AI FOR HEALTH

White Paper

AI in Health: Keys to Innovate While Addressing Digital Sovereignty Challenges

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Nesrine Benyahia, Founder and CEO, **DrData**

Elsa Biais-Sauvêtre, Senior Manager, Policy & Public Affairs, **Pfizer**

Marguerite Brac de La Perrière, Partner - Tech&Data, Healthtech, **Fieldfisher**

Yacine Daquin, Head of Legal, Health and Innovation, **Health Data Hub**

Paul de Balincourt, Consulting Partner, Healthcare Practice, **Artefact**

Yann-Maël Le Douarin, Head of the Health and Digital Transformation Department, **Directorate General for Healthcare Provision**

Jérôme Fabiano, Deputy Director General, **EIT Health France**

Manon de Fallois, Deputy Head of the Health Department, Legal Support Directorate, **CNIL**

Philippe Gesnouin, e-Health Program Director, **Inria**

Lucas Guichard, Head of technology - Datalab, **Presidency of the French Republic**

Chahra Louafi, Director of the Autonomous Patient Fund, **Bpifrance**

Dr. Louis Létinier, Co-founder, CMO and Head of Public Affairs, **Synapse Medicine**

Jean-Baptiste Masson, Director of the Decision and Bayesian Computation Laboratory - Epiméthée, **Institut Pasteur - INRIA**

Julie Paolantonacci, Principal, Real-World Solutions, **IQVIA France**

Raphaëlle Parker, Principal Scientist, **Johnson & Johnson Innovative Medicine**

Pr. Raphaël Porcher, University Professor - Hospital Practitioner, **AP-HP, Paris Cité University**

Iandry Rabearivelo, Chief Data Officer, **CircaGene**

Amélie Rocca-Serra, Public Affairs Senior Lead, **Doctolib**

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EXECUTIVE SUMMARY: OUR PROPOSALS TO FOSTER INNOVATION IN AI FOR HEALTH

The workshop we held at the French Ministry for Europe and Foreign Affairs on May 21st, 2024, unveiled potential solutions. These are summarised into key areas below, and are elaborated upon in following parts.

Design-thinking methods were employed to capture the essence of the two-hour debate. We hope this white paper will serve as a guide for developing innovative and effective strategies, thereby strengthening the ability of France and Europe to innovate in the health sector.

Establish sovereign, robust, and interoperable data infrastructures

- Facilitate data access through centralised or decentralised databases, building on existing initiatives like the European Health Data Space (EHDS)
- Support health innovation initiatives and medical research, while ensuring respect for privacy and data protection
- Establish clear rules, robust data governance strategies, and standardise data formats

Unite, collaborate, and finance

- Facilitate collaboration between the public and private sectors through a shared ecosystem
- Establish a roadmap for monitoring and decision-making through a public-private consortium responsible for investing in high-potential projects
- Launch a strategic plan for AI aimed at coordinating and guiding efforts, with priority objectives and key indicators
- Increase public funding and procurement, and facilitate private sector funding through grants and tax incentives
- Pool public funding at the European level

Harmonise the legal framework

- Increase awareness on applicable rules on information, data subject's rights and procedures for accessing health data
- Facilitate the distribution of new technologies using AI in health
- Reduce the administrative burden for startups and SMEs

Meet the real needs of ecosystem stakeholders and strengthen training

- Ensure that AI systems meet real needs and integrate into the work of health professionals and users
- Offer lifelong education to health professionals
- Train French and European AI developers and experts
- Strengthen the training of personnel responsible for applying regulations

Strengthen public trust

- Implement a data labelling and certification system
- Be transparent and implement effective communication to reassure users and health professionals about the benefits of AI

SOMMAIRE

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CONTEXT

01

METHODOLOGY

To address the topic of innovation in AI for health, while responding to the challenges of digital sovereignty, we identified and prioritised key issues related to digital sovereignty in the AI and health sectors.

The methodological approach was as follows:

- Individual reflection
- Pair discussions
- Discussions in subgroups of 3-5 people
- General sharing of ideas to all participants

This approach allowed for the **gathering and comparison of perspectives** in a plenary session, fostering a comprehensive and collaborative understanding among the various public and private stakeholders involved.

1/ Digital Sovereignty and Data Security

The choice of scope when it comes to digital sovereignty is a challenge for European stakeholders, who must **strike a balance** between **data protection**, **competitiveness**, and **international cooperation**.

Various options are available to decision-makers in this area, including national, European, or non-European partnerships. Each option presents pros and cons in terms of sovereignty, security, and innovation.

2/ Data Governance Strategy

Since health is a **competence reserved for Member States**, they have been authorised to introduce additional conditions to those of the General Data Protection Regulation (GDPR) concerning the processing of health data.

These **do not benefit from a harmonised framework within Europe**, with additional specific requirements for the hosting of health data in certain countries. In March 2022, the European Commission proposed the EHDS (European Health Data Space), a project that could address this lack of harmonisation. The creation of this framework was adopted by the European Parliament in April 2024.

3/ Building Data Infrastructures

Directly related to digital sovereignty, discussions on data infrastructures focused, among other things, on the following issues:

- **Interoperability**
- **Research**
- **Data pooling**
- **Pricing**

These issues are essential to support public health initiatives and medical research. We debated the **resources** needed to establish these robust infrastructures, as well as the **choice of essential data types** that must be secured and easily accessible.

4/ Data Access and its Legal and Ethical Framework

Access to data proves to be a determining factor in encouraging innovation. The challenge then lies in **striking a subtle balance** between **data protection** and **flexibility of use,** thus allowing the exploitation of new technologies while respecting the ethical and regulatory aspects that govern the use of health data.

Several regulations such as the GDPR or more recently the AI Act crystallise this regulatory challenge of harmoniously combining protection and flexibility.

5/ Suitability of AI Systems for Medical Needs and Training

We envisioned a system in which **AI systems** can be **funded**, **maintained**, evaluated, and **integrated** into the **daily practice of health professionals**, ensuring their relevance to the medical services provided.

Today, we realise that **health professionals lack sufficient training** and a clear understanding of the advantages and limitations of AI systems.

6/ Rights and Trust of Citizens

The development of AI systems in health is marked by the crucial question of **public trust.** Regarding citizens' rights over the **sharing of their data**, **clear and fair individual information**, accompanied by a **right to freely object**, seems to be an important step.

Transparency and **effective communication** are essential to establish this trust, which is a prerequisite for a wider and successful adoption of AI systems in health.

7/ Economic Challenges and Biases of AI Models

The challenges related to **economic attractiveness** and **market access pathways for AI systems** in health led us to consider the development of innovative solutions tailored to user needs. The market access pathway remains complex, requiring appropriate regulations and an enabling environment.

Furthermore, **biases in AI models**, stemming from **unrepresentative training data** and resulting **algorithmic biases**, can compromise the relevance and effectiveness of certain systems.

8/ Competitiveness Challenges

In addition to the economic challenges, there are also competitiveness issues, particularly concerning the **brain drain of French and European talent**, and the **sale of French and European companies to large groups outside European soil**.

The challenge of **training AI developers** and **specialists** in France and Europe also emerges as a decisive long-term competitiveness issue.

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COMMON CHALLENGES

02

Our focus then shifted to identifying obstacles within the health & AI sector. Following the same methodology, this second stage allowed us to **define the barriers** among the identified **challenges**, which could potentially **hinder the development** and **adoption** of AI in the health field.

Regulation

- Substantial **administrative burden**, hindering the ease and access to AI experimentation
- Understanding the **decision-making process** and identifying **relevant stakeholders** in health institutions, particularly **hospitals**
- Implementation and anticipation of various national and European regulations, notably the **AI Act** and the **GDPR**
- **Insufficient training** of agents responsible for **enforcing regulations**
- **Psychological barrier** for startups, regarding their perception of **regulatory complexity**, influencing their decision to launch and remain in France and Europe

Structuring and Coordination

- Absence of a **coordinating body**, of a clear structure, and of a unified decision-making entity for the entire EU market
- Insufficient and overly broad **common funding** for high-potential projects
- Lack of **common guidelines** for startups
- Lack of common **key indicators** to track specific objectives
- Absence of **interdisciplinary collaboration** between different AI experts
- **Evaluation processes** inadequate for the rapid evolution of AI

Sovereignty

- **Talent retention** in France and Europe
- **Sale** of French and European companies to large groups outside of European soil
- **Competitiveness** and **attractiveness**
- **Insufficient training** of French and European AI developers and specialists
- **Lack of awareness** regarding the existence of certain data centres, particularly the ones linked to sovereign institutions

Data Access

- Absence of a common pan-European **health data infrastructure**, even though the implementation of the EHDS is underway.
- Segmentation of **data formats**
- Difficulties in **training AI systems** with data, due to poorly understood data access procedures
- Challenges related to the **financing** and **maintenance** of French servers processing data
- A sense of **mistrust** among citizens, particularly regarding data confidentiality and security

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PROPOSED SOLUTIONS

03

The third and final part of the workshop was dedicated to **identifying solutions**, in light of the previously identified challenges and obstacles. The purpose of these solutions is to **create a sovereign and innovation-friendly environment**, enabling France and Europe to become global leaders in the AI for health industry, by stimulating research, development, and responsible adoption of these technologies.

1/ Foster Interdisciplinarity and Collaboration

By bringing together all AI & health stakeholders in a **collaborative** and **interdisciplinary ecosystem**, it is possible to create an environment conducive to innovation. This approach allows for the pooling and leveraging of individual expertise and skills, thus fostering the emergence of new and effective solutions.

2/ Labelling and Certification

To address the issues of citizen trust and data quality, the **creation of quality labels for health data** used in AI would help ensure their reliability for end-users and developers in Europe.

More broadly, the **establishment of a European health data certification system** would further strengthen this approach, ensuring compliance with existing ethical and technical standards. This system could also be applied to AI models and algorithms in a spirit of transparency, to ensure that the systems have a certain geographical origin, type of training, or specific type of operation. The European AI committee could play a role in the implementation and supervision of this system.

3/ Large-scale Investment in Projects and R&D

To overcome obstacles to innovation, one of the major priorities is the significant **increase in funding** and **public procurement** in health. This is particularly important in sectors where the potential of AI is promising, such as biotechnology, personalised medicine, or surgical robotics. This includes increased support for research institutes, public-private partnerships, and universities. At the European level, the logic of **pooling investments** remains a priority course of action.

In parallel, **private sector investment** should be encouraged and facilitated, through **tax incentives** and **subsidies** for companies investing in R&D in Europe.

To frame these investments and decide on which specific projects or sectors to invest in, a preferred solution is the creation of a **public-private consortium**. The aim would be to use this consortium to organise calls for expressions of interest, in order to **select high-potential projects** that could be supported to achieve faster proof of concepts.

4/ Construction of a European Health Data Infrastructure

The establishment of a pan-European infrastructure for the secure storage and sharing of health data is encouraged to provide researchers and health professionals with **access to vast and diverse data**, while ensuring respect for privacy. This access to data is essential to advance research and improve health. Although **sovereignty** is crucial for data security, it does not in itself guarantee protection against cyber threats.

This highlights the importance of **developing robust data defence and governance strategies**. This infrastructure could include the **creation of centralised or decentralised databases**. New techniques could be experimented with, such as federated learning.

The **standardisation of data formats**, mandatory for both primary and secondary use of data, would **facilitate interoperability** between countries and build an ecosystem of native health APIs.

The implementation of European projects like the EHDS can serve as a **structuring basis** to create standards for data and metadata standardisation, contributing to a coherent and effective European infrastructure.

5/ Development of a Strategic Plan for AI in Health

A comprehensive strategic plan for AI, at both the European and French levels, is proposed to **coordinate** and **focus efforts** effectively. This plan should establish major objectives to tackle priorities, with key indicators to encourage collaboration between the various stakeholders in the sector and promote a responsible and ethical use of AI in health.

6/ Strengthen our Training and Development Capacities

To stay competitive in the fast-paced race of AI development, and to quickly anticipate emerging challenges, it would be appropriate to strengthen training capacities. This involves **supporting the training of AI developers** to create AI systems for health. It also requires **investing in cutting-edge research infrastructure**. Finally, it is essential to **train hospital staff and company employees** responsible for **applying regulations** related to the use of AI, in order to better anticipate legal changes.

7/ Harmonisation of Regulations

The harmonisation of regulations is a means of **reducing barriers to the development and distribution of new health technologies**. An agile legal framework is needed that adapts to the innovation cycle and addresses the needs of facilitating access to health, and the dissemination of applicable rules regarding information and the exercise of user rights. Simplifying regulations for health startups and SMEs is also essential to **reduce administrative burden** and **encourage innovation and experimentation**, such as access to French supercomputers.

CONCLUSION

Our discussions highlighted the importance of a multidisciplinary approach to address the challenges of AI in health and stimulate innovation.

To meet these challenges, **close collaboration** between all stakeholders, united in a common and interdisciplinary **ecosystem**, is essential. A **strategic plan for *AI and health*** will enable the coordination of efforts and the establishment of priority objectives to be achieved.

The establishment of **robust health data infrastructures**, with **strong governance**, will facilitate **data access** while respecting security and ethical standards. These infrastructures incorporate the **creation of centralised or decentralised databases**, with standardised data to facilitate interoperability between different countries.

The implementation of simpler, more flexible, and harmonised **regulations**, accompanied by a reduction in **administrative burden**, is necessary to encourage innovation. It is necessary to provide **legal and administrative support** to innovation players, by recommending **best practices** and **guidelines** to follow, particularly with regard to new systems and texts such as the EHDS or the AI Act. The **harmonisation of rules** in Europe will simplify procedures and create an environment conducive to AI innovation in the health sector.

Significant **public funding** and an increase in **public procurement** are essential for Europe to remain in this race. The creation and monitoring of **public-private consortia** can propel high-potential projects, focusing on key sectors.

Training is a crucial lever to address the challenges. It is necessary to **train company** and **hospital staff** responsible for **applying new regulations**. For the safe adoption of AI technologies, it is also necessary to train health professionals in new AI technologies.

Finally, **data labelling** and **certification** will play a crucial role in validating practices and can help facilitate public trust.

The potential for the development of AI in health is immense. By following a coordinated, comprehensive, and collective plan, with an ecosystem-based operating model, we can strengthen our digital sovereignty, reduce our dependence, and avoid costly delays in the long term. This ambitious and collaborative dynamic will enable France and Europe to become leaders in AI and health.

Thank you !

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A follow-up to this workshop is planned to further explore the proposed solutions.

More opportunities for discussion are coming, and you can find all of our achievements on our website: *www.aiforhealth.fr/content/ecosystem*

If you would like to participate in our upcoming workshops, share your opinion, or be part of our next summit, please contact :

Sébastien Marguerès
sebastien.margueres@artefact.com

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Organisation : Sébastien Marguerès - *AI for Health Program Director, Public Affairs & Science Lead*
Facilitation : Christophe Fourleignie-Duc - *General Manager*
Note-taking and editorial collaboration : Diane Sales - *Service Designer*, Gabriel Roteta-Marañon - *Public Relations Project Manager*