Towards

European Health Data Space

November 28, 2022 – EHTEL SYMPOSIUM

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Ministerial Digital Health Delegation

French Ministry of Health and Prevention
Current status of EHDS proposed regulation

EU Council Presidency

**S1 2022**
- 04.05.22: Publication of the proposal
- June 2022: Instruction at council working parties starts
- 14.06.2022: EPSCO Luxembourg Presentation

**S2 2022**
- 1st draft of a compromise text on chapters II and III
- Progress report

**S1 2023**

**S2 2023**
France has been supporting the concept from start
To meet European challenges in health
France has been engaging on both sides of EHDS from start

European Health Data Space (EHDS)

- MaSanté@UE
  - MyHealth@EU
  - Primary use of health data

- DonnéesdeSanté@UE
  - HealthData@EU
  - Secondary use of health data

Comment contribuer ?
Participez à la concertation !

[European Health Data Hub logo]

[QR code with text: Participer à la concertation]
Way forward at the French Ministerial Digital Health Delegation

The Importance of smaller steps. Love It
The French eHealth landscape at a glance

Ministerial eHealth Delegation, Ministry of Health

National Digital Health Agency - ANS

Health Insurance CNAM

Health Data Hub

Regional/ local actors: ARS, GRAdes, hospitals, all actors of the digital health ecosystem...
A comprehensive strategy to implement and transform the delivery of digital Health in France 2019 – 2022, and a new one starting soon.
Former French digital health roadmap:
Five strategic focus areas for accelerating digital transformation

1st Orientation
- **Strengthening the governance of digital health**

2nd Orientation
- **Increasing the security and interoperability of health information systems**

3rd Orientation
- **Accelerating the deployment of core digital services**

4th Orientation
- **Deploying digital health platforms nationally**

5th Orientation
- **Supporting innovation and promoting stakeholder engagement**
Strengthening Digital Health governance - major national Milestones

2019
#MaSanté2022
#MyHealth2022
ehealth roadmap
Technical Doctrine

2020
Ministerial eHealth Delegation
Ethics Council

2021

2022

2023

Implementation of the Digital Health roadmap
French Digital Health Roadmap acceleration

MyHealthSpace

Ministerial Digital Health Delegation
France National digital health strategies and funding programs

Ministerial digital health roadmap
2018 – 2022
5 orientations, 25 actions
Accelerate the digital shift

Ségur de la santé – digital component
July 2020 – July 2025
€ 2 billion, including € 600 mio. medico-social sector
Modernization, interoperability, security of health information systems, etc.

PariSanté Campus
2020 – 2028
€ 400 mio.
Birthplace of tomorrow's digital health

« Grand Défi » AI & Health
2019 - 2023
€ 30 mio. to improve medical diagnostics using artificial intelligence

Medical Device Plan
2022 - 2026
€ 400 mio. to develop and produce innovative medical devices and digital and disruptive healthcare solutions

Digital Health Acceleration Strategy
2021 – 2025
€ 718 mio. to make France a leader in digital health
# France Digital Health Acceleration Strategy

A STRATEGY DESIGNED AND IMPLEMENTED IN COLLABORATION WITH REPRESENTATIVES OF THE ECOSYSTEM

## 2021

- **A large public consultation** to build the strategy
- 50 Qualitative interviews
- 429 réponses
- 6 months of interministerial working groups
- Une préparation collective aux appels à projets et à manifestation d'intérêt
- 12 webinars
- 120 meetings

## First semester of 2022

- **A « Tour de France »** to meet the actors who are making digital health happen in the regions
- 9 stages
- 14 field visits
- More than 600 meetings with actors of the ecosystem
- 27 roundtables and workshops
- More than 1,700 participants
# France Digital Health Acceleration Strategy

**A STRATEGY ALREADY WELL UNDERWAY WITH ANNOUNCED AMBITIONS FOR 2025 AND BEYOND**

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<tr>
<th>Today</th>
<th>Within the next 5 years</th>
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<td>Around <strong>150 M €</strong> committed at date</td>
<td>• <strong>500 000 health apprentices and trainees</strong> obtained digital health capacity building</td>
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<td>More than <strong>60 projet laureates</strong> rewarded</td>
<td>• 30 structures selected as third-party experimentation sites, <strong>100 experimented solutions</strong></td>
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<td><strong>31 launched actions</strong> including 9 calls for projets/ for expression of interest (AMI)</td>
<td>• <strong>2 new sustainable pathways to reimbursement</strong> for digital solutions</td>
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<td>More than <strong>500 candidates</strong> to all digital health calls</td>
<td>• <strong>70 clinical evaluations</strong> of digital medical devices funded</td>
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<td>• <strong>1 national gateway</strong> to facilitate the life of digital health entrepreneurs</td>
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<td>• Achieve scientific breakthroughs and bring out <strong>disruptive technologies</strong></td>
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One year of the Digital Health Acceleration Strategy, 2 years of G_NIUS

November 23, 2022
France Digital Health Acceleration Strategy

A €718 MILLION STRATEGY LAUNCHED ON OCTOBER 18, 2021

- Fostering the conditions for the **large-scale deployment** of successful projects
- Accompany the implementation of **real-life experimentations** and **first industrial stages**
- Support the **development** of structural projects to strengthen strategic advantages
- Prepare the future generation of key digital health technologies and facilitate **rapid transfer mechanisms of research results**
- Develop **stakeholder training**, stakeholder trust and professional attractiveness of the sector

Call for expression of interest for digital health (AMI)
STRATEGY FOR DIGITAL HEALTH in EUROPE
A single market approach empowered by the European Health Data Space

European ethical principles for digital health

Mission
To implement ethics by design Digital Health globally and report transparently to the citizen

Vision
To ensure progress in digital health follows humanistic values assets and tradition, and make it an enabler of success.

A European way of using Digital health
Towards a progressive harmonisation of market access

Digital medical devices
- Accelerate European market access through clinical evaluation criteria harmonisation for Digital Medical Devices (DMDs)

Digital health ecosystems
- Support European digital health entrepreneurs to navigate through the digital health ecosystem and accelerate market access in the EU

Initial steps
The different national laws of the EU Member States lead to different categorisations of DMDs and different clinical evaluation requirements, hence the need for harmonisation of the evaluation of digital medical devices to facilitate their integration into European reimbursement baskets and universal health coverage.

By developing a joint approach producing concrete outputs that can be used in the Member States, duplication of assessments can be avoided, patient access to innovative and proven digital health solutions can be accelerated, and health systems improved.
G_NIUS is a French initiative, part of the 2021-2025 Digital Health Acceleration Strategy (670 B€) willing to connect to European colleagues. A single gateway to support digital health entrepreneurs navigating through the ecosystem, save time and accelerate access to the market of their solutions.

**G_NIUS services**

- Decrypt national digital health regulation
- Identify actors of the digital health ecosystem
- Follow your healthcare pathway (MonEspaceSanté, Ségur numérique, National Health Identity (INS)…)
- Decipher funding keys and trends
- Commercialize a digital medical device
- Identify e-health events
- Discover eHealth news
- New: map of EU-level markets and hubs
International Service: Decoding digital health abroad

One «home page »

Decoding e-health abroad

If you want to develop internationally, take a look at our country fact sheets.

Country fact sheets

Helping entrepreneurs discover international e-health ecosystems and understand all steps to access the market there

Germany

Pioneering reimbursement of digital innovation and health applications

- The German healthcare system is financed through a system of compulsory public and private insurance. The health insurance funds are the key actors, although they operate within a legal framework set by the federal state and implemented by the 16 Länder (regions).
- It is the first country to have implemented the “Health Certificate” for reimbursement of mobile applications (SCA).

Belgium

Several initiatives to drive the digital transformation of healthcare

- At the European level, the country is very actively involved in major health information projects.
- Health Data Hub is the platform to facilitate and standardize the registration of health data.

eHealth in Germany

Key figures

83M people

2nd largest player in healthtech

13.1% health expenditure as a share of GDP in 2020

Decision-making powers are divided between the 16 Länder, the federal government, and the statutory professional organizations

The federal government prepares draft laws, regulations, and administrative provisions and the Länder are responsible for implementing them. The Länder are also responsible for ensuring compliance with national regulations. The Länder decide on health insurance contributions and benefits for both public and private, organized around public health insurance funds. Physicians and health insurance companies directly, not patients.

Germany has the second-largest industry in terms of medical technology after the United States.

Scan to access the service!