GOUVERNEMENT

Liberté
Égalité
Fraternité

The French National Strategy for Artificial Intelligence and Health Data

LA E-SANTÉ FRANÇAISE

SUMMARY

EDITORIAL BY THE MINISTER

The development of artificial intelligence (AI) in the field of health holds important promises on saving time for professionals, efficiency and improving patient care. To develop appropriate and relevant AI solutions, we have a crucial need for simplified access to quality health data.

Accurate and complete data are essential to train AI models capable of providing reliable diagnoses, personalised treatment recommendations or automated aids for the analysis of clinical outcomes. Data quality directly influences the performance and safety of AI systems, reducing the risk of errors with potentially serious consequences for patients. By minimizing algorithmic bias, it ensures fairer and more efficient AI for all. Training these algorithms on French and European health data also means choosing medical relevance and sovereignty.

AI and health data: synergies and new requirements

A national strategy for AI in health cannot be credible without an ambitious vision for health data. That is why we have chosen to develop a unified strategy, fully articulating the two strands.

France has an exceptional wealth of health data, as a result of world-renowned construction and expertise. The European Health Data Space Regulation (EHDS) calls on us to remove the barriers that still prevent the full mobilisation of this data for research, innovation and public policy tools. It also commits us to strengthen our strategic autonomy across Europe so that the future of our health systems is based on sovereign solutions and innovations, built on data representative of our societies.

With the HDH, we are making every effort to ensure that a copy of the main database of the National Health Data System (SNDS) can serve as the first projects from the summer of 2026 thanks to a so-called 'interlayer' hosting solution, in order to remove as quickly as possible the obstacles preventing it from being fully mobilised so far, in parallel with the rise in the cloud offer accompanied by the ministers responsible for the Economy and Digital Affairs.

Finally, to provide targeted support for the most promising uses of AI in health, we have identified several priority use cases that are open to consultation. This will feed concrete feedback from the ground into public action.

Our health system is on the verge of a profound transformation. To take full advantage of these new opportunities, our strategy is ambitious, pragmatic, and collective. Only then can data and AI become real levers for progress at the service of everyone's health.

Yannick NEUDER,
French Minister of Health
and Access to Care

INTRODUCTION

France spearheading the structuring and leveraging of health data

Health data plays a vital role in research and innovation, in evaluating public policies, and in guiding the healthcare system. With the rapid rise of artificial intelligence, France's vast health data resources have become an increasingly vital strategic asset.

In France, the provision of health data has been regulated for more than forty years to guarantee the protection of personal data. The Data Protection Act[1] provides a protective framework for the use of personal health data. This legal regime is now provided by the National Data protection agency (CNIL) and the Ethics and Scientific Committee for Research, Studies, and Evaluations in the Health Sector (Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé - CESREES),[2] whose secretariat is provided for by the Health Data Hub. In 2019, the Health Data Hub was set up to facilitate the provision of health data to those carrying out projects of public interest.

The construction of health databases of national interest has accelerated[3] in recent years with significant investments in the context of France 2030 (approximately €110 million), particularly on:

- The 2022 call for projects, "Support for the development of hospital health data warehouses," provided backing to 16 consortia, comprising in particular 31 university and regional hospitals (CHU/CHR), as well as public and private healthcare centers **France Cohortes**, the platform to support health research cohorts, from implementation to data sharing;

- The **FReSH** (France Human Health Research) portal, which has been tasked with identifying health research studies since 2021;

- The 'Digital Health' call for expressions of interest launched in 2021, which notably accompanied the **P4DP** project to build a warehouse for health data from city medicine;

These investments demonstrate the desire to position France as a true leader in health research and innovation.

(1) Law No. 78-17 of 6 January 1978 relating to data processing, files and freedoms (LIL)
(2) For the processing operations referred to in Article 72 of the LIL
(3) As part of the 'Digital Health' acceleration strategy of the France 2030 plan and ONDAM

An inter-ministerial strategy to give the main orientations for the coming years

Health databases are part of our national intangible heritage. They are created by our health system as well as by health studies and research, and are individually and collectively a unique source of incredible wealth to improve knowledge and inform decision-makers provided they organise, expand, protect and share it.

Today's strategy aims to continue and amplify this momentum by collectively preparing for the entry into force of the European Health Data Space (EHDS) Regulation. This regulation is a real pillar for Europe's strategic autonomy in the health sector. In France, it is an incredible opportunity to switch to a world where data is reusable by default and finally remove the obstacles to the valorisation of our intangible heritage while always respecting our ethical values.

This strategy, built with the ministries in charge of health, research and the economy, in collaboration with the National Health Insurance Fund (Caisse Nationale d'Insurance Maladie - CNAM)., the Health Data Hub (HDH) and relevant agencies, builds on the work of the Strategic Health Data Committee of the SNDS and the recommendations of the report 'Federating ecosystem stakeholders to unlock secondary use of health data' published in 2024. It sets out a coherent and ambitious national trajectory to foster the secondary use of health data and the implementation of new health databases.

This trajectory has been coordinated with all relevant stakeholders (data holders and users, users and professionals in the health system, public authorities and industyl actors, etc.). More than 300 pieces of feedback were received and analysed to take into account the experience and expectations of health data actors, producers and users.

Because data subjects and AI are now inseparable, this strategy will soon be supplemented by a section dedicated to the development of artificial intelligence in health. Indeed, the emergence of AI models adapted to our health system will have to rely on our data heritage and if uses emerge, there are many projects to accelerate and frame the relevant uses of AI.

This strategy reflects the shared work carried out with public stakeholders and relevant stakeholders (health, research, industry, innovation), in a spirit of consultation, coherence and collective ambition.

A European regulation with a major impact on the French health data space within four years

The European Health Data Space (EHDS) Regulation entered into force on the 26th of March 2025. It creates a genuine European policy for the use and sharing of health data in Europe[4]. Most of the provisions of the Regulation on secondary use of data will come into force on the 26th of March 2029.

The Regulation guarantees a secure and ethical framework common to the 27 Member States of the European Union, to encourage the re-use of health data for purposes of public interest, research, innovation, public policymaking, statistics or training.

The major paradigm shift introduced by this text is to make the provision of health data of interest for secondary use mandatory. The aim is to make it compulsory for pseudonymised[5] or non-personal personal data to be reusable[6], which therefore includes all health databases (warehouses, registers, cohorts, etc.).

It specifies how these health data are to be made available: A central role is given to the Health Data Access Bodies (HDAB) to be designated in each Member State. A Member State may, if it so wishes, designate several bodies to be responsible for specific tasks; however, only one must be appointed as the coordinator for all activities and as the single point of contact.

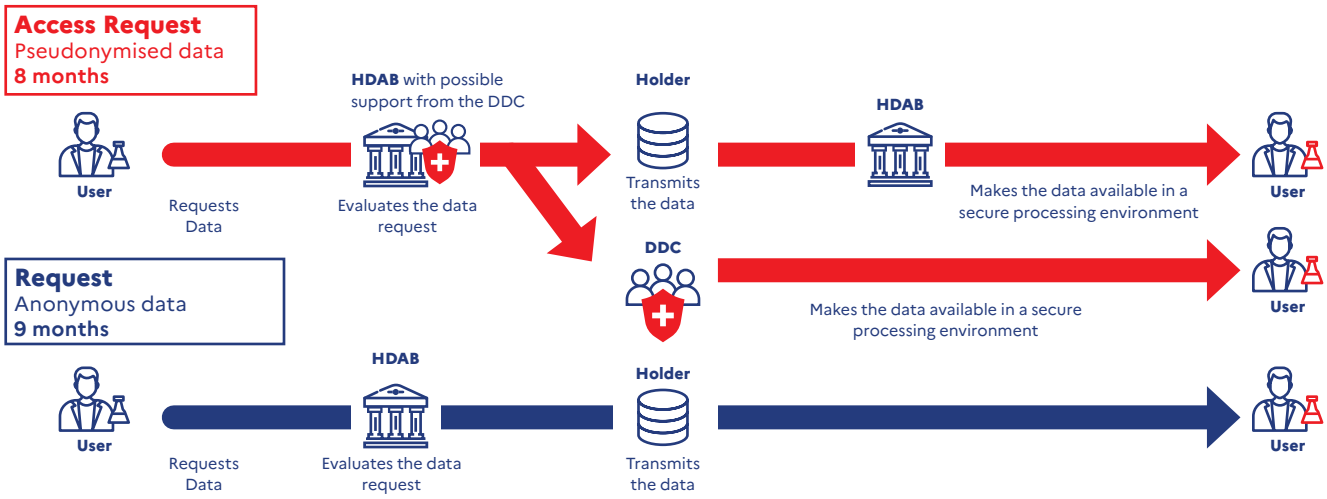
The tasks of HDAB include:

- Study the admissibility of requests for access to data for re-use;
- Issue data access authorisations,
- Unite the health data ecosystem;
- Accompany, monitor and sanction, where appropriate, users and data holders in the event of non-compliance with the obligations laid down in the Regulation,
- Contribute to the development and dissemination of quality and interoperability standards,
- Implement a national catalogue of available health databases,
- Ensure transparency of data re-use vis-à-vis data subjects and the exercise of their rights
- Promote the re-use of data at European level by working with other Member States and the European Commission.

The Regulation gives Member States the possibility to designate trusted data holders,[7] which gives the possibility to directly process access requests concerning them, to make the data available in a secure space and to levy fees.

(4) Accessible via the following link: https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=OJ:L_202500327
(5) General Data Protection Regulation No EU 2016/679, Article 9
(6) EHDS, Article 51
(7) EHDS, Article 72

The Regulation also lays down harmonised procedures for access to data. The text provides for shorter time-limits for examining applications and making the data available: 9 months for access to anonymous data[8], 8 months for effective access to pseudonymous data[9]. The Regulation allows Member States to provide for accelerated access procedures for public sector users or European institutions.



Source: Procedures for making EHDS health data available, DNS, 2025

In return for the obligation laid down in this Regulation for **data holders** to make available the health data they hold, they may levy **fees, covering costs linked to the compilation and preparation of the data with a view to making them available.** Alongside these fees, holders will also benefit from specific safeguards for the protection of their data covered by **intellectual property rights and/or trade secrets.**

Finally, the Regulation consolidates the **rights of individuals** regarding their health data in the context of secondary use. In addition to the information to be provided under the GDPR[10], the text requires data access bodies to inform data subjects about the conditions for making their health data available for secondary use. The text also provides for a right to refuse secondary[11] use of their health data.

The text gives flexibility to Member States by allowing them to maintain national provisions to access data for bodies entrusted with a task in the public interest,[12] as well as contractual mechanisms and agreements for access to pre-existing data at national level,[13] provided that their effectiveness justifies their maintenance (such as permanent access to the SNDS in France).

At national level, France, like the other 26 EU Member States, is preparing for the application of the Regulation, by conducting public consultations and pilot work under the aegis of this strategy on the secondary use of health data. The transposition of this regulation into national law will require a comprehensive draft law covering all the digital health challenges to be developed in France.

(8) EHDS, Article 69
(9) EHDS, Article 68
(10) GDPR, Article 14
(11) EHDS, Article 71
(12) EHDS, Article 1.7
(13) EHDS, Article 1.8

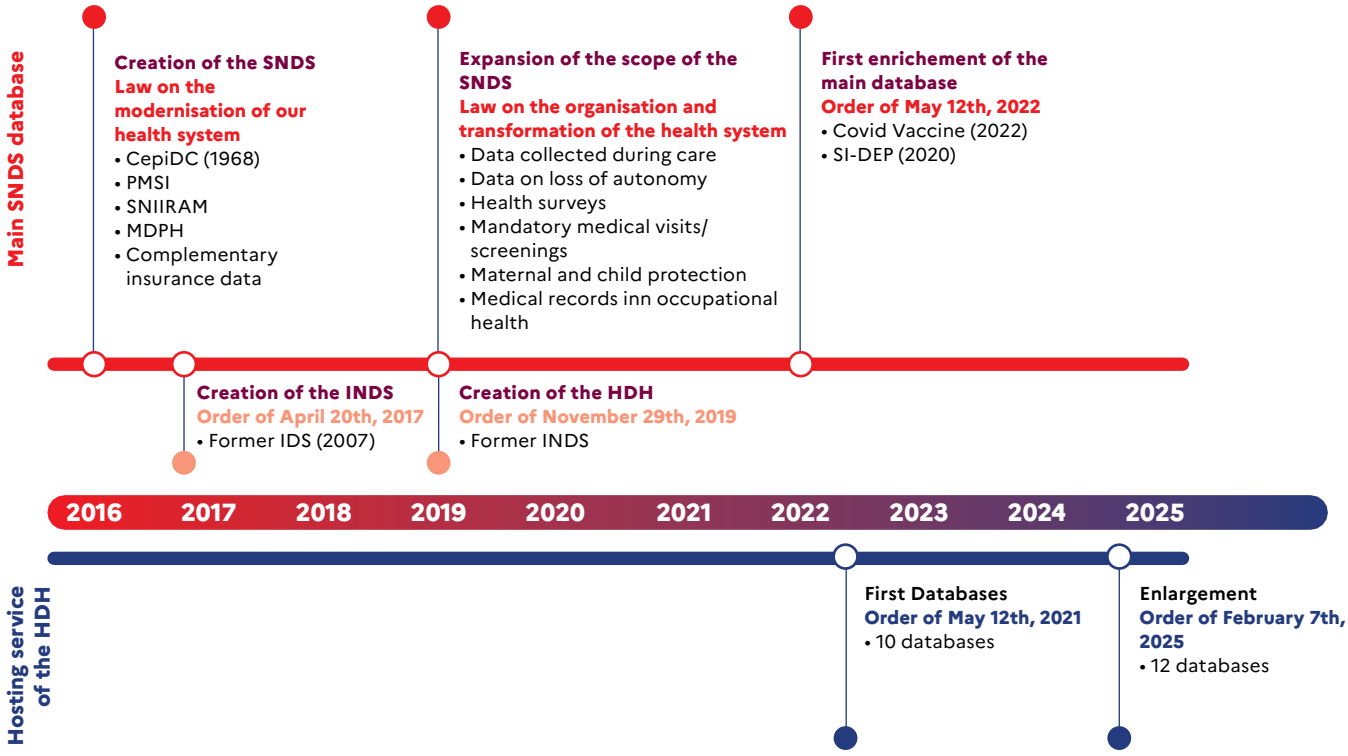
The national health data system, a unique object in the world

The National Health Data System[14] (SNDS) established in 2019 covers a wide range of health databases of national interest. The data relating to the entire French population are intended to be compiled in a single database called the 'Base Principal du SNDS', produced by the CNAM.

In 2019, the Health Data Hub was created to facilitate the availability of health data, including data from the main database. At the same time, a large number of health and research actors (research organisations, health institutions, etc.) are entitled to have permanent access to the main database via the CNAM portal.

Other databases are copied at national level to facilitate reconciliations (matches) with the main database and their reuse. Until then, the list of these copied and centralised databases had been laid down in legislative and regulatory texts. The strategy published today changes the doctrine of centralisation, and particularly the issue of copying data (see objective 4.2).

The SNDS Strategic Health Data Committee was created in 2021 mainly to provide guidance and recommendations on the national health data system: data enrichment, recommendation of databases of interest, recommendations to promote data sharing .... It will evolve to take the form of the Stakeholder Forum, in a structure inspired by the model provided for by the European regulation (see Objective 1.1).



Source: The bases constituting the main basis of the SNDS and hosted by the HDH, DREES, 2025

(14) Art. L. 1461-1 et seq. of the Public Health Code

1

A NATIONAL STRATEGY TO ADVANCE THE SECONDARY USE OF HEALTH DATA

2025-2028

AXIS 1
FOSTERING TRANSPARENCY AND PUBLIC TRUST

1. Establishing a clear and representative national governance structure

Preparing for the entry into force of the new European Health Data Regulation means changing French governance around health data.

1.1 Redesigning Health Data Governance

The Regulation for a European Health Data Space sets out harmonised governance schemes in Europe to improve the readability of organisations and foster European cooperation projects. In particular, it introduces the concept of the Stakeholder Forum aimed at bringing together all digital health stakeholders in the Member States (patients, professionals, industry, researchers, etc.). In this context, the Strategic Health Data Committee, created in 2021[15] and whose main mission is to propose guidelines and recommendations on the SNDS, will evolve.

The SNDS Strategic Committee will thus be replaced by the Stakeholder Forum and its steering bodies. The new governance will make it possible to fully involve research and education stakeholders; health institutions, both public and private, health professionals, industry actors, as well as patients and users.

All actors will be able to participate in the national work programme and contribute their views and expertise. All the work will be presented publicly at the Digital Health Council, redesigned as the unified governance body for digital health, covering both primary and secondary use of health data.

ACTIONS

→ **Launch legislative work to enshrine this new governance by S2 2025**
→ **Prefigure the Stakeholder Forum to be operational in early 2026.**

LEAD ORGANISATIONS:

DNS, DREES, DGRI, DGE

1.2 Gradually put in place the French governance of the European Health Data Space

The European Health Data Space (EHDS) requires that a Data Access Body (DAB) be designated by 2027. HDAB's tasks may be carried out by several entities at national level, but coordinated by only one HDAB per Member State.

Today HDAB's tasks are mainly carried out by the HDH and the CNIL.

(15) Order of 29 June 2021 establishing the Strategic Health Data Committee of the SNDS

HDAB's tasks may be carried out by several entities at national level, but coordinated by only one HDAB per Member State.

The Ministry of Health and the HDH play a central role in the foreshadowing of the EHDS: in the framework of the HealthData@EU project,[16] and in the two joint prefiguration actions TEHDAS[17] and TEHDAS2[18] which aim to prepare the European Commission implementing acts relating to the EHDS Regulation (see Annex).

In addition, the Regulation also offers the possibility to use trusted data holders with extended tasks to investigate authorisation requests and make the data available via a secure space.

In order to facilitate the availability of the data of certain holders, it may be considered when necessary to use data intermediation entities.

Various scenarios are under consideration for HDAB, with a view to a draft law planned for 2026.

ACTIONS

- → **Co-construct with data holders and users a first national urbanisation plan for health data warehouses anticipating key EHDS roles: HDAB, and trusted data holders by the end of 2025**
- → **Propose an action plan to ensure all HDAB missions according to the EHDS schedule by S1 2026**
- → **Carry out a draft law to prepare for the implementation of the EHDS in 2026**

LEAD ORGANISATIONS:

DNS, DREES, DGRI, DGE, with contributions from AIS, HDH, CNIL, CNAM, CESREES and representatives of data holders and users

2. Simplifying the exercise of rights and improving information for citizens

2.1 Centralising the rights and information of data subjects

Health data is used by many stakeholders for a variety of research and study projects. However, briefings to individuals (including how to exercise rights) are not always simply accessible.

The EHDS Regulation enhances transparency and mandates HDAB to communicate on the secondary use of health data by making public information available: a project directory, a catalogue of datasets (see 7.1), project results, ... and data holders are required to declare the data they produce and make available.

In France, part of the transparency is ensured by the public directory of HDH projects, each project implemented in the context of research not involving the human person, studies or evaluations in the field of health feeds a descriptive sheet published before its start. The register thus lists the characteristics of all projects using health data of a public interest carried out in France. Once the study is completed, the associated results are also published. This transparency reflects a twofold commitment: that of project leaders who want to share the impact of their work, and that of the HDH, which promotes the secure and open use of health data.

(16) https://ehds2pilot.eu/
(17) Joint Action Towards the European Health Data Space – TEHDAS1 – Tehdas
(18) Second Joint Action Towards the European Health Data Space – TEHDAS2 – Tehdas,detailed in Annex

From the point of view of citizens, work is underway to set up a single portal to exercise its rights on the re-use of data (opposition, information, etc.). The HDH has initiated work on a rights concentrator, concerning GDPR rights on the main basis of the SNDS and the bases hosted by the HDH. An articulation will also be studied with the holders of trusted data to structure local relays and pool the ways in which people's rights are exercised. This work will speed up the entry into force of the transparency portals under the European EHDS Regulation.

ACTIONS

- → **Establish, through the HDH, a national exercise of rights form for the central SNDS incorporating the modalities of exercise of rights and the relevant contact points by Q4 2025**
- → **Share a guide on how to report by the holder of the various directories: project repository, national repository of datasets (see objective 7.1), by 2028**

LEAD ORGANISATIONS:

HDH with DAJ/SGMAS, DNS, CNIL

2.2 Implement new EHDS rights

As the Regulation introduces the principle of default re-use of health data, it also guarantees the right of individuals to refuse such re-use. This right allows "to refuse at any time and without reason the processing of personal electronic health data concerning them for secondary use" (Art. 71 EHDS)

It also introduces an innovative mechanism that provides for notification in the event of a significant finding concerning the health status of a natural person (Article 61.5 of the EHDS), to which the individual may object. (Article 58.3 EHDS).

The practical arrangements for the exercise of these rights will have to be defined in consultation with the actors concerned. The implementation of these rights raises many technical questions on the determination of the interface for the exercise of the relevant rights, the synchronisation between existing portals and their articulation with reporting regimes (reference methodologies / CNIL repositories). The link with the single portal for the exercise of rights detailed in 2.1 will be examined.

ACTIONS

- → **Launch a working group dedicated to new rights in S2 2025**
- → **Consult on new rights via TEHDAS 2 (WP8) in S2 2025 and S1 2026**

LEAD ORGANISATIONS:

DNS with DAJ/SGMAS, CNIL

3. Building a secure and trusted framework for the re-use of health data

3.1 Provide suitable hosting and computing infrastructures adapted to specific use cases

The increasing use of health data requires the creation of many increasingly complex databases, both in terms of the amount of data they contain and the need to pool data from a variety of sources. This requires the development of appropriate technical environments to analyze data at all scales. In this context of developing infrastructures for the most innovative uses, particular attention must be paid to compliance with security standards consistent with the processing of personal health data.

As regards the security requirements linked to the use of SNDS data, DREES works to facilitate the appropriation and implementation of the SNDS security repository for all actors seeking to set up infrastructures to promote the re-use of health data from the expanded SNDS. A working group was launched by the Strategic Health Data Committee of the SNDS on the clarification of the repositories to carry out a comparative analysis of the different repositories and give the actors the elements to assess their ability to comply.

Consideration will be given on how to access, chain and copy the main database of the SNDS. Reflections are also ongoing regarding the expected minimization and the criteria for the «bubbles» that may receive extracts from the SNDS, with the aim of further streamlining data provision in the context of growing demand.

The EU Regulation adds new specific security and hosting requirements for HDABs, Trusted Data Holders (TDHs) and the EU Health Data Access Service. HDABs and TDHs must make data available through secure processing environments that meet strict requirements.[19] These actors must also store and process personal electronic health data on the territory of the European Union.[20]

This topic will be included in the work programme of the Stakeholder Forum and will propose simplifications and clarifications on:

- The security repositories of SNDS / Health Data Warehouses/ CNIL)
- Compliance procedures

The requirements chosen will have to consider the level of sensitivity of the data such as the processing of the National Identification Number (NIR) and the chaining or access to the main database of the SNDS. Faced with the multiplication of copies of the SNDS, a study will be conducted on the conditions for making a partial copy of the SNDS, in connection with security requirements.

(19) EHDS, Art. 73
(20) EHDS, Art. 87

Finally, the "Grand Equipment National de Calcul Intensif" (GENCI) coordinates French policy on intensive computing for research with three partner sites:

- The CINES (Montpellier)
- IDRIS (Orsay)
- CCGT (Bruyères-le-Châtel, CEA)

Other infrastructures, financed by the MESR, provide services for intensive computing,data archiving, or datahosting such as the IDRIS (Institute for Development and Resources in Scientific Computing) with the current supercomputer Jean Zay or the TGCC (Très Grand Centre de Calcul du CEA). A synthesis of existing infrastructures and the services they offer for health data will be useful for the community of holders and users. It will also guide, where appropriate, infrastructure for the development of new services linked to the EHDS.

ACTIONS

→ **Mapping operational infrastructures for research and their associated services for hosting, secure sharing and intensive health data calculation for Q3 2025**
→ **Clarifying the Safe Bubble Doctrine under the Stakeholder Forum by S1 2026**
→ **Strengthening the existing platform for the management of France Cohortes cohorts via national funding, France 2030 by S1 2026**

LEAD ORGANISATIONS:

DGRI, DREES, DNS with Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels) (pilot led by Inria), Health Research Programme Agency (Agence de programmes de recherche en santé) (pilot led by Inserm), Digital Components, Systems and Infrastructure Program Agency (Agence de programmes composants, systèmes et infrastructures numériques) (pilot let by CEA), DINUM, DGE, HDH, DNS, Stakeholder Forum

3.2 Ensure sovereign hosting of the Health Data Hub

The main base of the SNDS is hosted and operated by the CNAM (National Health Insurance Fund). A copy of the main database of the SNDS is intended to be hosted and operated by the HDH, co-controller.

In order to decongest projects awaiting access to data, the HDH launches a public contract to propose a solution for making available the copy of the main database of the SNDS, called the 'interlay solution'. The purpose of this platform will be to perform the extraction steps for projects using SNDS data. The main objective of this first step is to decongest the list of projects awaiting access to SNDS data, in an iso-functional approach.

At the same time, to support the development of hosting offers that can meet the needs of administrations, healthcare institutions, public and private research stakeholders and industry actors, the call for projects to 'strengthen the cloud service offer' of France 2030, led by the DGE, must make it possible to facilitate the development of trusted cloud offers. This call for projects should, in particular, make it possible to meet the requirements of the specifications for the target hosting solution of the Health Data Hub (HDH).

The hosting solution for the HDH projects will be adapted to ensure compliance with the framework set by the Securing and Regulating the Digital Space Act (SREN)[21], which provides that in the event of recourse to one or more commercial cloud offer(s), the HDH must call on one or more SecNumCloud[22] qualified offers by ANSSI.

A working group bringing together DINUM, HDH, DNS, and ANSSI, with the support of Inria, and in conjunction with trusted cloud providers will be set up to refine the needs of HDH for cloud services and define the minimum requirements for hosting on a SecNumCloud qualified offer. This solution will make it possible to host all the services of the HDH, known as the 'target solution'.

ACTIONS

- → **Notify the market for the interim solution for making available the copy of the main database of the SNDS by January 2026**
- → **Provide access to the interlayer solution operational for projects by the end of S1 2026.**
- → **Launch a working group with trusted cloud providers in Q3 2025**
- → **Adapt the hosting of the Health Data Hub (HDH) to legal and regulatory requirements in accordance with the provisions set out in a forthcoming ministerial order**

LEAD ORGANISATIONS:

DREES, DINUM, DGE, PDS, CNAM, with DNS, Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels) (pilot led by Inria), CNIL, ANSSI

(21) Law No. 2024-449 of May 21, 2024, aimed at securing and regulating the digital space (SREN), Article 31
(22) Developed by the French National Cybersecurity Agency (ANSSI), the SecNumCloud framework provides a set of security rules to be followed, guaranteeing a high level of requirements from a technical, operational, and legal standpoint. [Requirements framework Version 3.2 of March 8, 2022]

AXIS 2
BUILDING REUSABLE DATABASES OF INTEREST

4. Enhance the repository of health databases

4.1 Anticipate needs and continue data collection and preparation work

Better understanding the uses of data means not only facilitating access to data, but also supporting its optimal use for purposes that can be very broad (research and innovation, public policies, information for citizens and health professionals, etc.). Public health authorities (department, agencies, social security bodies) also have strong data needs to better manage the health system, make it more efficient and thus contribute to its sustainability.

The Stakeholder Forum should define public health and research needs and priorities for data collection and preparation. To achieve this, it will coordinate, in close collaboration with stakeholders and the Agency for Health Research Programmes, the mapping of the needs of different users of health data, be they researchers, institutions, agencies or industry. This mapping will link the uses and sources of data, whether they come from the SNDS or not, in the process of being compiled or already consolidated.

To cover as many priority use cases as possible, work will have to be started on:

- the identification of missing databases, variables or groups of variables, taking into account their interest according to the purpose, their geographical and temporal coverage, the quality of the information they contain and the technical feasibility of their retrieval;
- support for major programmes to deploy existing health data warehouses (hospital data, city data, biological laboratory data, etc.);
- the implementation of tools to speed up matching between data sources such as environmental and contextual data and the NIR, the collection and/or use of which for matching needs to be facilitated in line with the existing legal framework.

Particular attention will be paid to AI-related needs (see Chapter 2). These actions will need to be coordinated with those undertaken to promote the emergence of a national framework and arrangements for financing these databases (8.1).

ACTION

Continue to consider the needs of stakeholders in the enrichment of databases via the Stakeholder Forum according to their maturity (ongoing).

LEAD ORGANISATIONS:

Stakeholder Forum, Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels) (pilot led by Inria), CNIL, AIS, DGE

4.2 Specify the hosting services of the HDH

Today, the French scheme is composed of a hybrid hosting between centralised data from the main database of the SNDS, and data that remain with data holders to respond to the various use cases. The European Health Data Space is part of a decentralised model for making health data available. This will be maintained and supported, in return for increased transparency through the future national repository of datasets that will identify all available databases, regardless of where they are hosted (see Objective 7.1).

Some databases can be copied and hosted by the HDH to reconcile the data to the main database of the SNDS (pairing). This makes it possible to have available enriched data useful for certain secondary uses of health data but cannot cover all uses. Indeed, in many situations, depending on the project, it is preferable to mobilise expertise where it is most relevant: as close as possible to data producers.

To clarify this doctrine, the concept of the SNDS catalogue will evolve to include an optional hosting service offered by the HDH, allowing data to be linked to the main database of the SNDS. This mechanism aims to encourage the inclusion of more bases in the national repository, to facilitate their large-scale sharing. A first evaluation will be carried out one year after its implementation, to verify the effectiveness of this opening-up dynamic.

It is also necessary to think about the extractions, even partial, too numerous from the main base of the SNDS. These duplications, often driven by specific technical constraints or access needs, need to be framed in order to avoid data fragmentation, related infrastructure costs, and increased risks to data security and quality. A doctrine of rationalising copies, based on a detailed assessment of needs, possible alternatives and security requirements, will therefore be the subject of a dedicated project.

ACTION

Amend the Public Health Code to clarify the doctrine of centralisation of the NDSS by S2 2026

LEAD ORGANISATIONS:

DREES, DNS

5. Anticipating the principle of making data available by design

5.1 Facilitating the use of data through interoperability and quality

Harmonising approaches to the quality and standardisation of health data is a key issue for the reliable use of big data.

The production of the working group under the auspices of the Strategic Health Data Committee proposed the definition of a first version of a common core for hospital health data warehouses.[23] Following this definition, the development and sharing of common standards for the variables in this database will make it possible to structure these data and make them easily available to carry out multicentre, national and international projects.

(23) Detailed in objective 10-1

This approach to standardizing the content of databases aims more broadly to promote pooling and sharing and considering business needs. A key focus will be placed on aligning existing standards and frameworks (FHIR, OMOP, EHRxF) with practical applications.

Regarding hospital health data warehouses, the SNDS Strategic Health Data Committee has set up a committee to monitor the standardisation of actions on hospital data warehouses following the publication of technical-functional specifications to implement the common health data base according to the OMOP and FHIR standards co-constructed with the winners of the France 2030 AAP.

This work will make it possible to anticipate the introduction of a voluntary quality label as provided for in the European EHDS Regulation.

ACTION

Pursue the European Quantum project to develop a quality label for secondary use of health data in the EU, with a pilot phase in 2025 and a planned completionby December 2026

LEAD ORGANISATIONS:

Stakeholder Forum with HDH, ANS, ATIH

5.2 Enhancing accessibility of knowledge and tools

The provision of open-source tools (documentations, programmes, software, etc.) is an accelerator for studies, research and innovation in that it makes it possible to capitalise on the efforts of the community.

The data, algorithms and source code administrator of the Ministry of Health and the HDH set up a first 'open source working group' to share best practices on opening source codes, useful for the exploitation of health data.

As part of this open-source approach since its creation, the HDH offers free access to information, documentation and training in order to use data more easily. An Open Health Algorithm Library (BOAS)[24] was developed and put online in spring 2024. It aims to list algorithms for targeting/preparing health data, to facilitate their reuse in various research and innovation projects, and already offers 33 contributions accessible to the community, 21 of which relate to the SNDS Main Base.

In addition, the INRIA Digital Programs, Software and Algorithm Agency will integrate this work from S2 2025 to bring its business expertise, and enrich the services of the HDH with open-source tools from public research. As regards hospital data warehouses, the HDH has produced resources dedicated to Health Data Warehouse project leaders[25] (documentary kit, referencing health algorithms) enabling the rapid deployment of a hospital health data warehouse.

A reflection will also be conducted on the means of testing and prototyping projects based on partial and anonymized data.

(24) The library is available at the following link: https://www.health-data-hub.fr/library-open-algorithms-health
(25) link: https://health-data-hub.fr/page/our-offre-pour-les-entrepots-de-donnees-de-sante

ACTION

Continue the regular enrichment of the proposed resources (ongoing)

LEAD ORGANISATIONS:

PDS, AMDAC, with healthcare facilities, Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels) (pilot led by Inria)

6. Training the ecosystem for data reuse

6.1 Upskilling the entire ecosystem

With the gradual expansion of access to health data, the topic of training and skills development in health data processing is becoming an important focus to foster health innovation while ensuring responsible and efficient access to health data.

Aware of the need to develop training on the use of the main database of the SNDS and to adopt a logic of increasing and decentralising access to educational resources, a working group bringing together experts in the processing of this data was set up on 16 May 2024 with the aim of proposing an agile training programme facilitating the acquisition of key skills in the processing of this database.

This training programme will be expanded to prepare the EHDS[26], and provide tailored content for all stakeholders). The content will be broken down into awareness-raising or training actions according to the targets and will incorporate the key topics of the EHDS and the SNDS (use of the main database, databases hosted by the HDH, request for access to the SNDS, SNDS security repository, etc.)

ACTIONS

- → **Present an awareness-raising and training plan based on stakeholders' practices by S2 2025**
- → **Decide on an agile training programme for the ecosystem in order to familiarise it with the potential of the data in the main database of the SNDS and of the users of this data (researchers, health professionals, consultancy firms, academics) enabling the acquisition of key skills in the processing of the data referred to in a logic of dissemination and the widest possible appropriation by relying on the various partners by the end of 2025.**

LEAD ORGANISATIONS:

HDH with DNS, DREES, CNAM, ATIH, research organisations, design offices, CNSA, CNIL

(26) European Health Data Space regulation, article 59

AXIS 3
CREATING THE CONDITIONS FOR SHARING AND MAKING HEALTH DATA AVAILABLE

7. Identifying existing databases

7.1 Propose a national repository of datasets

By 2029, France must set up a national catalogue of datasets which must reference all existing databases and describe their content with complete metadata enabling potential re-users to prepare and build their projects[27].

The HDH has developed a directory of the SNDS databases referencing the databases hosted by the HDH. Work is underway with the CNIL so that this directory targets all databases on health data covered by the regulation. These will be registered in the national repository of HDH databases as soon as they are authorised by the CNIL.

A national repository of datasets containing more detailed information on the data contained in the databases hosted by the HDH has been put online by the HDH[28]. It verifies the Health-DCAT AP model and is in the process of connecting with the European central services aimed at connecting the other directories of the Member States.

The FReSH directory aims to renovate the Epidemiology France portal by widely exposing information on French health research databases, it is coordinated by IRESP (Institut de recherche en santé publique).

These repositories will be reconciled and extended to all national databases to allow project leaders to assess the relevance of a database to its research question. This national repository of datasets will be linked to the metadata catalogue provided by the European Commission at the level of the EHDS network.

ACTIONS

- → **Enrich the national directory of French databases, based on the directory already implemented by the HDH for databases hosted by the HDH from S2 2025**
- → **First version of the FReSH directory at S2 2025**

LEAD ORGANISATIONS:

HDH, Iresp, with Stakeholder Forum, CNIL and AIS

(27) Art. 77 EHDS
(28) The databases hosted by the HDH are available via this link: https://www.health-data-hub.fr/catalogue-de-donnees

8. Building a balanced model of data sharing

8.1 Foster the emergence of an economic and financial framework and modalities around data

Databases of national interest responding to the priority needs analysis (see Objective 4-1) need to be sustained through dedicated financial support. It should make it possible to build a national network and prepare for the implementation of the EHDS Regulation. It should be noted that some costs may be covered by income from different sources, such as fees (see Objective 8.2).

In general, all the measures to be taken to implement the EHDS will require specific national and European funding. These will be subject to an initial impact assessment (see Objective 1.2) before a financial analysis, in order to establish the funding needs related to the data holders, as well as all the tasks of the data holders, trusted data holders and HDABs.

The work carried out by the Strategic Health Data Committee on hospital health data warehouses led to an initial estimate of their financial needs of between EUR 60 and 90 million per year for all UHCs[29]. As a continuation of this initial work, the pricing grids, based on the analysis of the costs of making the data available, are being tested and model contracts are being drawn up (detailed in Objective 10-1).

This work carried out by the Stakeholder Forum in its revised governance (Action 1-1) will take into account all stakeholders in the ecosystem that will be consulted.

This work will aim in particular to:

1. **Investigate scenarios for sustainable funding**, starting with infrastructure, services and human resources of public health data holding structures, starting with hospital health data warehouses. As a second step, the issue of financing all warehouses (in particular town medicine, paramedics and professionals in the liberal sector) will be examined[30] in greater detail;

2. **Develop incentives for the** creation and provision and use of data (SIGAPS, MERRI, publications, clauses in calls for projects);

3. **Harmonise access practices, contractualisation, management of intellectual property rights, the terms and duration of scientific embargoes before publication, etc.**, in particular in relation to the fee arrangements and the European rules laid down in the DGA and EHDS Regulations. It will be necessary, in connection with Objective 10-1,to adjust the draft pricing grids in order to assess the potential contribution of the fee to the financing of the databases. DGA and EHDS Regulations. DGA and EHDS Regulations.[31]

(29) Available at the following link: https://www.health-data-hub.fr/actualites/comite-stratégique-des-donnees-de-sante-le-groupe-de-labor-financement-livre-une
(30) The issue of hosting registries and cohorts is dealt with in 3.2.
(31) European Health Data Space Regulation, Article 42(2). In particular, the specificity of the fees provided for holders will be deepened, whether public or private, with the clarification that when they are public the DGA does not apply. This is a sui generis fee.

ACTIONS

- → **Continue the financial estimation work initiated, including proposals for indicators and conditions of application. The analysis of the specific needs of registries and cohorts will be led by the Agency for Health Research Programmes.**
- → **Propose a first general framework of economic and financial modality in S1 2026**
- → **Gradual inclusion of funding for public warehouses of health facilities in relation to hospital funding to be fully operational by 2027**

LEAD ORGANISATIONS:

DNS, DGOS, Health Research Programs Agency (led by Inserm) with **DSS, DGRI, DGE, AIS, HDH**

8.2 8-2 Collectively establish a national fee structure for data provision

The Regulation provides for two forms of fees:

- A fee payable to the data access body or the trusted data holder for making the data available; and; and
- A fee payable to all data holders (both public and private) to compensate for the preparation of data for availability.

This scheme derogates from section 6 of the Data Governance Act[32] and allows public sector bodies to charge fees based on a broader base than the marginal costs of making data available.

The fees cover the provision of the data and part of their preparation. Apart from these fees, partnerships can be implemented (technical, scientific collaborations, user licenses), through dedicated agreements.

The European Commission plans to publish a guideline for fees, in view of the implementing acts it will take. The document will be submitted for consultation in September 2025 as part of the TEHDAS 2 Joint Action.

In France, work has been initiated by the SNDS Strategic Health Data Committee to propose fee schedules for hospital health data warehouses. This work will be adapted to the EHDS regime (derogation from the DGA) and extended to all holders covered by the regulation.

ACTIONS

- → **Extend work on data holder fees to all data holders based on work initiated in S2 2025**
- → **Launch work on HDAB/DCD fees by S2 2026**
- → **Consult on TEHDAS 2 (WP4) fees in S2 2025**

LEAD ORGANISATIONS:

Stakeholder Forum

(32) Regulation 2022/868 of 30 May 2022 on European data governance

AXIS 4
FACILITATING AND SIMPLIFYING THE USE OF DATA

9. Simplifying the procedures for making data available

To allow a delivery procedure adapted to the operational needs of users while securing data, the regulatory framework is evolving to be clearer, agile and forward-looking.

9.1 Encourage simplified delivery procedures

The European negotiations on the EHDS Regulation have made it possible to maintain the coexistence of national access mechanisms[33] and therefore to maintain any national procedures favourable to the re-use of data, such as permanent access to the SNDS and simplified access procedures in France.

France goes further in the accountability of the actors by privileging the declaration of compliance with the benchmarks. The CNIL authorisation application is now an exception.[34] Recourse to benchmarks is preferred and a single report will be possible for different treatments under the same benchmark.[35]

In order to adapt the benchmarks to the treatment needs, the CNIL launched a public consultation in 2024 to collect the needs that will be addressed in dedicated working groups scheduled from autumn onwards. The first updates are planned for early 2026. At the same time, the way in which benchmarks are developed is also evolving, and new benchmarks may be proposed by the Ministry of Health or by any representative stakeholder in the sector,[36] in particular the HDH, in so far as this falls within its legal remit.37 The arrangements for consulting the ecosystem will have to be specified in order to maintain a regular and structured exchange.

In connection with the legal analysis of the EHDS provided for in Objective 1.1, a plan to amend the Data Protection Act will be put in place with a view to simplification and harmonisation.

ACTIONS

- → **Enshrining the use of the declaratory regime in the law by S2 2025**
- → **Define an ecosystem consultation forum to collect needs for the development of new benchmarks by Q4 2025, linked to Goal 4-1**
- → **Update MR001 and MR003 by Q1 2026**

LEAD ORGANISATIONS:

CNIL, HDH, CNAM

(33) EHDS, Art. 1.6(a) and 1.6(b)
(34) Simplification Bill, Art. 22. II 3° and 4°
(35) Simplification Bill, Art. 22. II 3°
(36) Simplification Bill, Art. 22. II 2° and 5°
(37) Law No 78-17 of 6 January 1978 on information technology, files and freedoms, Article 66. II

9.2 Reduce the use of CNIL / CESREES authorisation procedures

The increase in the use of declarations of compliance via benchmarks (objective 9-1) will de facto lead to a decrease in the use of CNIL authorisation applications, which will only concern complex cases.

The use of CESREES is also evolving with the new alternative of the Scientific and Ethical Committees (SEC). The law will provide for an exemption from the prior opinion of CESREES in the event of a favourable opinion from the local ESC.[38]

The details of this scheme will be specified by implementing decree. A special point of vigilance will be given to the expertise and independence of the members of the ESC to investigate cases and appeals in the event of a negative opinion. To support the ESCs at operational level, the Strategic Health Data Committee has produced guides on data access governance: model opinion, rules of procedure, evaluation sheet, admissibility sheet[39].

This work will be reviewed with a view to a possible update to prepare the EHDS and provide for articulation with the trusted data holder role and ethical instructions.

ACTIONS

- → **Incorporate the exemption of prior opinion of CESREES in case of opinion of the CSE in the law by S2 2025**
- → **Publish the implementing decree by S1 2026**
- → **Launch a working group on the notion of public interest to be instructed by the ESCs.**

LEAD ORGANISATIONS:

Stakeholder Forum, DNS, CNIL, CESREES

9.3 Creating spaces for exploring new innovative use cases

Accelerating the availability of data will encourage the development of new practices. These new uses must be studied in a multidisciplinary and ethical approach. Their implementation could be accompanied and tested, for example in the form of sandboxes.

Use cases are already identified (synthetic data, federated learning, zero trust) but others will be added in a flexible and iterative approach.

Synthetic data and artificial data are data that are not real data. They are most often generated by different statistical, probabilistic, or artificial intelligence algorithm methods, based on real data and reproduce its main characteristics, whether personal data or not (anonymised by nature or anonymised data). This is not data used for synthetic control arms of clinical trials.

The process for obtaining such data is subject to different regulations (GDPR in case of generation from personal data, IA Act[40] when generated from an AI tool, DM Regulation if applicable, ...) on the other hand, the data thus obtained do not fall within the scope of the EHDS Regulation and fall outside the scope of the GDPR formalities since they are no longer identifying, even indirectly.

(38) Simplification Bill, Art. 22. II 6°
(39) Resources are available here: https://www.health-data-hub.fr/actualites/Comité-stratégique-des-donnees-de-sante-les-livrables-du-groupe-de-labour-governance
(40) Regulation 2024/1689 of 13 June 2024 laying down harmonised rules on artificial intelligence

Upstream, the generation of synthetic data questions anonymisation processes and compliance with data quality and reliability standards.

Downstream, re-use of this type of data can be facilitated when a number of regulations no longer apply. However, it seems necessary to reflect on the legal and ethical issues that such uses may raise, with implications to be differentiated according to the intended secondary use purposes. Indeed, possible questions and biases are not likely to have the same scope or impact depending on whether one wishes to use such data to conduct medical research, to train health professionals or to define public health policies, for example.

It will also have to carry out specific reflections on the anonymisation of personal health data and, if necessary, make proposals to feed into the ongoing work by the European CNILs to update the guidelines on anonymisation on this very specific subject.[41]

The HDH and Inria's pilot, the Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels) are working together to reflect on the challenges and opportunities associated with the use of synthetic data in the field of health research. A first seminar on the state of play will take place in September 2025. This inventory will make it possible to build an action plan incorporating the identification of promising projects to be supported or the facilitation of interdisciplinary working groups to address related issues.

ACTIONS

- → **Publish an inventory of the challenges and prospects of using summary data for health research by Q3 2025**
- → **Launch an action plan on synthetic data by Q4 2025**

LEAD ORGANISATIONS:

Stakeholder Forum, with HDH, Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels) (pilot led by Inria), DNS, DAJ/SGMS, DREES, AIS

10. Facilitating the availability of data

10.1 Establishment of harmonised principles for the provision of warehouse data

As indicated in the note from the 'Financing' working group[42] led by the Strategic Health Data Committee, one of the main obstacles to access to data today is the duration of the contractualisation of this access to data.

(41) G29, Opinion No WP-2016 of 10 April 2014 on anonymisation techniques, https://www.cnil.fr/sites/cnil/files/atoms/files/wp216_en.pdf
(42) Available at the following link: https://www.health-data-hub.fr/actualites/comite-stratégique-des-donnees-de-sante-le-groupe-de-labor-financement-livre-une

The work of the Strategic Health Data Committee of the SNDS, initiated several years ago, has already led to the conclusion of several deliverables whose objective is to significantly reduce this contractualisation time, to smooth the price inequalities according to the databases and thus to promote the development of health research and innovation by facilitating and accelerating the sharing of data, such as a standard contract for the provision of health data by a Health Data Warehouse, and two unified (simple and complex) grids for setting fees.

ACTION

Continue work by the Stakeholder Forum (e.g.: standard contract adapted to scientific collaborations in S1 2026, working group on scientific valorisation, monitoring the implementation of pricing, etc.)

LEAD ORGANISATIONS:

Stakeholder forum, with HDH, Health institutions, DGE, AIS

10.2 Optimize the availability of data from the main NDSS database

In order to speed up access times to the main SNDS database in the short term (now from 9 to 12 months),[43] CNAM and HDH have started work to streamline the process of making data available and to meet the needs of the ecosystem.

Thus, since 2021, the HDH has been supporting the CNAM in carrying out extractions for bearers, a partnership that was strengthened in November 2023. Joint CNAM/HDH work continues to improve the management of the access process.

At the same time, work on the information system to facilitate direct pairing with or without NIR reconstitution is being carried out by the HDH (the 'concentrator' information system was certified in late 2024 and has been in production since then).

This work will be accompanied by improved transparency on the timeliness of data availability, with the development of dedicated indicators.

Also, the work on hosting the SNDS described in Action 3-2 will structurally reduce access times in the medium term.

ACTIONS

- → **4 years to progressively reach access timeframe compatible with the requirements of the EHDS Regulation**
- → **Develop and monitor indicators for access timeframes between the submission of the CNIL application and the availability of data for all projects (for access via the CNAM, then via the HDH as soon as accommodation has been authorised) by S2 2025**

LEAD ORGANISATIONS:

CNAM and HDH, DREES, Stakeholder Forum

(43) Senate, information report No 873 on behalf of the Committee on Social Affairs on health data, 12 July 2023, https://www.senat.fr/rap/r22-873/r22-8731.pdf

ANNEXES

- Annex 1 – Glossary
- Annex 2 – Consulted entities
- Annex 3 – Presentation of TEHDAS2 action

ANNEX 1
GLOSSARY

AIS	Agence de l'Innovation en Santé du Secrétariat Général Pour l'Investissement (Agency for Health Innovation of the General Secretariat for Investment)
AMDAC	Administration Ministérielle des Données, Algorithmes et Codes sources du ministère du Travail, de la Santé et des Solidarités (Ministerial Administration for Data, Algorithms, and Source Code of the French Ministry of Labour, Health and Solidarity)
ANS	Agence du Numérique en Santé (Digital Health Agency)
APRS	Agence de programmes de recherche en santé Health Research Programme Agency led by Inserm
ARS	Agence Régionale de Santé (Regional Health Agency)
CEA	Commissariat à l'énergie atomique et aux énergies alternatives (Atomic Energy and Alternative Energies Commission)
CESREES	Comité Éthique et Scientifique pour les Recherches, les Études et les Évaluations dans le domaine de la Santé (Ethics and Scientific Committee for Health Research, Studies and Evaluations)
CHR	Centre Hospitalier Régional (Regional Hospital Center)
CHU	Centre Hospitalier Universitaire (University Hospital Center)
CNAM	Caisse Nationale de l'Assurance Maladie (National Health Insurance Fund)
CNIL	Commission Nationale de l'Informatique et des Libertés (National Data Protection Agency)
DAJ/SGMAS	Direction des Affaires Juridiques du Secrétariat général des ministères chargés des affaires sociales (Directorate for Legal Affairs of the General Secretariat of the Ministries responsible for Social Affairs)
DGE	Direction Générale des Entreprises du ministère de l'Économie, des Finances et de la Souveraineté industrielle et numérique (Directorate-General for Enterprise of the Ministry of Economy, Finance and Industry and Digital Sovereignty)
DGOS	Direction Générale de l'Offre de Soins du Ministère du Travail, de la Santé, des Solidarités et des Familles (Directorate-General for Care Offers of the Ministry of Labour, Health, Solidarity and Families)
DGRI	Direction Générale de la Recherche et de l'Innovation du ministère de l'Enseignement Supérieur et de la Recherche (Directorate-General for Research and Innovation of the Ministry of Higher Education and Research)
DNS	Délégation au Numérique en Santé du Ministère du Travail, de la Santé, des Solidarités et des Familles (Delegation to the Digital Health Department of the Ministry of Labour, Health, Solidarity and Families)
DREES	Direction de la Recherche, des Études, de l'Évaluation et des Statistiques (Directorate for Research, Studies, Evaluation and Statistics)
EDS	Entrepôt de Données de Santé (Health Data Warehouse)
EEDS	Espace Européen des Données de Santé (European Health Data Space - EHDS)

EHDS	European Health Data Space
GDPR	General Data Protection Regulation (EU 2016/679)
HDAB	Health data access body, as defined in the EHDS
HDH	Health Data Hub
IA	Artificial intelligence
INRIA	Institut national de recherche en sciences et technologies du numérique (National Research Institute for Digital Science and Technology)
INSERM	Institut national de la santé et de la recherche médicale (National Institute of Health and Medical Research)
IRESP	Institut de recherches en santé publique (Institute for Public Health Research)
NIR	Numéro d'Inscription au Répertoire National d'Identification des Personnes Physiques (Registration number in the National Physical Identification Directory)
SNDS	Système National des Données de Santé (National Health Data System)

ANNEX 2
CONSULTED ENTITIES

Independent agencies, operators and public authorities

- National Agency for the Safety of Medicines
- Digital Agency in Health
- Regional health agencies
- SNDS Strategic Health Data Committee
- Higher Health Authority
- Health Data Hub, General Assembly
- Caisse des Dépôts and Consignment Group including Bpifrance

Users

- France Asso Health

Health facilities

- National Conference of Directors General of CHRU / Commission Data
- Federation of Private Hospitalisation
- French Hospital Federation

Research and teaching

- Health Programme Agency, led by Inserm
- Digital, Algorithms and Software Program Agency (Agence de programmes numérique, algorithmes et logiciels), led by Inria
- Office of the Commissioner for Atomic Energy and Alternative Energies
- National Centre for Scientific Research
- France Universities
- National Institute of Health and Medical Research
- National Research Institute for Digital Science and Technology
- National Research Institute for Agriculture, Food and Environment

Health professionals

- National Council of the Order of Physicians
- National Union of Health Professionals

Industry actors

- Strategic Sector Committee Health Industries and Technologies
- France Biotech
- France Digitale
- Leem
- Numeum
- In Vitro Diagnostic Industry Union
- National Union of Medical Technology Industry

Expert companies and think tanks

- Institut Montaigne
- French Association of Correspondents for the Protection of Personal Data
- AI and Cancer

We would also like to thank the members of the mission led by Jérôme MARCHAND-ARVIER: Prof. Stéphanie ALLASSONNIERE, Aymeril HOANG, Dr. Anne-Sophie JANNOT always available to exchange during the construction of this strategy.

ANNEX 3
PRESENTATION OF THEDAS2 ACTION

Presentation of the TEHDAS2 Joint Action

TEHDAS2 ('Towards a European Health Data Space 2')[44] is a joint action launched in May 2024 to develop guidelines and technical specifications essential for the implementation of the New European Health Data Space (EHDS). The work will have a direct impact on the 20 or so implementing acts that the Commission will draw up in detail of the Regulation.

Funded by the EU4Health programme and coordinated by Sitra, the Finnish innovation fund, this project brings together 29 European countries with a total budget of €6 million, co-financed between the European Commission and the Member States.

The TEHDAS2 Joint Action follows a first initiative (TEHDAS), concluded in July 2023, which brought out the first recommendations that impacted the drafting of the text of the EHDS Regulation in terms of governance, interoperability, technical infrastructure and citizen involvement. The EHDS Regulation was published in the Official Journal of the European Union (EU) at the beginning of 2025, which entered into force on 25 March 2025[45].

Organisation of the TEHDAS2 Project

The TEDHAS2 project is divided into eight working groups:

- WP1 Management and Coordination
- WP2 Communication
- WP3 Evaluation
- WP4 Collaboration models
- WP5 Data discovery
- WP6 Access to data
- WP7 Safe and secure processing
- WP8 Serving citizens

France, represented by the DNS as competent authority and the HDH as affiliated entity, plays a central role in this TEHDAS2 joint action. The DNS co-pilots with the Danish Health Data Authority on WP4. The HDH co-pilots with the German BfArM on WP7 to *'safe and secure processing of health data'* and as a contributor to WP4, WP5, WP6 and WP8.

WP1, 2, 3 Management and Coordination / Communication / Evaluation
WP1 is dedicated to the overall management and coordination of the Joint Action. WP2 aims to ensure smooth and effective communication at every stage and WP3 foresees a rigorous assessment of the relevance, efficiency, impact and sustainability of the project. A newsletter is sent regularly by the TEHDAS2 coordinators.[46]

WP4: Collaboration models
Coordinated by the DNS and the Danish Health Data Authority, WP4 has three objectives:

- Develop guidelines for fees and penalties under the EHDS
- Create operational models and guidelines for cooperation models for the implementation of the EHDS, aimed at:

ensuring the engagement of the European ecosystem concerned with the implementation of the EHDS and the sharing of knowledge and awareness of future EHDS regulatory requirements.

- Guidance to health data access bodies on access to and transfer of electronic health data at international level and in third countries.

(44) Second joint action Towards the European Health Data Space – TEHDAS2 - Sitra
(45) The European Health Data Space - Ministry of Labour, Health, Solidarity and Families
(46) Second Joint Action Towards the European Health Data Space – TEHDAS2 – Sitra

WP5: Data discovery
WP5 aims to facilitate the discovery and enrichment of datasets for secondary use. WP5 aligns with the broader policy context defined by the Data Governance Regulation. It will also build on the results of the HealthData@EU (EU4HEALTH) pilot project and liaise with the QUANTUM (HORIZON) project on data quality.

WP6: Access to data
WP6 seeks to improve the common understanding and operationalization of access to electronic health data. The aim is to facilitate the exchange of this data by involving stakeholders from different countries and taking into account various use situations.

To do this, practical guidelines and technical specifications will be drafted through an iterative process. It will consist of several stages: draw up an inventory of what exists, seek common ground between the various players, compare the solutions proposed with the applicable legal framework, and finally draw up a harmonised proposal.

WP7 Safe and secure processing
WP7 aims to define precise guidelines and technical specifications for secure processing environments and data depersonalization.

WP8 Serving citizens

WP8 aims to strengthen citizens' commitment to EHDS with regard to the secondary use of health data. Thus, numerous guidelines for data access bodies concerning citizens' rights (opt-out, significant discovery, etc.) will be drafted.

TEHDAS2 also relies on the TEHDAS2 Advisory Board, which brings together the main actors, other than the institutional and public actors included in TEHDAS2, concerned with the construction of the European Health Data Space and the secondary use of health data in the EU.

TEHDAS2 Project Calendar

The Joint Action runs for 32 months (May 2024 – February 2027), mirroring the implementation of the EHDS Regulation.

All deliverables (guidelines and technical specifications) developed under TEHDAS2 are subject to public consultation.

The public consultations will follow a sequential approach, comprising three waves, allowing for a division of the work of the project and the solicitation of stakeholders:

- First wave: January/February 2025
- Second wave: September/October 2025
- Third wave: May/June 2026[47]

This calendar will take into account the timing of the preparation of the delegated/implementing acts provided for in the Regulation.

Three stakeholders' forums (Stakeholder Forums) are organised, the timing of which will coincide with that of the public consultation. These forums are open to all and are aimed at stakeholders working with health data.[48]

(47) Public consultations - Tehdas
(48) Get involved - Tehdas

2

BUILDING TOGETHER THE MINISTERIAL STRATEGY ON ARTIFICIAL INTELLIGENCE FOR HEALTH IN FRANCE

Note: For any references to annexes throughout this document, please consult the original version in French.

INTRODUCTION

Artificial intelligence is a major transformative lever for the French healthcare system. Its potential to improve the quality of care, optimise patient pathways and increase the efficiency of health organisations is now recognised. However, its large-scale deployment requires rigorous structuring, built around a framework of trust, appropriate regulation and support for innovation.

The assessment of AI in healthcare has made it possible to identify several key areas of work to ensure the effective and secure integration of these technologies:

- **Assessing the benefits and risks of AI solutions:** It is essential to measure the impact of these tools on the quality of care, patient safety and the organisation of the work of healthcare professionals. Improving diagnostics, personalising care and optimising resources are strategic priorities.

- **Supporting innovation and the development of AI technologies in the health sector:** Through the investments of France 2030, including the digital health acceleration strategy (SASN), initiatives are deployed to promote the research, development and adoption of AI solutions adapted to the needs of the health system.

- **Establishing a clear regulatory and ethical framework:** The integration of AI solutions in health must be carried out in compliance with the requirements of the European AI Act, the provisions relating to other European regulations[47], but also with the ethical principles and ecological sustainability, in order to ensure their reliability, safety and relevance.

A strategy for structuring artificial intelligence in health

Building on this assessment, the national strategy on AI in healthcare is based on strong commitments from the Ministry of Labour, Health, Solidarity and Families, and its partners, aimed at structuring and supporting the deployment of these technologies around four key priorities :

1. **Clarifying regulations and regulating practices by** improving the readability of regulatory texts and strengthening good practices that ensure patient safety and user confidence.

2. **Evaluating health AI systems,** integrating the specificities of AI solutions and measuring their impact on the efficiency of the health system.

3. **Supporting healthcare professionals** in the appropriation of AI tools, through targeted training and awareness-raising actions to ensure smooth and effective integration into medical practices.

4. **Creating a sustainable economic framework** to support innovation by defining financing, pricing and reimbursement models tailored to the specificities of AI technologies in the health sector

This strategy is based on a public consultation that will be held between July and September 2025 and involve all stakeholders (patients, health professionals, industry, researchers and citizens).

In order to prepare for this public consultation, a dedicated task force met within the Digital Health Council (CNS). It is co-led by the Digital Health Delegation for (DNS), the General Directorate for Healthcare Provision (DGOS), the National Union of Health Professionals (UNPS) and the national umbrella organisation for patient associations, France Assos Santé. It brought together more than 70 participants on three occasions between May and June 2025 to co-construct this first strategy proposal, ensuring a coherent, innovative approach adapted to the challenges facing the health system.

Health data and artificial intelligence: two national strategies developed in synergy to strengthen and support the healthcare system

ambitious strategy on health data that is accessible, high-quality, interoperable and governed in accordance with the principles of ethics, security and sovereignty. It is with this in mind that the strategy for AI in health is closely linked to the interministerial strategy to advance the secondary use of health data. These two strategies work hand in hand. Deploying AI across the healthcare system requires creating the conditions for responsible data sharing, ensuring citizens' trust, protection of their rights and efficient use. This approach is fully aligned with European initiatives, notably by connecting the European Artificial Intelligence Act with the European Health Data Space (EHDS) Regulation.

The large-scale adoption of AI systems in health poses other challenges, including:

1. the integration of AI solutions in compliance with the requirements of the European AI Regulation, which classifies most medical devices and DMN DiV embedding AI as high-risk systems

2. the rigorous evaluation of AI systems and the adherence of healthcare professionals and patients

3. the development of funding models based on demonstrated medico-economic efficiency or measurable improvements to the healthcare system, and iv. the training of users in new practices.

A well-structured public policy is therefore essential to provide a clear framework for this transition.

PURPOSE OF THE DOCUMENT: This document aims to present a proposal for a co-developed and coordinated strategy for artificial intelligence in healthcare. Grounded in emblematic use cases and concrete actions, it outlines **a structured approach to deploying AI in health for the benefit of all stakeholders**.

1. Methodology for structuring the Artificial Intelligence in Health Strategy

1.1 Methodology for building the Strategy

In recent years, work, several publications, many actions have been carried out and published by the actors of the AI in health ecosystem.

In January 2025, a National Committee for "Coordination of AI in Health" undertook a synthesis of these actions in the document outlining the state of play of actions carried out on AI in health. This document was published on 11 February 2025 and announced by the Minister of Health and Access to Care, Dr Neuder, at the AI Summit in Paris.


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.

On the same occasion, the Minister for Health and Access to Care announced the launch of a working group of the Digital Health Council (CNS) to launch discussions on the AI in health strategy.

To build this strategy, a methodology based on coordination between the different actors of AI in health has been implemented. The National Committee for "Coordination of AI in Health" worked in two stages:

Step 1: Identifying the common foundations needed for the implementation and application of AI in health

Step 2: Segment and select topics of interest to identify examples of emblematic use cases of AI applications in health.

From this initial work, a third stage was launched in May 2025. It made it possible to structure a working group of the Digital Health Council (CNS) in order to co-construct a proposal for a strategy on AI in health with stakeholders in the ecosystem.

Step 3: This participatory work of the working group of the CNS and with the ecosystem aims to propose a first version of the document which is put into public consultation.

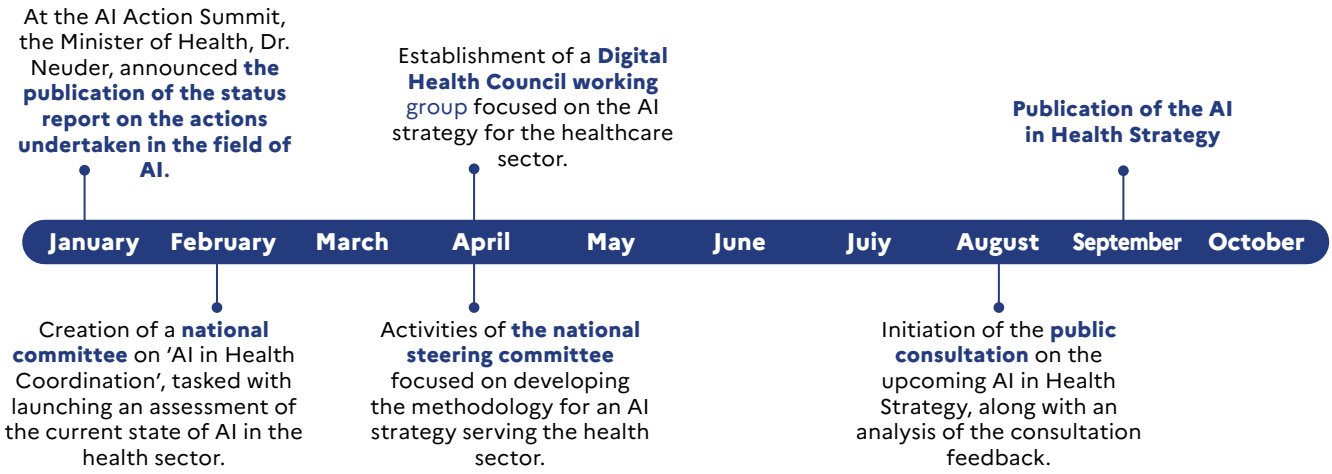
This process continues with a public consultation from July 2025. It will be conducted with the working group of the Digital Health Council (CNS) and will aim to gather the views and feedback of ecosystem stakeholders on the future ***Artificial Intelligence for Health strategy*** and the proposed broad strategic orientations, building on the deliverable co-built together.

Participants will be invited to answer structuring questions to guide the priorities for innovation, development, evaluation and even deployment of AI in health.

The contributions collected will help to better understand the expectations and obstacles to the adoption of AI solutions in health, and to identify the actions to be put in place to feed into the national strategy, thus ensuring a concerted approach adapted to the needs of the different actors of AI in health.

Each of these steps will help to structure the proposal for a strategic vision on AI for health, detailed in the rest of the document.

1.2 Proposed timetable for the structuring of the Strategy



2. Common foundations needed to build trustworthy, accountable, ethical, sovereign and effective AI systems in the health sector

The common foundations, detailed in this document, are the necessary elements for the implementation, validation, evaluation, application and deployment of trustworthy AI systems in health in order to meet the challenges summarised in the diagram below:

What are the key challenges for trustworthy AI systems in healthcare?

Distinctive characteristics of medical devices with AI

- Locked AI vs. adaptive AI
- Updates and monitoring
- Data
- Transparency of AI systems (SIA) and data, explainability, interpretability, choice of AI systems
- Operational robustness and cybersecurity
- Continuity plan

Evaluation models

- Methodologies and evaluation criteria
- Funding
- Market regulation
- Performance evaluation of (SIA)

Ethical, legal and social challenges

- Medical liability
- Training of healthcare professionals
- Ethical issues
- Human-machine relationship
- Human oversight
- New regulations
- Data protection and privacy
- Patient information

Systemic impacts on health

- Transformation of the healthcare sector
- Reorganization of care pathways
- Transformation of medical practices
- Changing patient behaviors and usage
- Environmental impact

Towards trustworthy AI at the service of patients and professionals

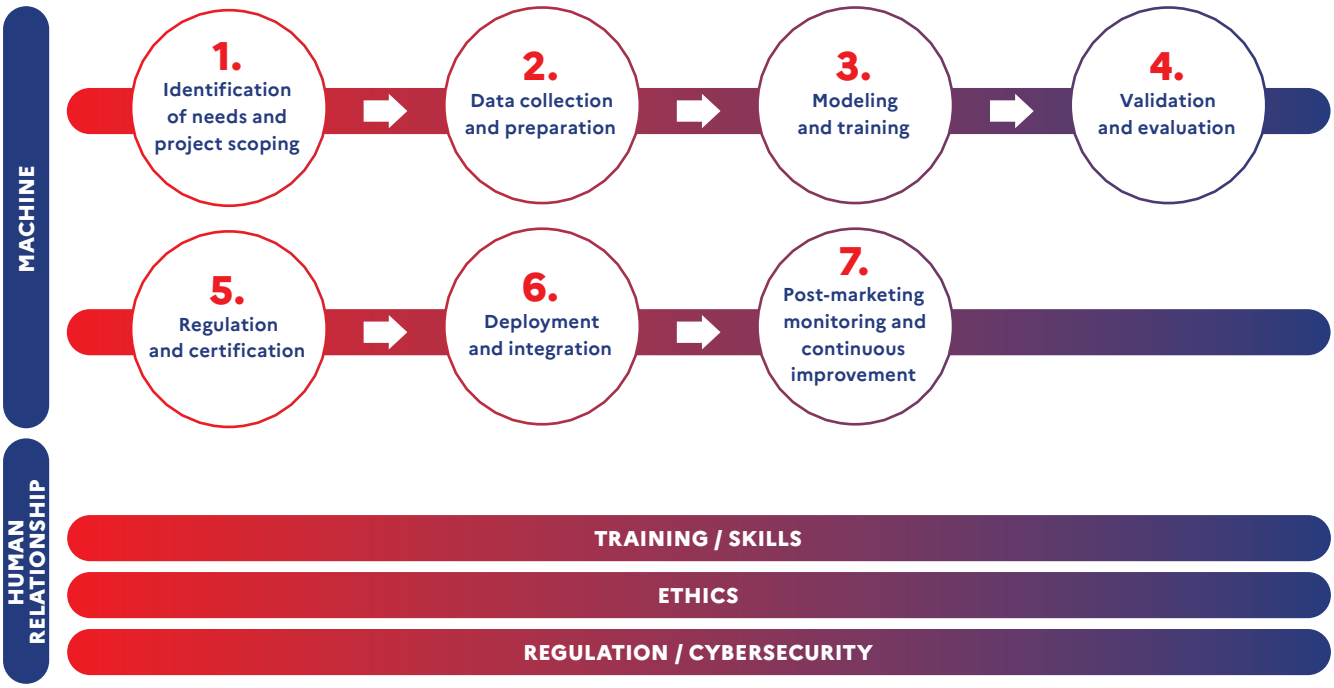
- **Lawful** (legislative, regulatory)
- **Ethical**
- **Robust** (technical, social, and societal)

Governance, responsibility, and sovereignty challenges of AI in healthcare

This approach is supported by **cross-cutting dimensions that** ensure the responsible and effective integration of AI into the health system:

- **Training and skills:** Development of know-how and upskilling of key actors, including healthcare professionals, patients, and adjacent professions
- **Ethics**: Supporting the use of AI to ensure compliance with ethical principles and patient rights
- **Regulation**: Legal framework structuring the use of AI in medical devices and health care pathways
- **Technology - Healthy AI systems lifecycle**: identification and response to a need, data collection and preparation, modelling, training, validation, evaluation, regulation, certification, financing, deployment integration, post-market monitoring, continuous improvement, cybersecurity...

These dimensions reinforce in particular the principle of the human-machine relationship and are to be put into perspective with the **life cycle of an AI system** (represented in the following diagrams):



1. Identification of needs and project scoping

- Definition of the medical or clinical problem to be solved.
- Analysis of the needs of healthcare professionals and patients.
- Study of technical and regulatory feasibility
- Definition of performance criteria and key performance indicators (KPIs)

2. Data collection and preparation

- Identification of data sources (medical records, imaging, sensors, etc.).
- Anonymisation and compliance with regulations (GDPR, HIPAA, etc.).
- Normalisation and preprocessing (cleaning, handling of bias and missing values)
- Creation of a training dataset and a test set.

3. Modeling and training

- Selection of AI algorithms (neural networks, supervised/ unsupervised learning, NLP, etc.).
- Train models on the data available.
- Cross-validation and hyperparameter optimisation.
- Comparison with existing methods (benchmarking).

4. Validation and evaluation

- Performance evaluation (accuracy, recall, specificity, etc.).
- Tests on independent data to avoid overfitting.
- Evaluation by medical experts (external validation).
- Clinical studies and regulatory trials if necessary.

5. Regulation and certification

- Verification of compliance with applicable standards (CE, FDA, French National Agency for the Safety of Medicines and Health Products [ANSM], ISO 13485, MDR).
- Assembly of the regulatory documentation for certification.
- Definition of the risks and limits of the model (bias, robustness, reliability).
- Ethical validation and assessment of the impact on healthcare.

6. Deployment and integration

- Development of a user interface and integration in existing systems (French Electronic Health Record [DMP], HIS).
- Testing under real-world conditions and collection of user feedback
- Training of healthcare professionals in the use of the model
- Definition of monitoring and update processes

7. Post-marketing monitoring and continuous improvement

- Monitoring of performance and detection of shifts.
- Collection of feedback from users and patients.
- Regular updates to improve accuracy and robustness.
- Assessment of actual clinical benefits and impacts on care delivery.

2.1 Training and skills: Development of skills of healthcare professionals, patients, and other actors around digital health

The rise of digital health technologies makes it essential to train professionals in these new tools, in particular artificial intelligence, which is a strategic lever to support the evolution of clinical and organisational practices. Aware of this challenge, the ministries in charge of higher education and in charge of health have included digital health training among their priorities. The ministerial decree of November 10, 2022 makes the teaching of the five key areas – telehealth, health data, cybersecurity, digital tools and communication – compulsory for all undergraduate health training.

However, limiting this teaching to a maximum of 28 hours does not allow to deepen all the necessary skills, especially those related to AI, which require a more specialised and contextualised approach. It is therefore essential to strengthen the training offer in graduate courses, in order to equip all professionals in the health and social care system – whether they are carers, lawyers, engineers, school directors, or other actors in the field – with skills adapted to their specific uses (e.g. AI in odontology imaging, AI for the analysis of data from anatomocytopathology, etc.).

These courses will have to be designed in close coordination with the needs of the specialties and offer content differentiated according to the contexts of practice, to promote a concrete, operational and ethical appropriation of AI at the service of the quality of care.

They will also need to draw on the diverse expertise of sector stakeholders—including caregivers, engineers, lawyers, and administrators—to develop educational pathways that are both collaborative and specialized. Multidisciplinary training programs (such as doctor–engineer tracks) can foster this cross-disciplinary approach while addressing the increasing technical demands of professional practice.

In addition, to ensure effective implementation of these pathways, support for training institutions is essential. It will make it possible to mobilise the necessary pedagogical expertise, to acquire the appropriate technological resources, and to structure innovative training schemes, commensurate with the challenges of transforming the health system.

PROPOSED ACTION: Supporting the provision of digital health training in the 2nd and 3rd cycle of health studies

Provide funding, via the CMA AMI (Appel à Manifestation d'Intérêt Compétences et Métiers d'Avenir / Call for Expressions of Interest for Skills and Professions of the Future), the design of specific competency frameworks, integrating the cross-cutting dimensions between disciplines and specialties; have them validated, disseminated and then integrated into the training of health system professionals.

TARGETS • Students in the second and third cycle of their health studies.

The integration of AI into training pathways should not come at the expense of developing critical thinking and analytical skills.

There is a risk of gradual de-skilling if AI uses systematically replace professional reasoning.

PROPOSED ACTION: Monitor and evaluate the integration of AI in the training of future healthcare professionals

Establishment of a working group to assess the benefits and risks of introducing AI education in health pathways and propose national recommendations to ensure a controlled complementarity between knowledge of prerequisites on AI systems and the training of future health care professionals

TARGETS • Actors in the health sector

In addition to initial training, and in accordance with the criteria set out in the sixth cycle of health institution certification, effective from September 2025, institutions must implement ongoing training for professionals using artificial intelligence technologies. This continuous education should ensure that practitioners understand the capabilities, appropriate use, and limitations of these systems. Furthermore, there is a recognized need to increase awareness and train healthcare professionals on the use of AI in clinical practice, encompassing topics such as algorithm functioning, result interpretation, impacts on care delivery, ethical considerations, and demystification of AI.

It would therefore be appropriate to create a structured territorial dynamic, based on regional actors such as regional health agencies (ARS) and GRADeS (Groupements Régionaux d'Appui au Développement de l'e-Santé which translates to Regional Groups for Supporting the Development of e-Health), in order to bring together and support health professionals in cities and institutions around the challenges of artificial intelligence in health. This would aim to:

1. institutionalise regional governance arrangements on AI in health
2. foster the acculturation and upskilling of health professionals
3. create a space for dialogue and coordination between professionals, healthcare facilities, and institutions to develop a shared culture of AI in health at the regional level.

PROPOSED ACTION: Structure a regional governance that allows the upskilling of active health professionals around AI topics in health

Develop support for professionals in cities and institutions with the support of ARS and GRADeS:

- institutionalising governance on health AI in health facilities to assess AI readiness and monitor AI projects in institutions and with city professionals in order to track results at national level
- adapting, for example, to the health system, the "AI café" methodology developed by the National Digital Council **(https://cafeia.org/)**.

TARGETS • urban and institutional health professionals, health care facilities (health and social care).

2.2 Ethics and artificial intelligence: AI in health at the service of humans, supervised, transparent and accountable

The development of artificial intelligence in health represents an opportunity to improve the quality of care, anticipate pathologies, and support professionals on a daily basis. But this transformation can only succeed if it is accompanied by a strong commitment to ethics and user rights.

Under the impetus of the DNS, a working group **of more than 40** institutions, experts, health professionals, user representatives and innovation stakeholders has developed a guide to implementing AI in ethical health. This **guide**, which is currently being finalised, aims to **frame the entire life cycle of health AI systems** – from their design to their evaluation, to their deployment on the ground – in a spirit of shared responsibility and transparency.

Built according to a rigorous, open and iterative approach, this guide is based on the **five main principles of the Digital Health Ethics Framework:** benevolence, non-malfeasance, autonomy, justice and eco-responsibility. Three successive versions have been drawn up, gradually integrating:

- alignment with European regulations (AI Act, Medical Device Regulation),
- mapping of existing labels (Labelia, Ethik-IA, Ekitia),
- and feedback from the field.

Version V3, which will shortly be subject to public consultation, includes **44 operational criteria**, organised according to the stages of the life cycle of AI systems: framing, data collection, design, user interfaces, evaluation, deployment, post-implementation monitoring.

These criteria relate to key issues:

- **transparency** of algorithms and traceability of decisions,
- tackling **bias** and ensuring **fair access to** innovations;
- **health data protection** and digital **sovereignty**;
- **training** of professionals and co-construction with patients,
- the preservation of **decision-making autonomy** and the management of responsibilities.

PROPOSED ACTION: **Two use cases to test the guide to deploying ethics-based AI in health**

The approach provides concrete evidence to support progressive implementation by actors on the ground, as well as articulation with existing sectoral benchmarks. A public consultation is planned from May 2025, before an official publication of the guide accompanied by its drafting report. Proof of concept to demonstrate proof of use of this guide is offered in the fields of speech-to-text for healthcare professionals and AI in decision support in imaging for example.

TARGETS • healthcare facilities and industry actors.

This approach, based on ***ethics by design***, aims to establish a framework of shared trust, ensuring that AI in health is not an imposed technology, but a controlled, explainable and useful tool for all, at the service of humans, the safety of care and the fundamental principles of our health system. Far from holding back innovation, ethics must guide its meaning, so that France continues to innovate while remaining faithful to the requirement of a humane, fair and solidarity-based health system.

2.3 Regulation: Legal framework structuring the use of AI systems in health

The development and use of AI solutions in medical devices, in vitro diagnostic medical devices and care pathways is part of a legal framework that is based on a combination of European regulations aimed at ensuring a high level of protection of health, safety and fundamental rights enshrined in the Charter of Fundamental Rights of the European Union.

The AI Act aims to regulate the development, marketing, and use of artificial intelligence systems that may pose risks, particularly to health. It specifies that any AI system used for medical purposes is subject to Regulation (EU) 2017/745 on medical devices or Regulation (EU) 2017/746 on in vitro diagnostic medical devices. For high-risk AI systems, the AI Act introduces additional requirements that complement those established under these existing regulations.

These health products must be assessed by a Notified Body (NB) as part of their CE conformity marking before being placed on the market under the respective Regulations.

The challenge is also **regulatory and strategic**: In order to ensure secure and rapid access to innovation, it becomes essential to structure an assessment that is consistent with **the requirements of the Medical Devices Regulation, the European AI Act and the Common European Framework for Health Technology Assessment (HTAR)**. This calls for the harmonisation of criteria at the European level, the integration of real-world data, and the recognition of alternative assessment methods—particularly for emerging use cases.

PROPOSED ACTION: **Supporting the implementation of the AI Act in the health sector in France**

A draft stakeholder FAQ on the links between Regulation 2024/1689 laying down harmonised rules on artificial intelligence and Regulations 2017/745 and 2017/746 on medical devices and in vitro diagnostic medical devices is being developed. The framework for the identification of AI competences of notified bodies authorised to certify medical devices and in vitro diagnostic medical devices integrating high-risk AI systems is also under preparation.

TARGETS • Health institutions, healthcare professionals, industry actors, research institutes, etc.

2.4 Technology – The lifecycle of AI systems in the health sector

The life cycle of AI systems in the field of health includes both identification and response to a need, data collection and preparation, modelling, training, validation, evaluation, regulation, certification, financing, deployment, integration, post-market monitoring, continuous improvement, continuity plan, cybersecurity. Several courses of action can be proposed at each stage and then supported by use cases detailed in the last part of the document.

Preparation, operation and governance of health data:

Data quality is key to ensuring the performance, robustness and security of AI systems. This requires rigorous collection, expert annotation, standardisation and ethical governance, based on interoperable formats and anonymisation or pseudonymisation in line with current standards.

In this context, the **national strategy to advance the secondary use of health data** plays a key role. It makes it possible to optimise the availability of health care and research data, simplifying compliance procedures while maintaining high standards of safety, ethics and accommodation. This development is accompanied by increased transparency in order to have a better visibility on the available databases and on-going projects and also to facilitate the exercise of rights. National governance is also planned to involve health data stakeholders and contribute together to the opening up of health data, with a view to continuous improvement of care, generation of evidence and medico-economic evaluation.

The secure provision of such data for the purposes of research, evaluation or development of AI algorithms is a major strategic lever for training, testing and adapting models to real-world conditions. This involves consolidating representative, multicentre and longitudinal databases, improving the quality of coding, and creating sharing infrastructures in line with the national trust framework.

Validation, certification, evaluation:

Validation of AI systems is based on rigorous protocols, integrating clinical studies, multicentre tests and benchmarks on real data. It allows verification of robustness, reproducibility, safety and algorithmic non-discrimination. Collaboration with healthcare professionals is essential to ensure real-world validation and a good understanding of usage limits.

The technical peculiarities of AI systems, especially AI-embedded medical devices and in vitro diagnostic medical devices, imply specific **certification** procedures. The implementation of a 'dynamic certification' has already been tested by the Food and Drug Administration (FDA) in the United States since 2017. AI in health systems sometimes require regular updates, which can be costly, due to advances in medical knowledge and the risks of prosecution for medical negligence. Managing the consequences of an algorithm update is tricky because it can lead to the withdrawal of the product from the market. Lifecycle certification therefore seems to be a possible avenue, but it involves adjusting methodologies.

The **assessment of artificial intelligence systems in health** is now a central issue to ensure their responsible integration into the health system. The context is marked by a rapid growth of AI solutions in health, but also by persistent uncertainties about the methodologies to be mobilised to demonstrate their clinical, organisational and economic interest. As such, health AI systems pose specific challenges compared to standard health products.

Current assessments are still largely dominated by technical approaches focusing on the performance of algorithms, in addition to prospective clinical studies, real-life analysis, measuring the impact on care pathways and taking into account acceptability. The analysis carried out as part of a systematic review showed that many key criteria, such as explainability, medico-economic assessment, security or organisational impact, were undervalued.[1]

It is therefore necessary to extend the assessment to a multidimensional approach, combining criteria common to any medical device (clinical effectiveness, safety, economic impact, organisational impact, quality of evidence, ethics) and criteria specific to AI, in particular:

- **Performance of AI systems**, especially when it comes to adaptive or scalable AI (generative AI);
- **Explicability and interpretability**, essential for enhancing transparency and user confidence;
- **Follow-up of generative AI**, with ongoing post-market validation issues.

To address these challenges, France is coordinating the SHAIPED project, via the Health Data Hub, and with the participation of the Ministry of Labour, Health, Solidarity and Families (Digital Health Delegation) and the French High Authority for Health (HAS). One of the objectives is to propose an **assessment process that takes into account the specificities of medical devices embedding AI**.

At the same time, the HAS has already assessed the value of certain digital medical devices embedding artificial intelligence as part of its missions to inform reimbursement decisions. However, most professional AI systems fall outside the scope of the current HAS assessment. Given the current technological boom, it is unrealistic to envisage a comprehensive assessment of all these systems. Therefore, new frameworks for assessing AI systems need to be structured.

PROPOSED ACTION: **The French High Authority for Health (HAS) is leading work in this direction to assess and support the use of AI in health.**

This work is structured around the three core tasks of the HAS (detailed in Annex II): (i) recommend good practices for the use of AI in health, (ii) evaluate health products with AI as part of new approaches to be built, (iii) measure and improve the safety, quality and efficiency of care. HAS is initiating new work with the aim of using AI as a lever for professional ownership of all its recommendations.

TARGETS • patients, healthcare professionals, health institutions

(1) Farah L. et al. Are current clinical studies on artificial intelligence-based medical devices comprehensive enough to support a full health technology assessment? A systematic review. Artif Intell Med. 2023 Jun;140:102547. doi: 10.1016/j.artmed.2023.102547. Epub 2023 Apr 23. PMID: 37210155.

In addition, other levers can be mobilised to strengthen this dynamic, in particular: a proposal for digital biomarkers and indicators for the assessment of digital medical devices (DMDs) in optimising the reorganising health care; the use of innovative statistical methods and designs for real-life clinical trials or studies; the development of methodological guidelines adapted to European advance regulatory procedures; the structuring of a classification and evidence grid, linked to a clear taxonomy for a better assessment of AI-enabled DMDs at the European level; the development of national datasets and a centralised portal for the validation of AI algorithms in health.

The **Third Places of Experimentation in Digital Health** (Tiers-lieux d'expérimentation en santé numérique - TLEs) could also be testing grounds for AI-based solutions.

PROPOSED ACTION: Leverage TLEs to evaluate and test real-life AI solutions

TLEs could enable the **co-development** of these solutions with healthcare professionals and users and their **evaluation** under real-world conditions of use. TLE, depending on their service offering, could assess the clinical, organisational, budgetary impact of AI-based solutions and secure the acceptability and uptake of AI-based solutions with future users.

TARGETS • Industry actors, TLEs

Several TLEs can accompany AI solution holders (see **list of TLE on G_NIUS**). One of them, the TLE PETILLANTe en Santé (PEPS) (supported by the Reims University Hospital, the Institute of Artificial Intelligence in Health (IIAS) and PÉTILLANTeS) supports the uptake AI solutions in health.

Unlock the support for DMDs embedding AI for professional use

Economically, AI-embedded schemes raise **new issues of funding and pricing**. Their evolutionary nature, the infrastructure costs necessary for their integration (upgrading IS, training, cybersecurity), as well as the diversity of dissemination models (licence, subscription, billing for use) require an adaptation of economic tools and valuation criteria. Stakeholders stressed the value of mobilising **Value Based Health Care** (VBHC) models, combining clinical effectiveness, quality of life, and impact on the organisation of care. The entry into the common law on remote monitoring and the implementation of PECAN have opened market opportunities for companies developing remote monitoring medical devices or digital medical devices for individual use. **However, innovative digital solutions for healthcare professionals to enhance quality, relevance or efficiency are still struggling to develop massively**.

Their deployment is still slow, although some digital solutions manage to generate a sufficient productivity gain for the healthcare organisations that are clients (biology laboratories, imaging technology platforms, hospitals, etc.), others improve the quality of care and are efficient from a health system perspective but require time and financial resources for professional users, which considerably slows down the deployment of these useful solutions. To address this question, the four critical issues are therefore their funding, the assessment of the budgetary impact of the use of digital solutions, the modalities of funding their use and the support to enable the acquisition of the most effective solutions to allow a coordinated implementation.

The National Health Insurance Fund (CNAM) and the French National Authority for Health (HAS) have launched an experimental initiative to evaluate the medico-technical integration of artificial intelligence in ECG interpretation. The aim is to support healthcare professionals in detecting anomalies, enhance their confidence in result interpretation, and assist in the diagnostic process.

In parallel, the 'Impact AI' Call for Projects[2], launched in February 2025, will enable the funding of approximately 50 impact studies by mid-2026, each with a maximum duration of two years.

PROPOSED ACTION: Define a framework for the evaluation and funding of digital medical devices (DMDs) for professional use, in particular those embedding AI

As a follow-up to these studies, it is proposed to reflect on a sustainable mechanism for framing, funding the use and evaluation of DMDs for professional use, and referencing DMDs with AI for each technology selected.

The aim would be to assess the actual impact and make public the results achieved. The framework would incorporate a step-by-step deployment logic, allowing solutions to be tested in real and controlled conditions. At each stage, precise criteria would make it possible to assess their clinical effectiveness, their impact on the organisation of care, and their efficiency.

TARGETS • Industry actors, healthcare professionals.

This framework would provide a dual lever: targeted financial support to assist with the initial phase, and a monitoring governance structure ensuring traceability and the generation of evidence-based information. This step-by-step experimentation mechanism would thus make it possible to combine agility, security and collective learning, by preparing the conditions for a possible transition to general law. This would make it possible to structure a deployment through possible national calls for tenders focusing on the uses of AI and other innovative technologies for the efficiency of health actors in cities and hospitals, while retaining control over the innovations used to secure ethics and sovereignty.

In addition, an international vision could serve as a lever for this axis. For example, we could consider a Franco-German call for projects dedicated to the development, evaluation and clinical integration of AI-based digital medical devices for professional use.

PROPOSED ACTION: Launch a Franco-German call for projects dedicated to the development, evaluation and clinical integration of digital medical devices embedding AI for professional use

This call for projects should build on the existing European regulatory frameworks (AI Act, EHDS) and foster synergies between industry, researchers and health care facilities in both countries. The aim is to accelerate the uptake of innovative, secure and interoperable solutions, while strengthening European sovereignty in terms of health data hosting and medical technologies.

TARGETS • Industry actors, researchers and healthcare facilities.

(2) https://www.bpifrance.fr/nos-appels-a-projets-concours/appel-a-projets-etude-dimpact-de-lusage-de-dispositifs-medicaux-numeriques-innovants-dans-des-etablissements-de-sante-ou-du-medico-social

This support action would stimulate joint innovation, meet the requirements of the new European regulatory framework and accelerate the integration of AI into clinical practice for the benefit of healthcare professionals and patients. The first step would be to organise a matchmaking meeting between French startups and research teams identified as laureates of the France 2030 calls for projects and German teams having received federal funding, with the aim of training peers who will be able to develop cross-border projects. This will be followed by a series of meetings and joint presentations at national conferences on the French and German sides of the Rhine, SantExpo in France and DMEA in Germany.

Support for use:

The Observatory of AI uses in healthcare (IA en Santé - Observatoire des usages de l'IA en Santé), established in 2025, aims to support healthcare professionals in adopting AI technologies and to facilitate their integration into care pathways. It will assess the current uses of AI in healthcare and serve as a foundation for developing structured public policies to guide this transformation, ensuring the controlled and responsible diffusion of these technologies.

The lessons learned from the Observatory can feed into policy recommendations based on a thorough understanding of the real uses and needs of the field.

PROPOSED ACTION: stablishment of a national governance to guide AI in health

Governance could be established within the Digital Health Council (CNS) to support the development of the use of artificial intelligence in health. The objective is to assess the level of AI readiness[3] and make recommendations on which guidance should be prioritised or avoided, depending on the evolution of practices and needs identified on the ground.

TARGETS • Institutional actors, patients, healthcare professionals, digital health actors.

(3) For example, using a framework such as the one designed by the International Telecommunication Union (ITU), a Geneva-based United Nations development agency specializing in information and communication technologies.

Continuing in this spirit of guidance and support, the development of a practical guide for healthcare professionals will operationalize the identified recommendations. This resource will translate insights from the field and strategic advice into actionable tools, enabling the useful, secure, and compliant use of AI systems within care settings.

PROPOSED ACTION: Production of a guide to support the proper use of AI systems in healthcare settings

The guide will aim to:

- Clarify the legal and regulatory framework to be implemented by healthcare facilities and healthcare professionals;
- Issue best practice recommendations to promote the proper use of AI in healthcare settings. These recommendations may be weighted according to their impact on the quality and safety of care.[4]

TARGETS • Healthcare facilities and healthcare professionals.

Resource-efficient and eco-conscious AI:

The development of AI systems in health must be part of a global efficiency approach integrating the business, technical, economic and environmental dimensions. This means thinking about AI systems not only in terms of performance and accuracy, but also taking into account their ecological and energy footprint, right from the design phase.

PROPOSED ACTION: Resource-efficient and eco-conscious AI

A first way forward is to foster a shared approach to infrastructure, be it computing power (sharing of GPUs, clusters, servers) or storage (sharing of volumes, cloud instances, etc.). This logic avoids duplication or underuse of costly and energy-intensive infrastructure, while strengthening cooperation between actors.

Optimising AI approaches by considering lighter, simpler and targeted models is also a strong lever for efficiency. It is not always a question of mobilising deep neural networks or massive models, especially if the tasks to be solved do not require it. Reducing the size of the models and adapting the frequency of retraining significantly reduces the need for calculation. This results in calculation savings, but also in a direct reduction of the environmental footprint. Solutions exist to measure the energy consumption of a drive, or to calculate the carbon footprint of a model per user or per query.[5] The integration of such metrics into project dashboards will have to be studied to initiate a continuous improvement approach.[6]

TARGETS • Industry actors, healthcare facilities.

(4) More details: https://www.has-sante.fr/upload/docs/application/pdf/2025-04/note_de_cadrage_-_ia_en_context_de_care_accompany_les_usages.pdf
(5) Example of an open access calculator: https://www.green-algorithms.org/
(6) Example of an open access calculator: https://www.green-algorithms.org/
alites/referentiel-pour-mesurer-et-reduire-impact-environnemental-de-ia/»https://www.afnor.org/news/referential-to-measure-and-reduce-environmental-impact-of-ia/

3. Concrete use cases on artificial intelligence systems in the health sector

An in-depth analysis was then carried out to segment and select topics of interest in order to identify emblematic use cases of AI applications in health.

3.1 Methodology for identifying topics and associated use cases

Nine themes could be identified in the event of the use of AI in health, in particular with:

- the state of play of actions carried out on AI in health;
- mapping the supply of digital health care;
- feedback from members of the AI in Health Steering Committee;
- the collection of feedback from the working group of the digital health council (CNS) «AI strategy in health»

Each use case was then detailed by means of a SWOT summary available in Annex III (of strengths, weaknesses, opportunities and threats) and an assessment based on the following six criteria:

1. Public health needs and public interest
2. Technological maturity
3. Availability and quality of health data
4. Operational feasibility
5. Framework and associated costs
6. Implementation deadlines

3.2 Identification of use cases of AI systems in health

Use cases of AI in health have been proposed in the list of nine topics identified according to the criteria mentioned above in the methodology section.

1. ACCESS TO CARE

- Development of tools for professionals to guide patients toward appropriate healthcare facilities based on their condition, while optimising the allocation of emergency medical resources.

2. PATHWAY

- Optimisation of the patient care pathway (e.g., oncology)

3. CARE ACTIVITIES

- E.g., automation of consultation and medical report transcription to reduce the administrative burden on healthcare providers.
- E.g., alert system to ensure safe prescribing.

4. TECHNICAL PLATFORMS

- Assistance in the early detection of breast cancer through AI-powered automated analysis of mammograms
- Automation of anatomopathological analysis

5. PREVENTION

- AI systems for predicting individual risk and adapting prevention plans (chronic diseases): e.g., detection of cardiovascular conditions, etc

6. LOGISTICS

- Prediction of equipment and medication needs to prevent shortages and reduce waste, predictive modeling of demand, and prevention of supply disruptions.

7. ADMINISTRATIVE

- Simplification and optimisation of administrative processes (scheduling management, billing and financial tracking, coding assistance)

8. RESEARCH

- Identification of new drug candidates
- Development of new evaluation methodologies

9. MANAGEMENT

- Modeling and monitoring of key indicators for managing the public health system (e.g., territorial organisation, infectious risk prevention, population health…)
- Analysis of patient satisfaction surveys (IFAQ) using AI systems

3.3 Summary table of the SWOT analysis of AI in health use cases

A SWOT analysis (strengths, weaknesses, opportunities and threats) of each identified use case has been summarised in the table below.

We have also proposed a structured approach to the AI in health strategy, supporting the use cases specified above according to the level of progress compared to the AI in Health Baselines (lifecycle stages of AI systems) as specified in Annex IV.

USE CASES	FORCES	WEAKNESSES	OPPORTUNITIES	THREATS
AI for Access to Care (SAMU/SMUR: Urgent Medical Aid Service / Mobile Emergency and Resuscitation Service)	Optimization of resources, faster referral of patients	Complex integration with IS, important need for training	Reduction of response times, improvement of territorial coverage	Legal liability in case of error, resistance to change of professionals
AI in Health Pathways (Oncology)	Improved coordination, early detection of complications	Strong reliance on structured data, high deployment costs	Replicable model to other chronic diseases	Risk of digital divide, privacy issues
Voice recognition for healthcare professionals	Reduced administrative burden, facilitated documentation	Reliability varies according to sound and speaker context	Harmonization of practices, significant time savings	Voice data security issues, heterogeneous adhesion
Digital medical devices (ECG, imaging)	Rapid diagnostic support, reduction of waiting time	Quality dependent on learning bases	Diagnostic capacity building in under-endowed areas	Algorithmic bias, regulatory burden
Securing prescription services	Reduction of dangerous interactions, decision support	Overloading alerts, adapting to existing software difficult	Prevention of serious adverse reactions	Liability in case of bad recommendation
AI in technical trays (diagnostic aid – ex: Anatomopathology)	Improved diagnostic accuracy, standardization of practices	Need for rigorous scientific validation, heterogeneity of imaging practices	Reinforcement of secondary prevention, reduction of diagnostic delays	Risk of loss of human expertise, very restrictive regulation
Personalised prevention through AI (chronic diseases)	Better risk stratification, earlier orientation	Lack of clinical validation, heterogeneous data	Population deployment, increased effectiveness of prevention plans, particularly in My Health Area	Acceptability, data protection, unequal access
Logistical optimization (stocks, supplies)	Prevention of ruptures, better forecasting of needs	Dependence on unreliable histories, rigidity of models	Reduction of waste, continuity of care in crisis	Cyber threats, difficulty adapting in the event of an exceptional event

USE CASES	FORCES	WEAKNESSES	OPPORTUNITIES	THREATS
Automated Hospital Planning	Better organisation of human resources, reduction of planning conflicts	Low flexibility in the face of contingencies, lack of buy-in	Reduction of organizational stress	Incomprehension of the realities on the ground
AI-assisted medical billing and coding	Improved coding quality, increased productivity	Complex interoperability, necessary training	Reducing fraud, better budget management	Dependence on proprietary systems
Discovery of new drugs	Acceleration of the R&D pipeline, rapid identification of molecules	Long validation, limited access to data	New partnerships with and by industry, therapeutic innovations	High regulatory constraint, uncertainty about results
AI assessment	Optimization of trials, better patient selection	Long ethical and scientific validation	Innovative methods, accelerating market access	Acceptability by authorities, regulatory complexity
Health system management	Consolidated vision, results-oriented management	Uneven data quality, possible under-exploitation	More targeted public policies, enhanced transparency	Overinterpretation or biased decisions
Improving patient care through AI	Advanced search in the medical history of My Health Area	Complex integration with IS	Better support	Regulatory constraint, liability in case of bad recovery

4. Proposals for use cases and actions in the identified thematic cases, recommendations, and perspectives

Following the identification of the nine priority themes and the first emblematic use cases of Artificial Intelligence applications in health, working groups were set up in consultation with the Digital Health Council, with the aim of stimulating, refining and consolidating these pre-identified use cases. The main objective of this approach was to identify, on the basis of the use cases examined, key actions enabling harmonised dissemination to all stakeholders.

Proposals for action by theme and by use case are detailed below:

Thematic	Action name	Background	Objective
Access to care	**Develop a patient grading and referral support tool for healthcare professionals**	Faced with difficulties in accessing care and sometimes complex pathways for healthcare professionals to manage, patient grading and referral tools for healthcare professionals can help to streamline pathways, optimise medical resources and better meet patients' needs.	**Assist in the development of AI to support healthcare professionals to facilitate access to care:** qualification, gradation and orientation of patients according to the severity to fluidize the management. **Identify and support the deployment, in real life, of concrete experimental projects carried out** by health care facilities engaged in the digital transformation of critical care (reduction of errors and bias, acceleration of medical decision-making and anticipation of patient flows)
	AI and patient use: ensuring quality and safety of uses, trust and health democracy	Generative artificial intelligence is already deployed and used by patients, including via health chatbots, but its use often remains unframed on consumer tools not adapted to health. This is all the more the case in the field of mental health, where the quality and relevance of counselling is important.	**Put in place governance to ensure the quality of the advice provided and to prevent any risks associated with its use**, while ensuring that patients and citizens are fully involved in these processes, **in particular with Mon espace santé**. Similarly, AI must be a tool for health democracy and not a source of mistrust.
Route	**Map pathways and identifying risks of care breaks**	Patient care pathways are often complex, fragmented and difficult to trace on a large scale, making it difficult to identify breakpoints.	**Map healthcare pathways to remove existing barriors, and developing tools to identify the risk of failure** in healthcare pathways for patients using AI adapted to process mining methods.

Thematic	Action name	Background	Objective
Caregiving activities	**Structure medical reports through AI to improve the work of practitioners**	On average, 20% of caregiver time is dedicated to administrative management. Precious time at the expense of caregiver time and the quality of the doctor/patient relationship. Moreover, the structuring and integration of medical data remains heterogeneous and often under-exploited, limiting their re-use for research, DMP implementation and route optimisation.	**Enable broad uptake of AI systems, including generative ones, that have demonstrated their efficiency and usefulness for professionals.** These tools, including those for structuring medical reports, must make it possible to regain care time, improve the doctor-patient relationship, and help structure the data (research, DMP implementation, etc.). It can be extended to other tools using speech-to-text, such as the generation of address letters, consultation reports or orders, but also telephone appointment-taking assistants for example.
	Develop a state medical knowledge platform	Access to the standard of medical knowledge (medical recommendations, medical rules, decision trees, etc.) and key to developing trusted AI in the services of professionals (diagnostic assistant, prescription assistant, prevention assistant, assistance with sorting/care pathways, assistance with evaluation, calculation of scores) There is now a proliferation of sources (HAS, SPF, learned societies, etc.) and a low level of APIsation. Work has begun to this end: HAS, NICE Syndication API (UK), **Helsebiblioteket.no** (Norway), HHS Syndication Storefront (USA), Digital Health Standards Catalogue (Australia), EBM France.	**Develop an API sandbox environment and actionable medical knowledge platform for developers, professionals and research.** Example: develop automated tool(s) for aligning French medical information terminologies with international standards based on automatic natural language processing
Logistics	**Reduce waste in the operating room with the help of an AIS**	The analysis of current practices in the operating room reveals a significant waste of sterile equipment, particularly because of the lack of an approach adapted to the habits of surgeons and the types of interventions.	**Integrate an AI model to optimize operating kits to reduce waste**, improve traceability and align real consumption with best practices, while providing a more responsible economic and environmental vision.
	Explore the potential of AI for optimising working time in health, social or medico-social institutions (planning & RH)	The management of hospital working time, which has long been structured around declarative or semi-automated logics, is now facing increasing limits: complexity of cycles, expectations of professionals (particularly regarding QVCT and work-life balance), heterogeneity of benchmarks, mismatch between theoretical planning and operational realities, management of absenteeism and vacancies. These tensions contribute to the demobilization of teams and lower efficiency of organizations.	**Launch a call for expressions of interest to promote ownership of artificial intelligence tools to improve work organisation and human resources management**, and structure an ecosystem of sharing and feedback, allowing all hospital stakeholders to benefit from the lessons learned from these initiatives.

Thematic	Action name	Background	Objective
Administrative	**Automate the coding and reporting of indicators**	There is a significant administrative burden for clinicians, linked to the coding of diagnoses from hospitalisation reports. For example, pathos cuts in EHPAD or the deployment of ICD-11 are essential to better describe care pathways, ensure the financing and monitoring of indicators but complicated and time-consuming to implement.	**Code 90% of diagnoses automatically by 2031 using a national platform to free up medical time, reduce the risk of error, improve traceability, standardise data.** Ex: increase the frequency of renewal of Pathos cuts for healthcare facilities
Research	**Build control arms with AI to facilitate the research and evaluation of medicines and medical devices and DM DiVs**	A synthetic control arm is a control group built from existing data, to avoid including a real group of patients receiving placebo. It allows clinical research to reduce the number of patients exposed to placebo, speed up and reduce the costs of trials (useful for biotechs), test treatments for rare or highly targeted populations.	**Develop open source methods to reliably build control arms**, reduce regulatory uncertainty, and co-construct approaches accepted by academic, industry and regulatory actors.
	New assessment methodologies for AI-embedded digital medical devices	In a European regulatory landscape in full structuring, marked by the multiplication of texts governing the use of AI and MDs which have significant potential for the care system but also many risks for the patient, it becomes essential to ensure a rigorous and adapted evaluation of these technologies. This assessment adapted to the specificities of AI will be able to maximise the positive impacts for patients, while securing market access and reimbursement for these technologies, and thus support the emergence of truly useful and safe tools, at the service of care pathways.	**Define assessment frameworks adapted to digital medical devices (DMDs) incorporating AI through the construction of robust methodological foundations for clinical, regulatory and organisational assessment.** This can build on the many ongoing initiatives described in section II.5. Technology - Lifecycle of AI systems in health - Validation, certification, evaluation »

Thematic	Action name	Background	Objective
Technical Platforms	**Supervise and finance the use and evaluation of pro-use NMDs with AI, in particular for the early detection of breast cancer**	Digital medical devices (DMDs) for professional use, often based on AI, support healthcare professionals in diagnosis, follow-up or treatment. They are therefore essential to improve patient care and support the work of professionals. They contribute to more targeted, faster and less error-prone medicine.	**Consider a long-term mechanism to regulate and finance the use and evaluation of digital medical devices for professional use.** A first use case could concern tools to assist early detection of breast cancer through automated mammography analysis.
	Automate analysis of anapath blades	Anatomocytopathology allows the analysis of tissues and cells to establish an accurate diagnosis of diseases, and guide the choice of treatments, particularly in oncology (75% of acts). It is estimated that 15 million acts of anapathy and 29 million glass blades are performed per year.7	**Define a framework for the deployment of digital anatomy pathology blade reading and analysis solutions** in healthcare facilities. This swarm will facilitate the pooling of tools, strengthen the standardization of practices and allow the constitution of richer databases. It will thus contribute to the training of robust AI models and the development of new algorithms.
Prevention	**Improve the prediction of individual risks and adapt prevention plans (e.g. chronic diseases)**	Prevention, especially of chronic diseases, requires a coordinated mobilization of health professionals, patients and digital tools. Artificial intelligence can play a key role in strengthening this momentum throughout the prevention journey, from early detection to long-term support.	Strengthen cardiovascular prevention through actions throughout the care pathway: 1. **Facilitate the transfer of skills between specialists and primary care professionals through AI** by, for example, deploying diagnostic support tools for reading ECG, echocardiography or electrophysiological signals by general practitioners and/or nurses. 2. **Deploy digital medical assistants** for healthcare professionals 3. **Implement smart health companions to strengthen prevention** at all three levels: primary, secondary and tertiary.
Management	**Analyze and monitor public health system management indicators**	The health system must face the challenges of an ageing population, climate risks and challenges, shortages of health workers and future health crises. At the same time, the available data is increasingly rich (EEDS regulation, dual strategy data & AI) and presents a strong potential for technological innovations in modeling (France 2030	**Create a tool to support public decision-making, decision-making support for territorial actors**, impact assessments for innovative devices, etc. using a digital twin of the health system: Junior Project.

(7) Source: https://france-biotech.fr/wp-content/uploads/2024/07/20240704_Synthese-TF-ACP-5June-FINAL.pdf

CONTRIBUTORS

Coordination: DNS & DGOS

Steering Committee for AI in Health:
Ministry of Health and Access to Care

- **DNS :** Line Farah, Vincent Vercamer, Aymeric Perchant, David Sainati, Hela Ghariani
- **DGOS :** Yann-Maël Le Douarin, Judicaël Thévenard, Camille Oms
- **DGS :** Clément Lazarus, Camille Mesnage, Mélanie Cailleret
- **DSS :** Romain Bey
- **DREES :** Claude Gissot, Arnaud Bonnard

Health Innovation Agency (AIS): Charles-Edouard Escurat, Agathe Doutriaux, Florie Fillol

National Authority for Health (HAS): Corinne Collignon, Julie Marc, Simon Renner, Aude Rochereau

National Agency for Performance Support (ANAP): Stéphane Pardoux, Anaëlle Valdois

Caisse Nationale d'Assurance Maladie (CNAM): Laurie Soffiati, Erin Johns, Victor Mauvady

PariSanté Campus (PSC): Antoine Tesnière

Health Data Hub (HDH): Emmanuel Bacry, Nicolas Bellière, Rémi Ferraille

Directorate-General for Enterprises (DGE): Annaëlle Paris

AI in Health Strategy Working Group of the Digital Health Council (CNS):

Coordination of the Working Group: DNS, DGOS, UNPS (Mathilde Guest, Mélanie Ordines), France Asso Santé (Arthur Dauphin)

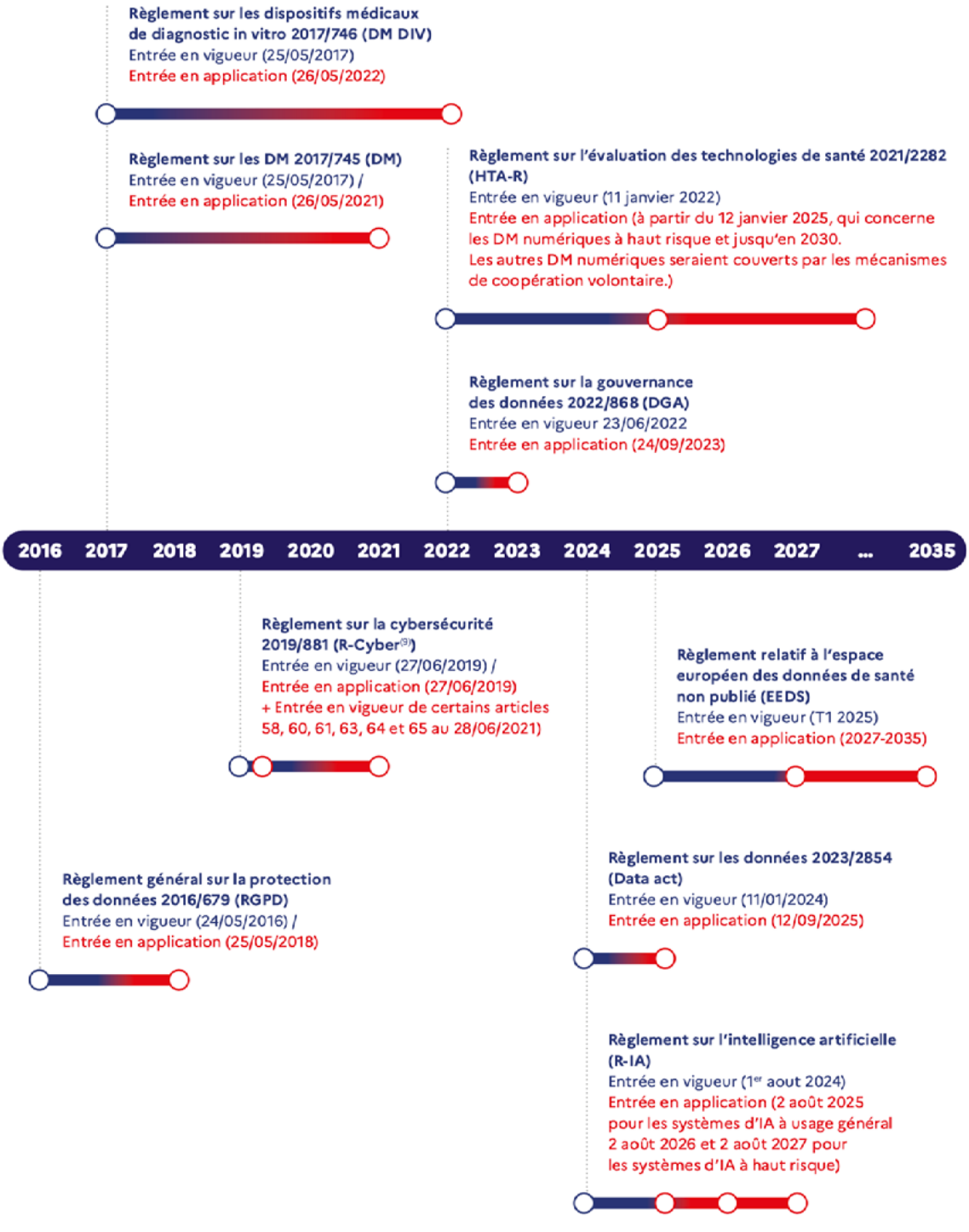
Working group members:

- ARS
- CNSA
- DGCS
- DGRI
- FHF, FHP, FEHAP
- INRIA
- LEEM, SNITEM, France Biotech, Numeum, FEIMA
- Other stakeholders
- Members of the COPIL «Coordination IA en santé»

Rédaction coordonnée par Line FARAH (DNS)

ANNEX 1
SUMMARY OF VARIOUS EUROPEAN REGULATIONS IMPACTING DIGITAL HEALTHCARE SOLUTIONS

A decade marked by numerous European regulations with structuring impact on digital healthcare solutions (illustration only available in French):



(9) Les DM et DM/DIV sont exclus du Règlement

ANNEX 2
MAIN PROJECTS CARRIED OUT BY THE HIGH AUTHORITY FOR HEALTH ON AI

The main work currently being carried out by the High Authority for Health (HAS) on AI is detailed below (only available in French): **Planned publications for 2025**

- Mapping of the different types of assessment for digital health technologies based on their purposes, implementation methods, and associated assessment criteria
- Guide to conduct budget impact analysis to provide tools for healthcare professionals or healthcare facilities wishing to carry out a budget impact analysis prior to purchasing a DMD, including those embedding AI, for professional use, in order to support the economic side of decision-making.
- Medical-technical evaluation of AI-enabled DMDs for professional use as part of a pilot project with the aim of developing an evaluation framework tailored to digital health tools, outside the scope of the HAS evaluation fields.
- Basic guides for internal evaluation processes or outsourced evaluations involving third parties.
- Recommendations for the proper use of generative AI for healthcare professionals.
- Development of a quality approach related to the use of an AI-enabled DMD in the healthcare context, integrating an assessment of the risks associated with the use of generative AI.
- Recommendations for the proper use of generative AI for healthcare professionals.
- Development of a quality approach related to the use of an AI system in the healthcare context, including a legal and regulatory overview and recommendations for best practices for healthcare institutions and professional users.
- As part of the SMATCH project of the Digital Health Research Program (PEPR SantéNum), identification of needs and applications for the evaluation of health technologies (medicines and DMDs) in interventional clinical trials, in interaction with research teams (INRIA, INSERM).

ANNEX 3
METHODOLOGY FOR SELECTING THEMES AND USE CASE

The themes and use cases were selected using a methodology based on six criteria (information only available in French)

CRITÈRE 1 **Besoin et intérêt en santé publique**	CRITÈRE 2 **Maturité technologique**	CRITÈRE 3 **Données de santé**
Ce critère évalue l'impact potentiel du cas d'usage sur la santé des populations ou l'offreur. Il inclut la prévalence de la protblématique ciblée, la gravité des conséquences sanitaires, l'amélioration attendue en termes de prévention, de diagnostic, de traitement ou de suivi, ainsi que les bénéfices pour l'équité et l'accessibilité aux soins.	Il s/agit d'évaluer le niveau de développement de la technologie d'A proposée et la technologie sous-jacente à l'IA. Ce critére repose sur des éléments tels que le niveau de preuve scientifique, la validation clinique (marquage CE, validation par des agences de santé, etc.).	Ce critère évalue la disponibilité, la qualité et la représentativité des données nécessaires à l'entrainement et à l'évaluation des modeles d'IA. Il prend en compte la robustesse des bases de données, leur accessibilité, aingi que le respect des réglementations en matière de protection des données de santé. Il s'agit de s'assurer de la capacité à mobiliser ces données de manière sécurisée et éthique, en garantissant leur interopérabilité avec les systèmes d'information de santé existants
CRITÈRE 4 **Faisabilité opérationnelle (RH)**	CRITÈRE 5 **Cadre et coûts associés**	CRITÈRE 6 **Délais nécessaires (à court, moyen ou long terme)**
Ce critère mesure la capacité des acteurs du système de santé à déployer et à intégrer l'IA dans la requise pour les professionnels de santé, l'adaptation des flux de travail et l'acceptabilité par les utilisateurs (patients et professionnels).	Ce critère peut prendre en compte les ressources financières et matérielles nécessaires et la conformité aux reglementations en vigueur pour la mise en couvre de ce cas d'usage sur l'A en santé (cn perspective de passage à l'échelle)	Il s'agit d'évaluer le temps nécessaire à l'implémentation effective du cas d'usage. Cela inclut les phases de développement, de validation réglomentaire, de formation des professionnels, d'intégration dans les systèmes d'information hospitaliers et d'sdoption par les utilisateurs finaux.

La méthodologie appliquée pour attribuer une note sur chaque critère afin de sélectionner les thématiques et cas d'usage à prioriser est disponible ci-dessous.

CRITÈRE	1/5 (FAIBLE)	3/5 (MODÉRÉ)	5/5 (ÉLEVÉ)
CRITÈRE 1 **Besoin et intérêt en santé publique**	Faible besoin ou impact limité sur la santé publique (ex. problème peu fréquent, faible gravité, bénéfices marginaux).	Impact modéré sur la santé publique (ex. problème répandu mais avec solutions alternatives déjà existantes).	Impact majeur sur la santé publique (ex. enjeu de santé publique prioritaire, réponse à un besoin médical non couvert).
CRITÈRE 2 **Maturité technologique**	Technologie au stade expérimental ou preuve de concept (peu ou pas de validation clinique, données limitées).	Technologie en phase de développement avancé, mais nécessitant encore des validations (ex. essais cliniques en cours, début de marquage CE).	Technologie mature et validée (ex. largement utilisée, données robustes, conformité réglementaire établie).
CRITÈRE 3 **Données de santé**	Données inexistantes, très limitées ou non représentatives. Problèmes de qualité, de fiabilité et d'accessibilité (ex. absence de bases de données adaptées, manque de standardisation, absence de cadre réglementaire).	Données disponibles mais nécessitant des efforts d'exploitation et de standardisation (ex. bases de données partielles, nécessité d'anonymisation, interopérabilité limitée avec les systèmes existants).	Données robustes, représentatives et facilement mobilisables. Disponibilité de bases de données de haute qualité, standardisées et conformes aux exigences réglementaires.
CRITÈRE 4 **Faisabilité opérationnelle (RH)**	Mise en œuvre très complexe (besoin de formations longues, résistance des professionnels, incompatibilité avec les pratiques actuelles).	Mise en œuvre envisageable mais nécessitant des adaptations (formation spécifique requise, ajustements des processus cliniques).	Mise en œuvre facile et immédiate (formation minime, compatibilité avec les flux de travail existants, forte acceptabilité).
CRITÈRE 5 **Contraintes et coûts associés**	Coûts et contraintes élevés (investissement majeur, maintenance complexe, nombreux obstacles réglementaires).	Coûts modérés et contraintes gérables (budget important mais soutenable, nécessitant des ajustements réglementaires).	Coûts faibles et peu de contraintes (solution peu coûteuse, facile à maintenir et conforme aux réglementations).
CRITÈRE 6 **Délais nécessaires (à court, moyen ou long terme)**	Mise en place à long terme (>5 ans), nécessitant de nombreuses étapes de validation, tests et développements.	Mise en place à moyen terme (2-5 ans), avec des ajustements nécessaires mais une implémentation progressive possible.	Mise en place rapide (<2 ans), solution prête à être déployée avec peu d'obstacles techniques ou réglementaires.

ANNEX 4
VISION MATRICIELLE DE LA STRATÉGIE IA EN SANTÉ PAR CAS D'USAGE

Cette section propose une approche structurée de la stratégie IA en santé en France, en étayant les cas d'usage en fonction du niveau d'avancement par rapport aux socles communs sur l'IA en santé (étapes du cycle de vie des systèmes d'IA).

Cas d'Usage	Identification du besoin et cadrage	Collecte et préparation des données	Modélisation et entraînement	Validation et évaluation	Réglementation et certification	Déploiement et intégration	Suivi post-commercialisation et amélioration continue et cybersécurité
Accès aux soins (SAMU/ SMUR)	✔	↺ ✔	↺ ✔	↺	↺	↺	↺
Parcours patient	✔	↺ ✔	↺ ✔	↺	↺ ✔	↺	↺
Activités soignantes	✔	✔	✔	↺	↺ ✔	↺	↺
Plateaux techniques	✔	✔	✔	↺ ✔	↺ ✔	↺	↺
Prévention	✔	↺ ✔	↺ ✔	↺	↺	↺	↺
Logistique	✔	✔	✔	↺ ✔	✔	↺	↺
Administratif	✔	✔	✔	↺ ✔	↺ ✔	↺	↺
Recherche	✔	✔	✔	✔	↺	↺	↺
Pilotage	↺ ✔	↺ ✔	↺ ✔	↺ ✔	↺ ✔	↺	↺

✔ **Étape bien avancée** ↺ **En cours d'étude et de mise en œuvre**

NOTE

French National Strategy for Artificial Intelligence and Health Data

Media relations:
cabinet of France's Minister of Health
and Access to Care, Dr. Yannick Neuder
Tél. : 01 40 56 60 60
e-mail: sec.presse.cabsante@sante.gouv.fr
Digital health delegation (DNS):
marion.fevrier@sante.gouv.fr

Édtion : Ministère du Travail, de la Santé et des Solidarités • Maquettage : Dicom des ministères sociaux / Parimage • Juillet 2025