



MINISTÈRE
DU TRAVAIL, DE LA SANTÉ,
DES SOLIDARITÉS
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Délégation au numérique en santé

EUROPEAN HEALTH DATA SPACE – PERSPECTIVES FROM FRANCE

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- 1. Context and Key Challenges**
 - 2. Primary Use of Health Data**
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The French Digital Health Delegation (DNS)



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

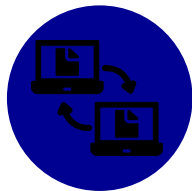
1. Context and Key Challenges

The EHDS Regulation: Creates common rules, standards, infrastructures and a governance framework to facilitate access and exchange of data in the future European Health Data Space

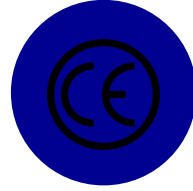
- Fragmentation of health data in Europe
- Need for trust, security and interoperability
- Balancing innovation with citizen's rights



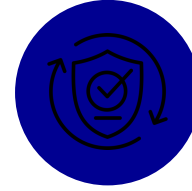
Enhancing individuals' access to and control over their personal electronic health data



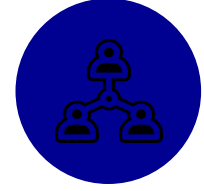
Harmonize rules for sharing health data



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

Impact on Key Actors



Citizens

- **Reinforced rights** (in particular opt out)
- Improved **transparency**
- Improved **health care provision** through **innovation and research** as a result of secondary use of health data



Data holders

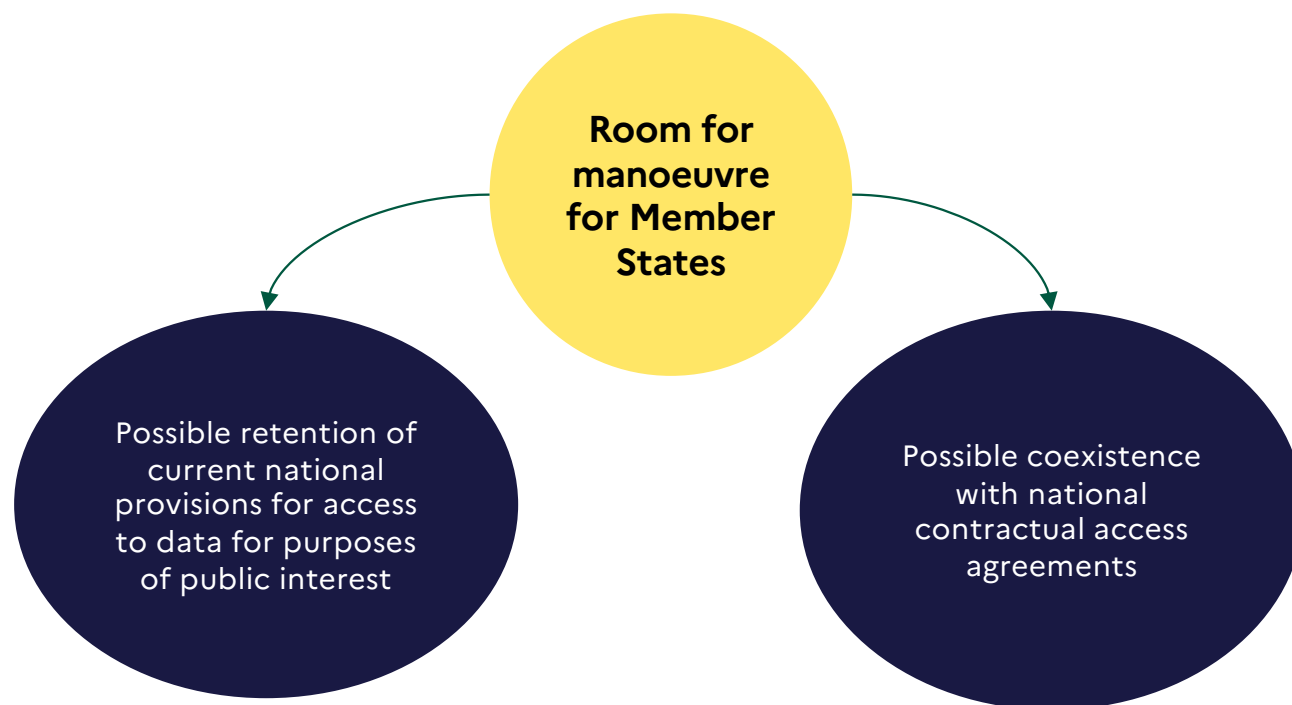
- **Obligation to make data available for reuse**
- **Compensation for making data available:** collection of fees and protection of intellectual property rights and trade secrets
- Contribute to the **national metadata catalogue**



Data users

- Knowledge of **available data sources**
- Request **data access via harmonised gateway** (co-existence of national mechanisms)

A coexistence of national frameworks allowed by the regulation



Example :

- Permanent access to the National Health Data System (SNDS)
- Simplified authorisations if compliant with reference methodologies

2. Primary Use of Health Data

What is primary use of health data?

The processing of electronic health data for the provision of health services aimed:

- To assess, maintain or restore the state of health of a natural person to whom those data relate
- Including the prescription, dispensation and supply of medicines and medical services
- And the use of social security, administrative or reimbursement services

Sharing infrastructure at the European level: **MyHealth@EU**

In France: **MonEspaceSanté**



Empowering citizens & enabling cross-border care

- **Citizen's Rights** (art. 3 – 10 EHDS)
 - Right to access, right to object to access, right to insert, right of rectification, right to data portability and right to restrict access.
- **Cross Border Exchange – MyHealth@EU** (art. 23 – 24 EHDS)
 - Secure sharing of personal electronic health data between National Contact Points
 - Continuity of care across EU countries
- **Interoperability and CE Marking** (art. 30 – 41 EHDS)
 - EU standards for EHR systems

3. Secondary Use of Health Data

Reuse of health data for purposes other than individual care, such as research, innovation, public health, or policy-making.

Article 51(1) EHDS: Minimum categories of electronic health data for secondary use

- ❖ Electronic health data from EHRs;
- ❖ Data on factors impacting on health, including socio-economic, environmental and behavioural determinants of health;
- ❖ Aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- ❖ Pathogen data, impacting on human health;
- ❖ Healthcare-related administrative data, including dispensation, claims and reimbursement data;
- ❖ Human genetic, epigenomic and genomic data;
- ❖ Other human molecular data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;
- ❖ Automatically generated personal electronic health data, through medical devices
- ❖ Data from wellness applications;
- ❖ Data on professional status, specialisation and institution of health professionals involved in the treatment of a natural person;
- ❖ Population-based health data registries (public health registries);
- ❖ Data from clinical trials, clinical studies and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively
- ❖ Other health data from medical devices
- ❖ Data from registries for medicinal products and medical devices;
- ❖ Data from research cohorts, questionnaires and surveys related to health, after the first publication of results;
- ❖ Health data from biobanks and associated databases.

Purposes for which electronic health data can be processed for secondary use

Article 53: Allowed

- Public interest in the area of public and occupational health,
- Policy making and regulatory activities in the health or care sector,
- Statistics related to health or healthcare sectors
- Education or teaching activities in health or care sectors
- Scientific research related to health or care sectors,
- Improving delivery of care, treatment optimization and providing healthcare,

Article 54: Prohibited

- Taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data;
- Taking decisions in relation to a natural person or groups of natural persons in relation to job offers or offering less favourable terms in the provision of goods or services ;
- Advertising or marketing activities ;
- Developing products or services that may harm individuals, public health or societies ;
- Activities in conflict with ethical provisions pursuant to national law

Duties of Data Holders (Article 60 EHDS)

- Make electronic health data available under **Article 51(1) upon request to the HDAB**
- Communicate to the HDAB a description of the dataset it holds
- Provide sufficient documentation to the HDAB to confirm the accuracy of the data quality and utility label
- Obligation to cooperate with the HDAB with its tasks

Guaranties for Data Holders

Article 62

FEES

For the HDAB

Fees for making electronic health data available for secondary use:

- cover all or part of costs related to the procedure for assessing a data access application or a data request,
- costs related to the consolidation, preparation, anonymisation, pseudonymisation, and provisioning of the electronic health data

For data holders

Cover costs incurred for **compiling** and **preparing** the electronic health data to be made available for secondary use.

Article 52 : intellectual property rights and trade secrets

Electronic health data protected by intellectual property rights, trade secrets or covered by the regulatory data protection right [...] shall be made available for secondary use in accordance with the rules laid down in this Regulation.

Duties of Data Users (Article 61 EHDS)

Health data users may access and process electronic health data for secondary use only under a valid permit or approval, and must respect strict privacy and transparency obligations.

Key Duties:

- **Data protection & confidentiality:** Must not share data with unauthorized third parties or attempt to re-identify individuals.
- **Transparency & reporting:** Must publish results of secondary use (anonymized) within 18 months and inform health data access bodies.
- **Cooperation & acknowledgment:** Must assist access bodies, acknowledge data sources, and report significant findings affecting individuals' health.

New Key Actors



Health Data Access Body (HDAB)

Key missions :

- **Assess health data application** and deliver data permit if conditions are met
- **Provide secure access to** datasets for authorised users
- **Provide information** to citizens and stakeholders, including dataset catalogue
- **Manage** fees
- **Control and penalize** abuses in accordance with regulations

Requirements :

- Provide a secure processing environment
- Offer an infrastructure capable of processing cross-border requests via HealthData@EU
- Protect against the risk of conflicts of interest



Other relevant actors

Trusted data holders

Key missions :

- **Support HDAB** in the provision of health data

Data intermediation entities

Key missions :

- **Accompagner le** détenteur de données pour la mise à disposition des données
- **Supporting data holders** in making data available

Health Data Access

 Data User

 HDAB

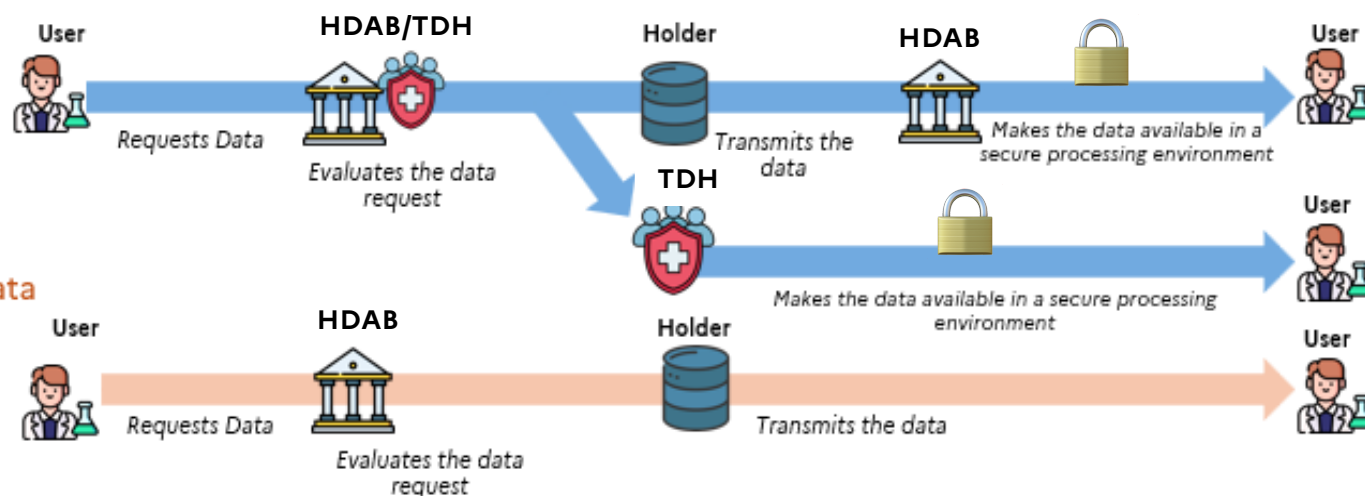
 TDH

 Data Holder

 Secure Processing Environment

 Secure Processing Environment

Access Request
 Pseudonymised data
 8 months



Article 55(2) EHDS: “Where an assessment by **ethics bodies** is required under national law, those bodies shall make expertise available to the health data access body. As an alternative, Member States may provide for **ethics bodies** to form part of the health data access body.”

Article 57(2)b: HDABs shall “cooperate with all relevant stakeholders, including [...] ethics committees, where applicable in accordance with Union or national law”

Right to Opt Out from Secondary Use (Art. 71 EHDS)

Natural persons have the right to opt out at any time from the processing of their personal electronic health data for secondary use. This right is **reversible** and must be implemented through an **accessible and clear mechanism**.

Key Points:

- **Exclusion from processing:** Data of individuals who opt out cannot be accessed or processed in new secondary use projects.
- **Reversibility & exceptions:** Opt-out can be reversed; in exceptional cases, public sector or public health research may access data if justified and necessary.
 - **Exception allowed by national law:** Member States may permit access to data to public authority even when individuals opted out for essential public health purposes or scientific research in the public interest, when no alternative data is available.
 - **Strict safeguards required:** Such mechanisms must protect fundamental rights, be necessary and proportionate, prohibit re-identification, and include specific legal safeguards for personal data protection, with Member States notifying the Commission of these rules.

4. Transversal Issues

ARTICLES 86 AND 87 EHDS



Storage of electronic health data

Possibility for Member States to require the storage of electronic health data within the EU for the purpose of primary use

Requirement for HDAB to store and process electronic health data in the EU (secondary use)

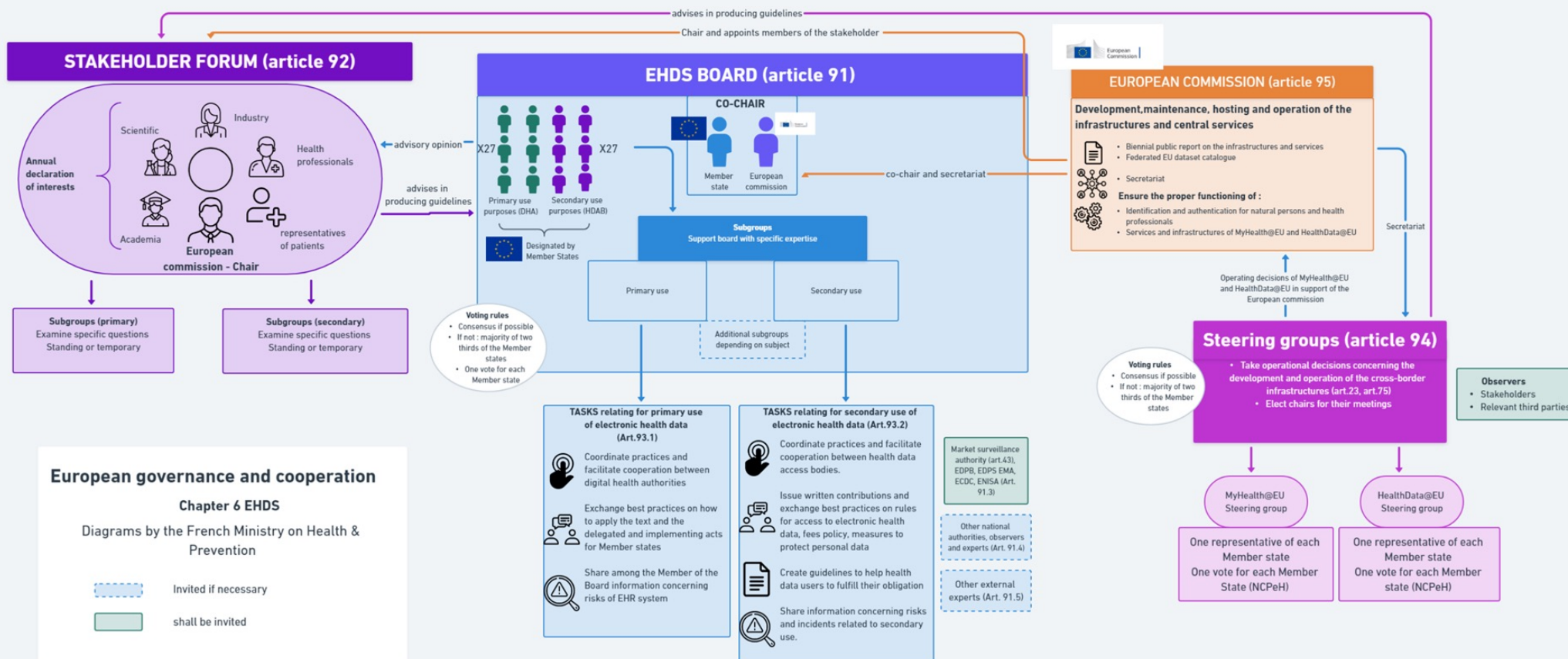
Exchanges, transfers and remote access to electronic health data remain possible, provided that they comply with the RGPD.

Exception: Possibility of storing and processing data **on the territory of a third country covered by an adequacy decision**, pursuant to Article 45 of the GDPR

Consultation

Strategical decisions

Operational infrastructure



Capacity Building, Training & Digital Literacy

Article 82 – Capacity Building:

- **Strengthening digital health systems:** The Commission supports sharing best practices and self-assessment tools for primary and secondary use of health data.

Article 83 – Training Programmes and information for Health Professionals:

- Member States shall **provide training & information for health professionals** to understand and effectively manage primary use and access to electronic health data.
- The Commission shall support Member States in that regard.

Article 84 – Digital Health Literacy for Patients:

- Promote digital health literacy and awareness of EHDS rights, benefits, risks, and opportunities.

5. Timeline of Implementation

March 25th 2025 : Entry into force

March 25th 2027 :

- Designation of the digital health authority by Member States
- Designation of the market surveillance authority by the MS
- Designation of the health data access body(ies) by MS.

Next entry into application in 2029

- Entry into application of the main provisions provided in Chapter IV regarding secondary use of data.

Following entries into application in 2031 and 2035

The implementation of the EHDS requires adjustments to French legal frameworks. Work on these adaptations is currently ongoing.



Time for discussion



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