



**MINISTÈRE
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DE L'AUTONOMIE
ET DES PERSONNES HANDICAPÉES**

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The French Perspective on the EHDS

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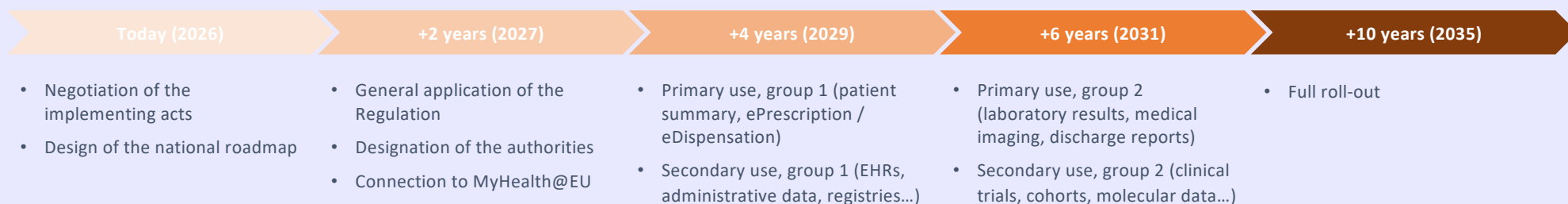
Heidelberg, 6 October 2026



Introduction: the time to act is now



Key milestones following the publication of the Regulation in 2025



A long and demanding journey ahead of us...

...on top of a national digital health roadmap that is already very ambitious and heavily mobilises our teams



Wave 2



Building on existing assets



Primary use

A national infrastructure already deployed

- Mon espace santé (the French equivalent of the ePA) and the DMP shared record, backed by national core services: health identifier, secure messaging, Pro Santé Connect
- The Ségur digital health programme (waves 1 and 2): structured documents and systematic DMP feeding, already anticipating much of the Regulation
- A nationwide ePrescription system securing the prescriber–pharmacy circuit
- Ongoing programmes on hospital IT modernisation, cybersecurity and resilience of care providers, and simple, secure authentication of professionals



Secondary use

A long-standing health data ecosystem

- The SNDS, the national health data system covering almost the entire population
- The Health Data Hub (Plateforme des données de santé)
- Hospital clinical data warehouses, research cohorts and registries
- CNIL reference frameworks enabling simplified access procedures

The EHDS extends a national dynamic that is already under way: it does not create one from scratch.

A wide range of national stakeholders on board



Ministries


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DGRINES, DGOS,
DSS, DGS, DREES


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DGRI


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DGE


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Agencies / Operators

 **AGENCE
DU NUMÉRIQUE
EN SANTÉ**
La transformation commence ici

 **ansm**
Agence nationale de sécurité du médicament
et des produits de santé

 **PLATEFORME
DES DONNÉES
DE SANTÉ**
FRENCH HEALTH DATA HUB

 **CNIL**
COMMISSION NATIONALE
INFORMATIQUE & LIBERTÉS

 **l'Assurance
Maladie**
Agir ensemble, protéger chacun



One programme, structured workstreams



EHDS Programme Directorate

Consolidated roadmap, steering of all workstreams, committee structure, strategic oversight and cross-cutting expertise

CROSS-CUTTING WORKSTREAMS

5

Funding

Budget impact of the Regulation, EU funding

6

Communication

Communication plan

1

Legislative reform

- National room for manoeuvre
- Draft bill (PJL DDADUE) and impact assessment
- Interministerial coordination and mandatory consultations
- Parliamentary follow-up and secondary legislation

2

EU governance & regulation

- Consolidated French position on implementing acts
- Participation in EU governance and Commission cooperation networks
- French input to EU joint actions: Xt-EHR (primary use), TEHDAS 2 (secondary use)

3

Preparing for data sharing (BUILD)

- Operational implementation strategy and support to field actors
- Data security and sovereignty
- Adapting Mon espace santé and the DMP
- Connecting to MyHealth@EU and HealthData@EU
- Citizen transparency and trust
- Building reusable datasets of interest and preparing compliance processes

4

National EHDS governance

- Setting up the Digital Health Authority and the Market Surveillance Authority
- Setting up the Health Data Access Bodies
- Co-chairing the national health data steering committee

A programme driven by active communities



National steering

National Coordination Committee

Fortnightly committee of the main national authorities involved

Quarterly EHDS Committee

Public, online and open to all stakeholders

Annual event

The EHDS Day, gathering the whole ecosystem



Co-construction with the ecosystem

12

Digital Health Council working groups

Stakeholders commit staff to explore topics upstream

Examples of topics

Security requirements

Assessing access requests

Interoperability, standardisation & quality

Funding, partnerships & contracting

EHDS governance & roles

Citizen awareness & exercise of rights

Major issues justifying data sharing

Calculating fixed costs for fees

National implementation framework

Public reference document in two volumes: primary use and secondary use

Citizens' committee (2024)

29

citizens

52

recommendations

A national implementation framework



Purpose: give all stakeholders an evolving view of how the Regulation will be implemented in France, for primary and secondary use, distinguishing what is settled from what still needs to be clarified.

Who it is for



Citizens and patient representatives



Health professionals and care providers



Public administrations, authorities and operators



Software vendors, EHR manufacturers and digital health industry



Actors in national and cross-border data exchange

Each section answers four questions

	EU level	France
Already settled	1 What does the Regulation require?	3 How will France implement it?
Still open	2 What is still to be specified at EU level?	4 What is still to be decided in France?

The institutional set-up (to be officially designated by March 2027)



PRIMARY USE

Digital Health Authority



Ministry of Health
 Coordination missions



ANS (Digital Health Agency)
 Pivot for implementing Chapter II of the
 Regulation



ANS
 Market surveillance of EHR systems, with ANSM
 (medicines agency) and DGCCRF (consumer
 protection) within their remits

SECONDARY USE

Three Health Data Access Bodies (HDABs)



Coordinator
Ministry of Health
 Regulation and coordination



Single entry point
Health Data Hub
 Pivot for making data available



Data protection
CNIL
 Guarantor of the protection of personal health
 data

Our objectives



Primary use



Make Mon espace santé **(the French equivalent of the ePA)** the electronic health data access service under the Regulation, for citizens and health professionals, and the pivot of cross-border care



Support industry towards compliance, combining EU and national requirements smoothly



Secondary use



A single entry point, operated by the Health Data Hub



Keep the existing simplified access procedures (reference frameworks)



A high level of protection to build trust for all: data holders, data users and citizens

Primary use: key challenges



1

A centralised architecture

Mon espace santé and the DMP carry the new rights on behalf of care providers and health professionals

2

Transition to the EEHRxF

Moving to HL7 FHIR while CDA documents coexist: migration paths without a "big bang"

3

A two-tier compliance landscape

EU self-certification of EHR systems combined with national prior verification

4

MyHealth@EU

National contact point live since 2019, cross-border use cases scaling up

...while continuing to improve our services in depth



AI features in Mon espace santé



New prevention features



Preparing data availability for secondary use



Leaving room for industry to keep innovating



Monitoring and developing uptake by care providers and health professionals

Secondary use: key challenges



A paradigm shift

- Making data available becomes mandatory for data holders (Art. 60(1))
- Hospital clinical data warehouses are directly concerned



Simplicity

- Simplified reference frameworks remain the norm
- The existing single entry point is strengthened, no new body
- Permanent SNDS access is maintained



Trust & sovereignty

- Hosting in the EU, without using the Art. 87(2) exception
- Secure processing environments
- Right to opt out (Art. 71) and a transparency portal run by the Health Data Hub



Quality & discoverability

- National dataset catalogue
- Data quality and utility label (Art. 78)
- OMOP-CDM work



A balanced model for data holders

- Fees to compensate data preparation
- Protection of IP and trade secrets
- Option to become a trusted data holder

For researchers:

one entry point, familiar procedures, and better-documented, more discoverable data across Europe

Conclusion: we will have succeeded if we...



make Mon espace santé the EHR access service within the meaning of the Regulation, for citizens and health professionals, and the pivot of cross-border care



support industry in meeting the Regulation's technical requirements, combined seamlessly with national requirements



simplify and speed up access to health data for secondary use, with effective governance



establish a framework of trust for data holders, data users and citizens



Thank you!
Vielen Dank!

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French Ministry of Health

