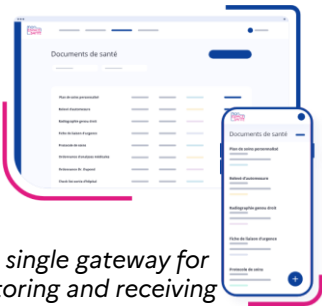
- National strategy
- European Health Data Space (EHDS)



# Mon Espace Santé

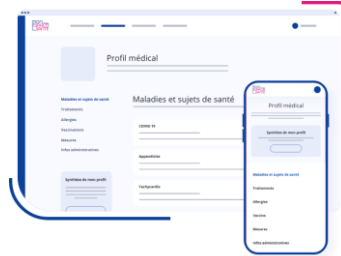
## A secure personal digital health record for all French residents

**A secure personal medical file (EHR) to find relevant health documents**



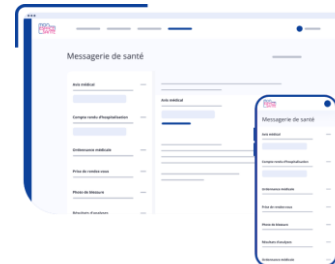
*A single gateway for storing and receiving medical documents (prescriptions, reports, etc.)*

**A medical profile to share all the relevant information with healthcare professionals**



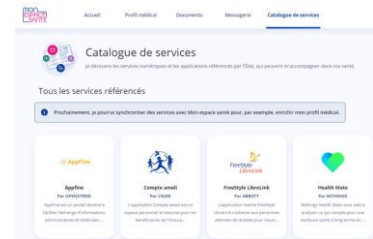
*A medical summary: treatments, allergies, other health measurements such as weight, height, etc.*

**Secure messaging to exchange with healthcare professionals**



*Talk to a professional. The opening of the contact channel is at the initiative of the professional.*

**A catalogue of applications for managing one's health using trusted websites and applications listed by the public authorities**



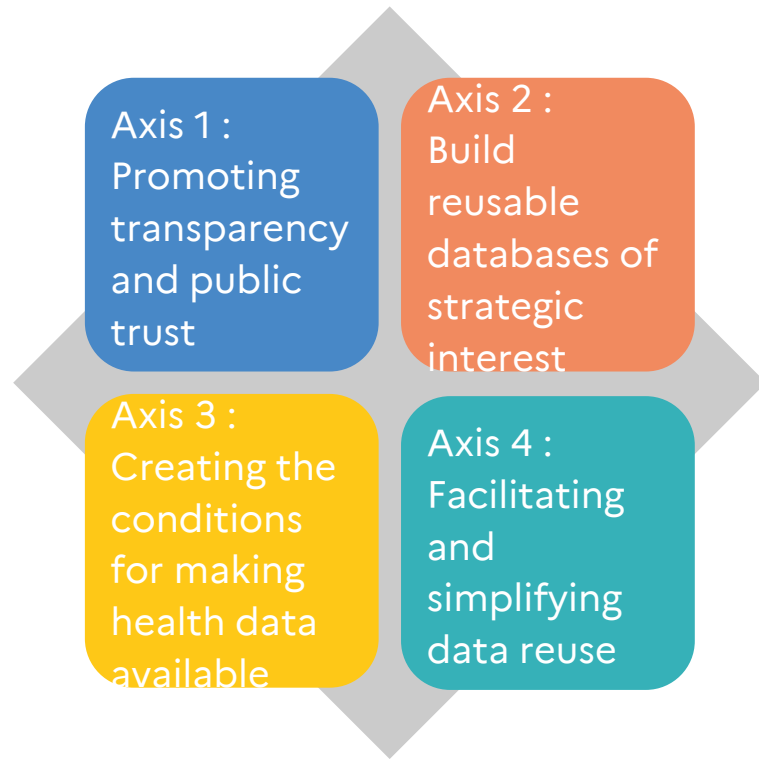
**Coming soon: a medical calendar to centralise appointments and receive reminders**



# National strategy on secondary use of health data



# Interministerial strategy for building our national health data heritage 2025–2028



## Axis 1: Promoting transparency and public trust

- Establish a legible and representative national governance
  - Simplify the exercise of rights and improving the information provided to citizens
  - Build a secure and trusted framework for reuse of health data
-

## Axis 2: Building reusable databases of strategic interest

- Enrich the heritage with databases of interest
- Anticipate the principle of data sharing by design
- Train the ecosystem in data reuse

## Axis 3: Creating the necessary conditions for making health data available

- Identify existing databases
- Build a balanced data-sharing model

## Axis 4: Facilitating and simplifying data reuse

- Simplify data access procedures
- Facilitate data availability

# A strategy for AI in Health in France

## Regulatory Context



Implementation of the **Artificial Intelligence Act** published in July 2024



## Political Context



Organization of the Summit for Action on AI in February 2025: The **French Minister of Health**, Dr. Neuder, reaffirmed the importance of AI in healthcare and announced the publication of the **State of art of AI in healthcare in France**

## Objectives



To **coordinate** at the national level and to **provide clarity** to stakeholders on our vision for AI in healthcare.

To **structure a document for an AI strategy in healthcare** to co-develop the **vision and health public policies** of the Ministry and national institutions.



# Publication: State of the art assessment of AI in health in France



## Artificial intelligence at the service of healthcare

### Overview of actions taken in the field of artificial Intelligence in health to accelerate innovation

*AI for health: accelerating innovation for a  
more efficient, humane and accessible healthcare system*

February 2025

### SUMMARY

The 4 axes of the 2023-2027 digital health roadmap lay the foundations for the dissemination of artificial intelligence in health, which is rooted in stable cardinal values: ethics, sovereignty, sustainability.

Actions dedicated to AI in health have already been implemented in each of these areas.



### PREVENTION.....p.6

Developing prevention and making everyone an actor in their health with AI systems



### CARE MANAGEMENT.....p.9

Giving back time to health professionals and improving the care of people with the support of AI



### ACCESS TO HEALTHCARE.....p.13

Improving access to health for people and the professionals who guide them, by integrating AI tools into pathways



### ENABLING FRAMEWORK.....p.16

Deploy a framework conducive to the development of AI uses in health and build a sustainable economic model for AI in health based on efficiency gains

Conclusion and perspectives.....p.23



### PREVENTION

Developing prevention and making everyone an actor in their health with AI systems

*Artificial intelligence plays a key role in transforming the health paradigm with a focus on prevention and citizen engagement. AI technologies can personalize health recommendations, anticipate risks, and improve health education. Digital tools incorporating AI make it possible to adapt prevention messages to the specific needs of each individual, based on available health data. This paves the way for a more proactive approach, aiming to identify risks upstream and propose targeted actions to improve overall well-being.*

#### AI 1-1 Support for the development of Innovations embedding artificial Intelligence for preventive and participatory health

Support for the dissemination of AI uses in health is based on the "Digital Health" (SASN) acceleration strategy of France 2030, which has invested €500 million to date, 50% of which is dedicated to AI-based projects such as:

DEEP Project Société Withings	Consortium PortraIT Tribun Health Company	@Hôtel-God Platform APHF, Withings, Lifan, Nabla, Implicity, MN Santé
<b>Objective:</b> To create new connected medical devices, augmented by artificial intelligence, to enable early detection of cardio-metabolic pathologies and have a significant impact on screening and care pathways.	<b>Objective:</b> To develop AI-based image analysis tools to help pathologists in their diagnosis and better guide clinicians in their therapeutic decision.	<b>Objective:</b> To develop a digital solution for remote polypathological monitoring, born from the collaboration of public and private experts in e-health. It integrates a platform to generate exhaustive data with connected devices, including AI (blood pressure monitors, connected scales, sleep sensors, temporal thermometer and connected watches). This data will be uploaded to the platform for patient monitoring. This project is also revolutionizing clinical research thanks to AI and its hospital network. Its SaaS platform generates high-quality, real-time databases to understand diseases, accelerate therapeutic innovation, and accelerate precision and preventive medicine.

## Publication: State of the art assessment of AI in health in France

1

**Benefits/  
Risks**

1

- ✓ Actions to assess the benefits and risks for patients and healthcare professionals.



2

**Support for  
Innovation**

2

- ✓ Actions implemented to support innovation in projects integrating AI, particularly within the framework of France 2030 investments and the “Digital Health” acceleration strategy (SASN).

3

**Enabling  
Framework**

3

- ✓ An evaluation, regulation, and ethical principles framework to ensure trustworthy and secure AI, adapted to the requirements of the healthcare sector.

**Objective: Develop sovereign, competitive, and trustworthy AI in Healthcare**

## European health data space (EHDS) Regulation



## French national strategy on secondary use of health data



# European Health Data Space in a nutshell

**March 5th 2025** : Publication in the OJEU

**March 25th 2025** : Entry into force



Enhancing individuals' access to and control over their personal electronic health data



Harmonize rules for sharing health data



Foster a single market for electronic health record systems



Creating a harmonized European framework for the reuse of health data



Establish a strengthened European framework for digital health governance

# Context of the European Health Data Space (EHDS)

The European Data Strategy is part of the Digital Decade for Europe, which aims to:

- Strengthen digital sovereignty and set standards for data, technology and infrastructure;
- Responding to the challenges of protection of people, economic development and geopolitics;
- Empowering businesses and citizens to act in a humanistic, sustainable and prosperous digital future.

The European data strategy aims to create a single market for data

- Data flows within the EU and across sectors
- Compliance with European rules on privacy, data protection and competition law
- the fairness and clarity of the rules for access and use of data.

## General Regulations

Data Governance Act (DGA) 2022

Data Act (DA) 2023

Artificial Intelligence Act (AIA) 2024

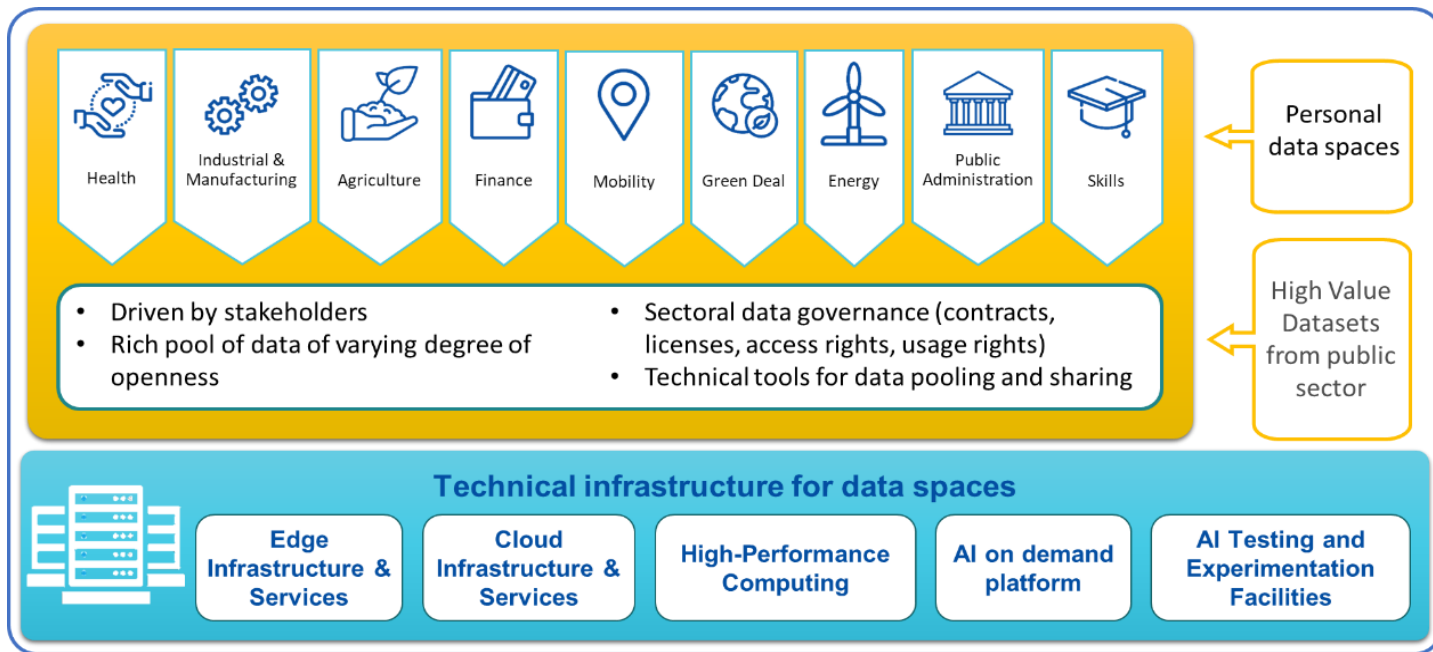
## Sectorial regulations

Sectorial data spaces

EHDS is the first



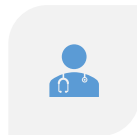
# The EHDS is the first sectorial data space



# Cross-border data sharing already a reality in many EU Member States via MyHealth@EU



## European Health Data Space



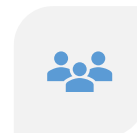
Allow sharing of health data for primary use, with strengthened rights for persons



A Single Market for Electronic Health Record (EHR)



Harmonization of Secondary use of electronic Health data



Governance

# Primary use

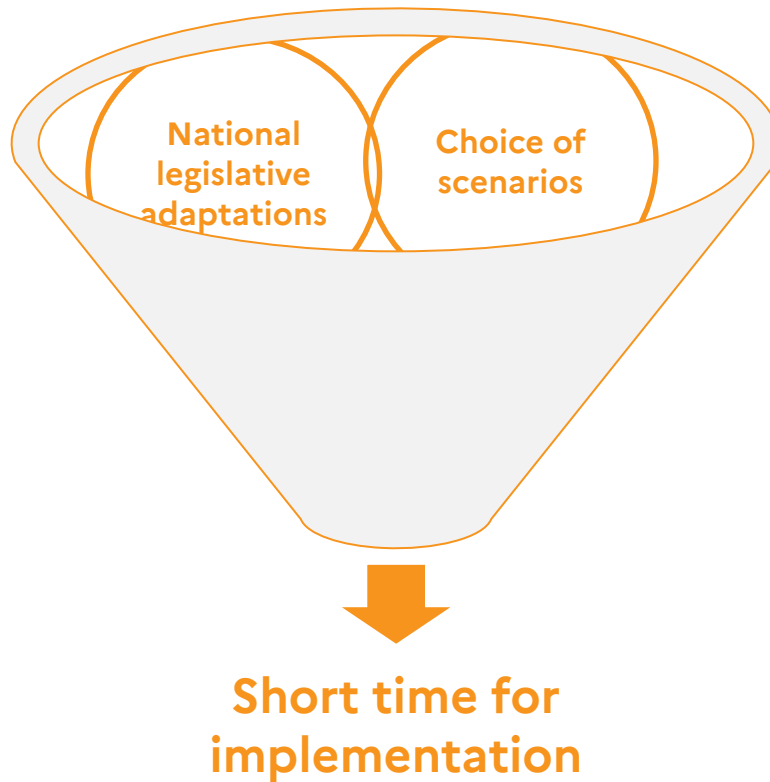


# Primary use





# National work to implement EHDS



# Internal working groups on EHDS

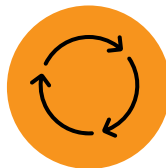
Preparation of position papers on all major topics of the regulation where there is room for manoeuvre for Member States.

Position paper organized into 3 themes, describing the **issue, planned scenarios and their impacts, as well as suggested solutions**



## Primary use

- Mon espace santé (MES) to become the data access service for citizens and healthcare professionals / establishments
- Share priority data categories in the European interoperability format
- Full connection to MyHealth@EU
- CE marking for medical record software



## Secondary use

- Individual rights
- Modalities for secondary use – Governance and balanced model
- Ethical evaluation



## Governance

- Designation of digital health authority/Market surveillance authority
- Designation of HDAB
- National contact points (MyHealth@EU and HealthData@EU)
- Data security
- Penalties

# The road to national implementation

Subgroups for the first circle

**March 19th 2025**

Public webinar on  
EHDS

**Mid-April**

Presentation of thematic  
conclusions to first  
consultation circle

**May**

3 work groups with the  
second circle  
(1 par topic)

**End of May**

Summarizing  
findings from both  
circles

**Early June**

Feedback meeting  
with first circle

**Mid-June**

Deciding on scenarios,  
working group as part  
of the Digital Health  
Council

**June 24th 2025**

**National Digital  
Health Council**  
Public presentation

**Solid  
input  
for law**

# Communication around the EHDS

Ministry of  
Health  
website

All **updates on the regulation**  
and national consultations  
([Link](#))

Citizen  
committee

**52 recommendations on the  
EHDS implementation**  
formulated by 30 citizens  
representative of the French  
population ([Link](#))

LinkedIn

**12 videos** to explain the  
regulation and national  
impacts ([Account link](#))

## Events and conferences linked to the EHDS

The Digital Health Delegation is actively participating  
in national and EU conferences



#SANTEXPO



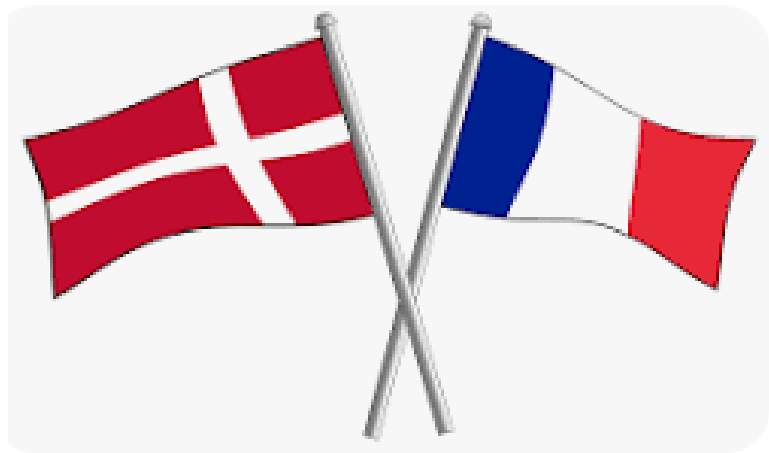
**SAVE THE DATE**

**Conference on national  
EHDS implementation**

Organized by DNS

September 30th, 2025

# Time for discussion





# MINISTÈRE DU TRAVAIL, DE LA SANTÉ, DES SOLIDARITÉS ET DES FAMILLES

*Liberté  
Égalité  
Fraternité*

Délégation au numérique en santé