

# Planned digital medical device (DMD) reimbursement in France and perspectives for harmonized evaluation in the European Union

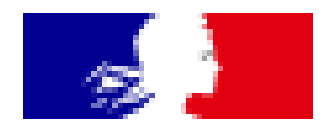
**November 23, 2022**

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**Ministerial Digital Health Delegation**  
**French Ministry of Health and Prevention**

# The French eHealth landscape at a glance



Ministerial eHealth  
Delegation, Ministry of  
Health



**MINISTÈRE  
DES SOLIDARITÉS  
ET DE LA SANTÉ**

*Liberté  
Égalité  
Fraternité*

National Digital Health  
Agency - ANS



Health Insurance  
CNAM

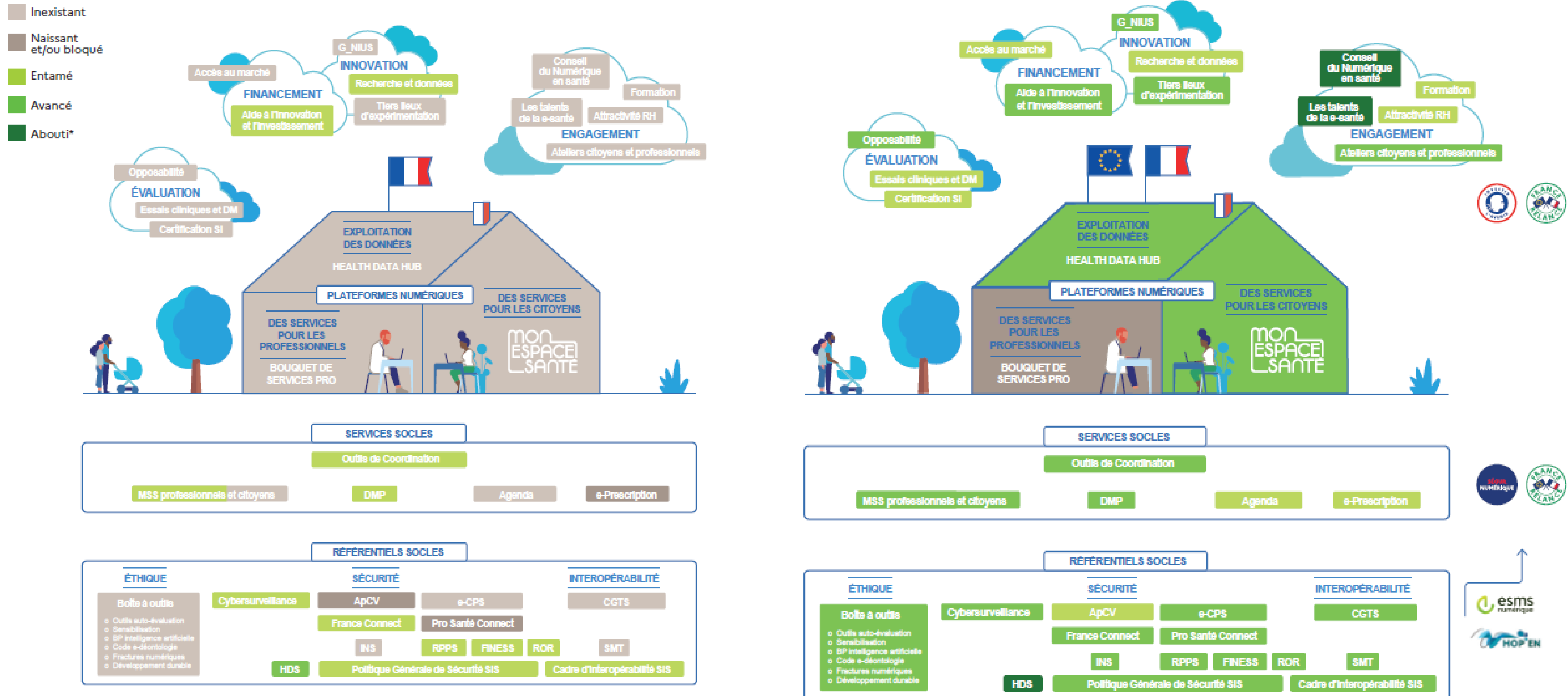


Health Data Hub



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





# 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



Implementation of the Digital Health roadmap



French Digital Health Roadmap acceleration

2019

2020

2021

2022

2023

#MaSanté2022  
#MyHealth2022  
ehealth roadmap  
Technical Doctrine



Feuille de route  
« Accélérer le virage numérique »



Ministerial eHealth  
Delegation  
Ethics Council



Dominique Pon  
& Laura Létourneau

Ministerial Digital Health Delegation



MyHealthSpace



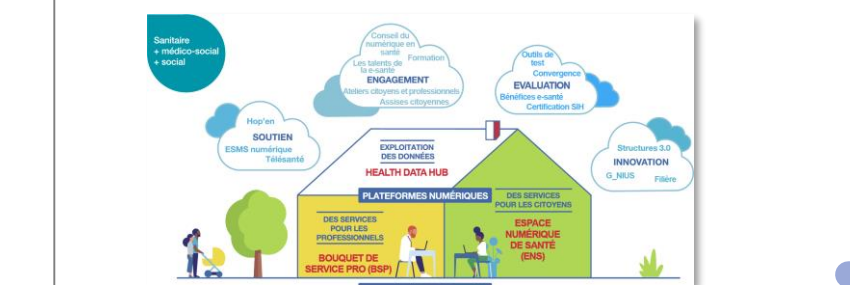


## National digital health strategies and funding programs

## Ministerial digital health roadmap

2018 – 2022

## 5 orientations, 25 actions Accelerate the digital shift



● **Séjour 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.

**SÉCURITÉ**  
**DE LA SANTÉ**



**PariSanté Campus**

2020 – 2028

€ 400 mio.  
Birthplace of tomorrow's digital health



2018 2019 2020 2021 **2022** 2023 2024 2025 2026 2027 2028

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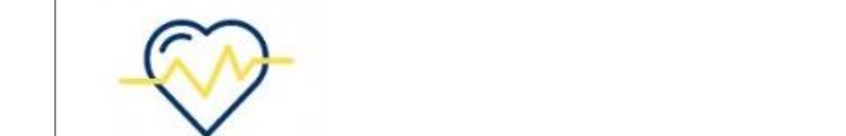
2018 2019 2020 2021 **2022** 2023 2024 2025 2026 2027 2028

2018 2019 2020 2021 **2022** 2023 2024 2025 2026 2027 2028

## « Grand Défi » AI & Health

2019 - 2023

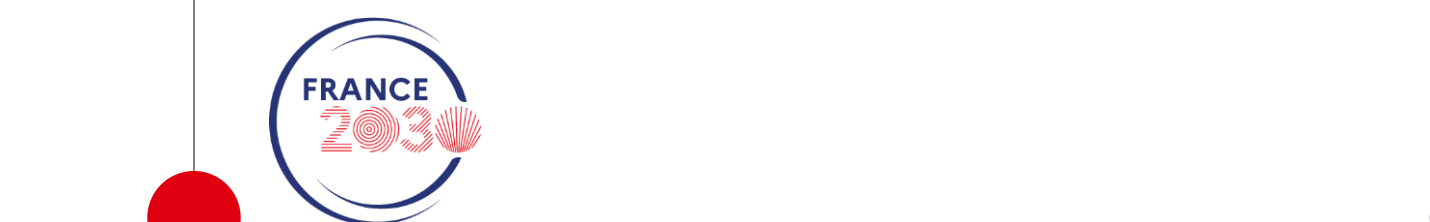
€ 30 mio. to improve medical diagnostics using artificial intelligence



## Health Medical Device Plan

2022 - 2026

|                    |  |
|--------------------|--|
| Medical<br>Digital | € 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



# 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

reponses

6

months of interministerial working groups

Une **préparation collective** aux appels à projets et à manifestation d'intérêt

12

webinars

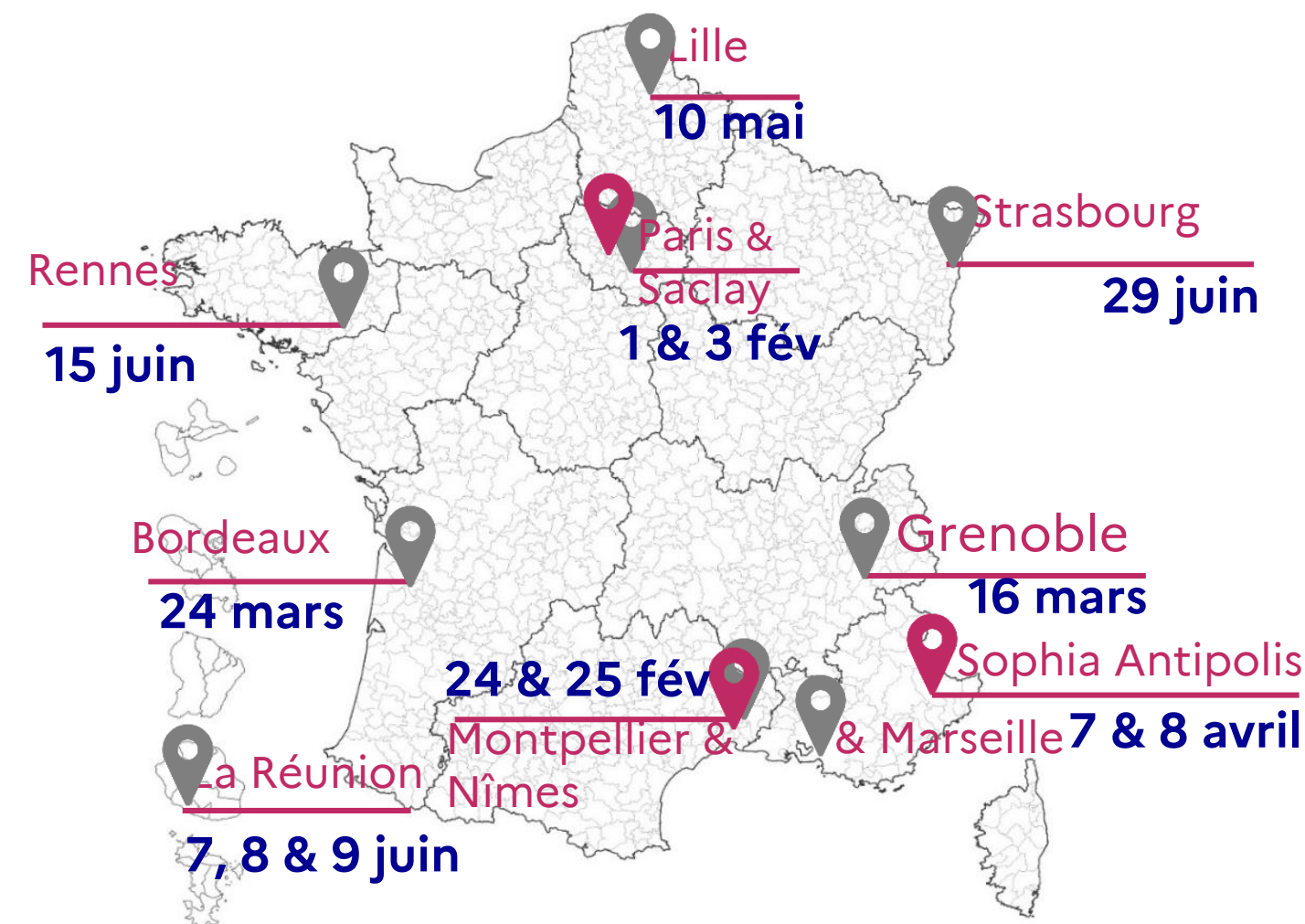
More than

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

# Digital Health Acceleration Strategy

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

## Today

Around **150 M €**  
committed at date

More than **60** projet  
laureates rewarded

**31 launched  
actions**  
including 9 calls for  
projets/ for expression of  
interest (AMI)

More than **500**  
candidates to all digital  
health calls

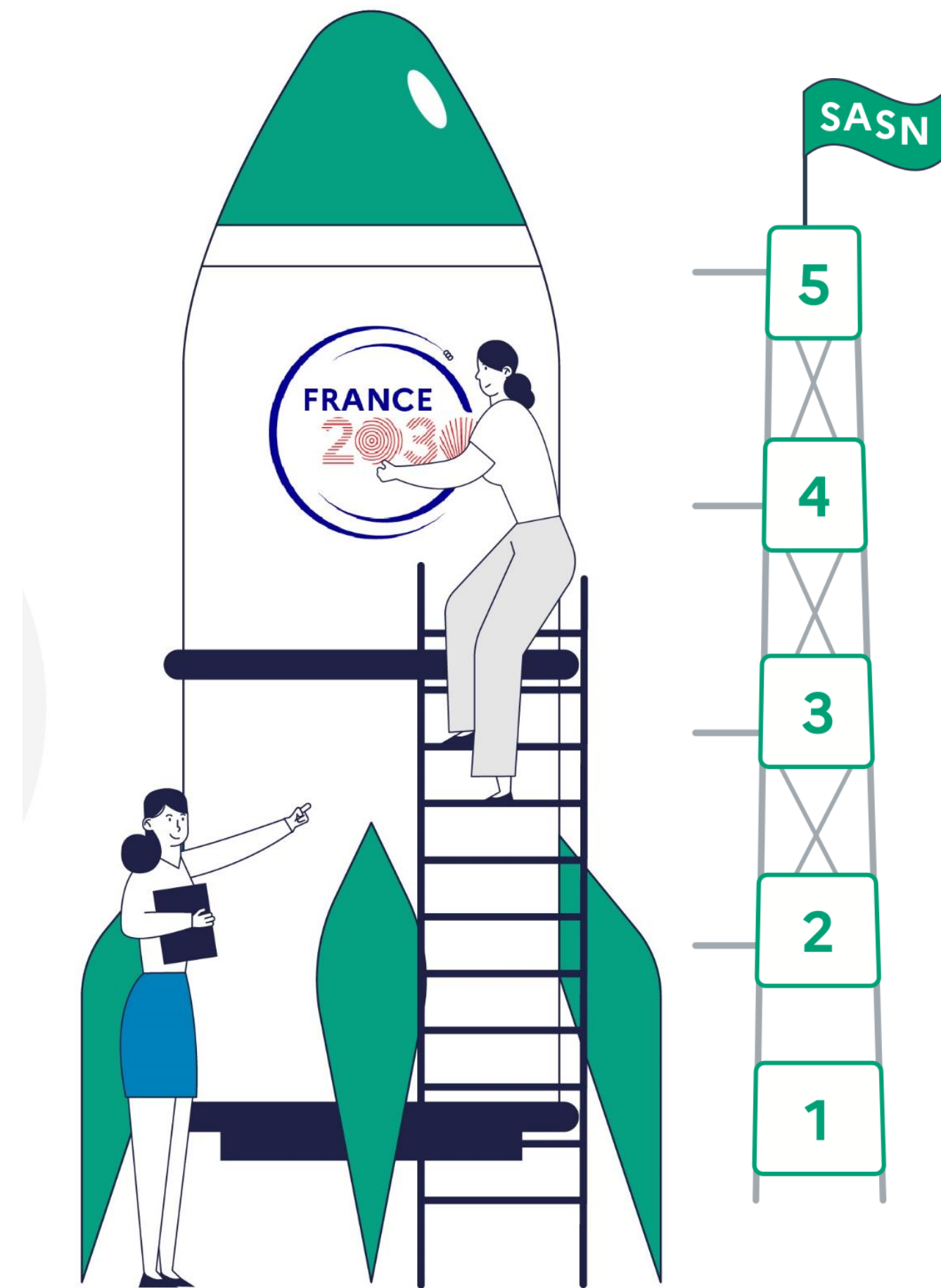
## Within the next 5 years

- **500 000 health apprentices and trainees** obtained digital health capacity building
- 30 structures selected as third-party experimentation sites, **100 experimented solutions**
- **2 new sustainable pathways to reimbursement** for digital solutions
- **70 clinical evaluations** of digital medical devices funded
- **1 national gateway** to facilitate the life of digital health entrepreneurs
- Achieve scientific breakthroughs and bring out **disruptive technologies**



# 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)

# Paving the way to a fast-track DMD access in France

PRIOR EXPERIMENTATIONS TO A NATIONAL TRANSITIONAL AND TEMPORARY ONE-YEAR REIMBURSEMENT ACCESS SCHEME FOR DIGITAL MEDICAL DEVICES AND TELEMEDICINE IN FRANCE



- France has been looking at **improving care pathways since 2018 by experimenting telemonitoring prior to reimbursement** (ETAPES program - Telemedicine Experimentation for the Improvement of Healthcare Pathways), until June 2023
- **Scope:** chronic pathologies (heart failure, renal failure, respiratory failure, diabetes and implantable heart prostheses)
- The **health technology assessment** of the program was coordinated by the French National Authority for Health (**Haute Autorité de Santé, HAS**).
- In prolongation, the French government paved the way to implement a **fast track reimbursement for DMDs by 2022** in its 2022 Social Security Funding Bill of December 2021. *Ministerial order to implement the article is pending as of October 19, 2022*



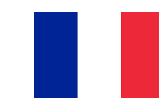
# Paving the way to a fast-track DMD access in France

DIGITAL MEDICAL DEVICES (DMDS) ARE SUBJECT TO CLINICAL EVIDENCE-BASED REQUIREMENTS AND REACH A NEW LEVEL OF REGULATORY CHALLENGES LINKED TO MARKET ACCESS AND REIMBURSEMENT OF DIGITAL SUPPORTED PATIENT CARE.



## German Digital Healthcare Act:

- **DiGA Fast Track** : market access for certain categories of digital health applications that may be prescribed by doctors and reimbursed by the statutory health insurers.
- Eligibility criteria for such solutions is a **positive healthcare effect**.



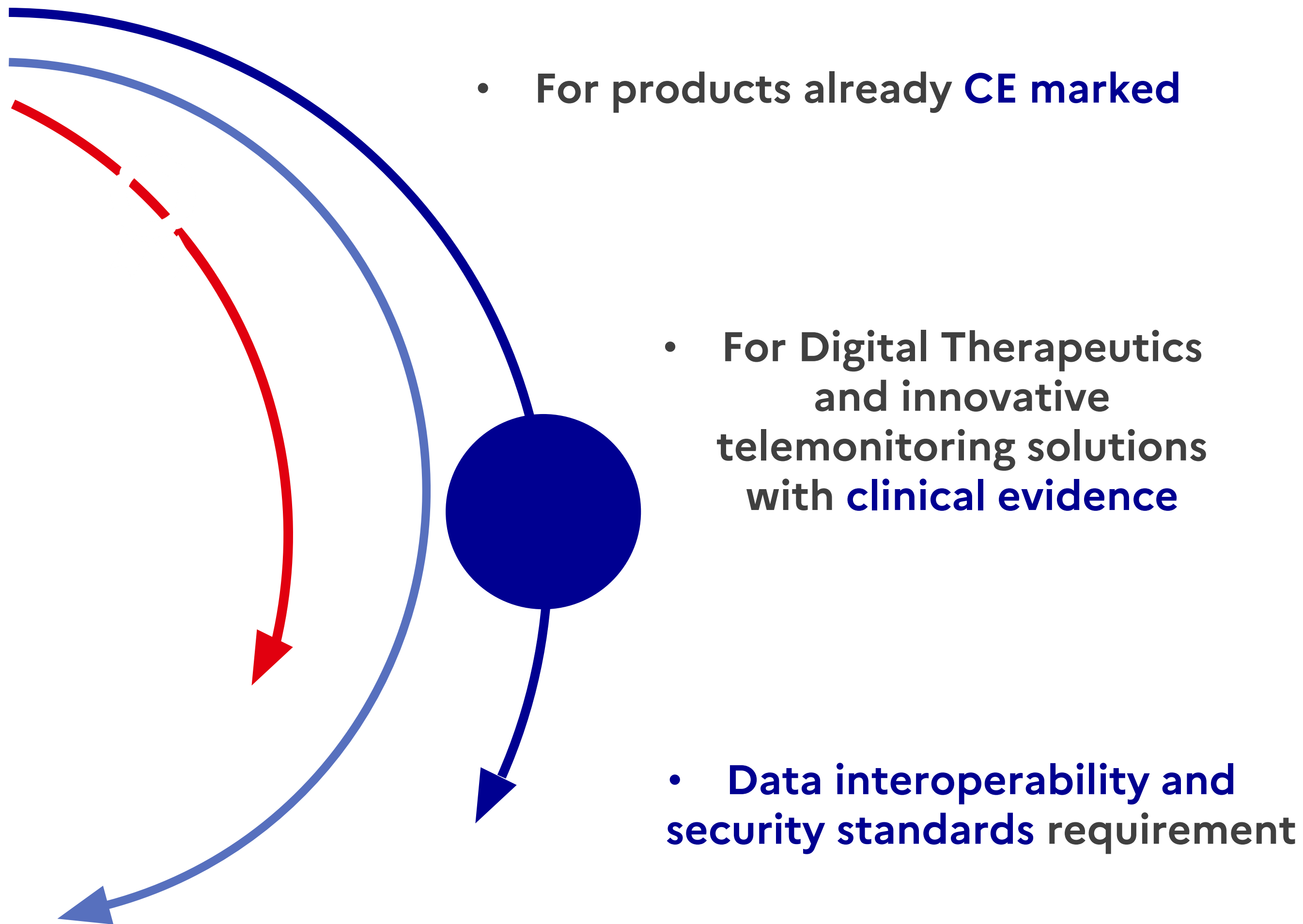
## Article 58 - Social Security Funding Law of 2022

- New **transitional and temporary one-year reimbursement access** scheme for certain digital medical devices or for remote monitoring solutions.
- The digital medical device is presumed to be innovative, especially in terms of **clinical benefit or progress in the organization of care**.

Other European countries are actively working on the implementation of similar regulatory procedures

# Paving the way to a fast-track DMD access in France

IMPLEMENT EARLY ACCESS FOR CE-MARKED DIGITAL DEVICES FOR INDIVIDUAL USE THAT MEET THE CRITERIA FOR INCLUSION ON THE LIST OF PRODUCTS AND SERVICES AND FOR REMOTE MONITORING DEVICES



## A Fast Track preliminary access

- Accelerated access to reimbursement
- 1 year to apply for normal reimbursement pathway
- Initial fixed price, tailored after 1 year



# Paving the way to a fast-track DMD access in France

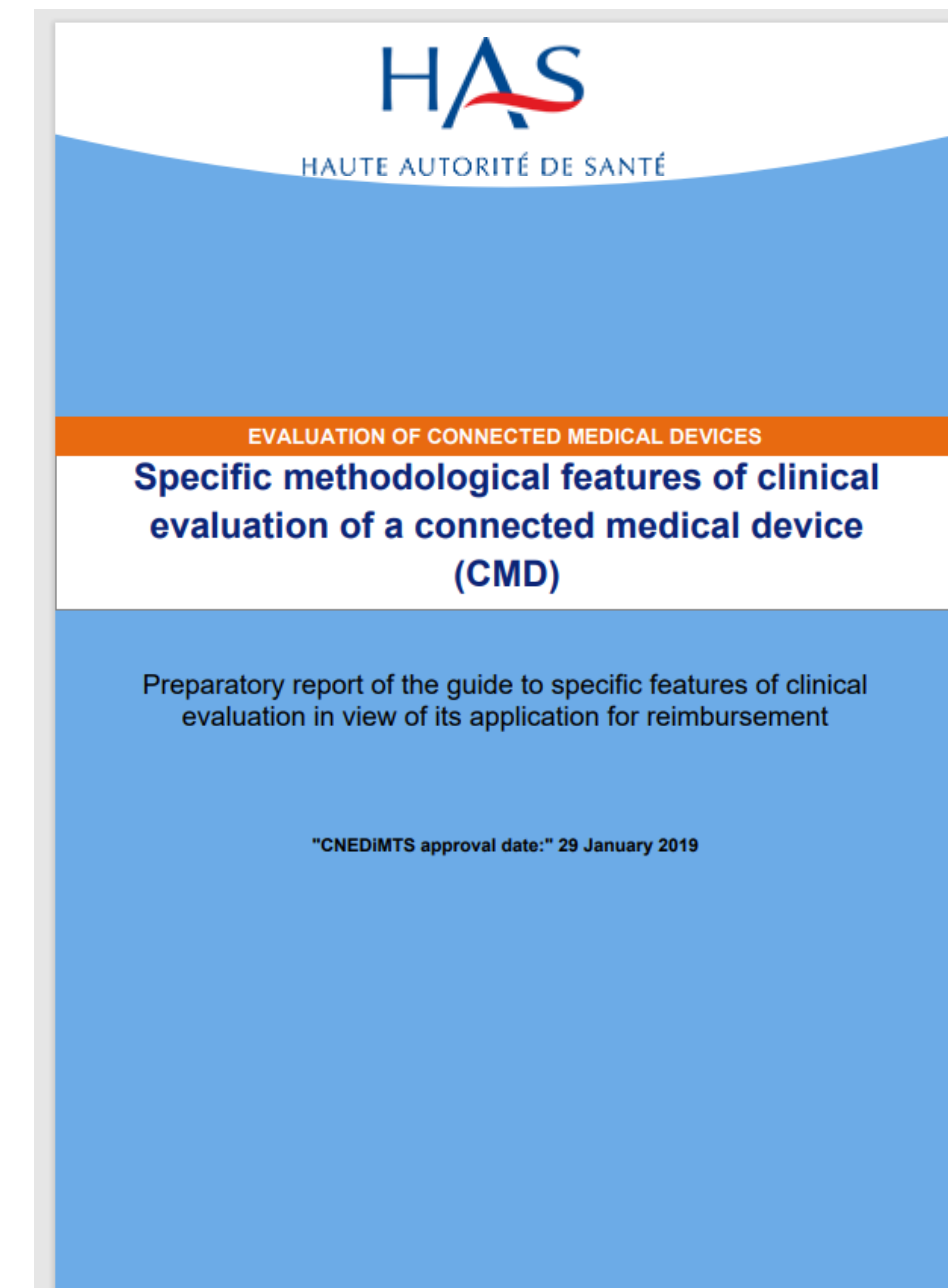
IN FRANCE, THE NATIONAL HEALTH AUTHORITY HAS PUBLISHED A CLASSIFICATION OF DMDS ACCORDING TO THEIR FUNCTIONALITIES, INTENDED USER AND AUTONOMY

## Guidelines by the National Health Authority (HAS):

- Medical device evaluation by the CNEDiMTS (Medical Device and Health Technology Evaluation Committee): Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement [Link](#)
- Methodology for the clinical development of medical devices [Link](#)
- Analysis grid for the AI component in medical devices [Link](#)
- Real-world studies for the assessment of medicinal products and medical devices [Link](#)
- Guidelines for telemonitoring on 5 chronic diseases (as in ETAPES) [Link](#) (In French)
- Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care [Link](#)

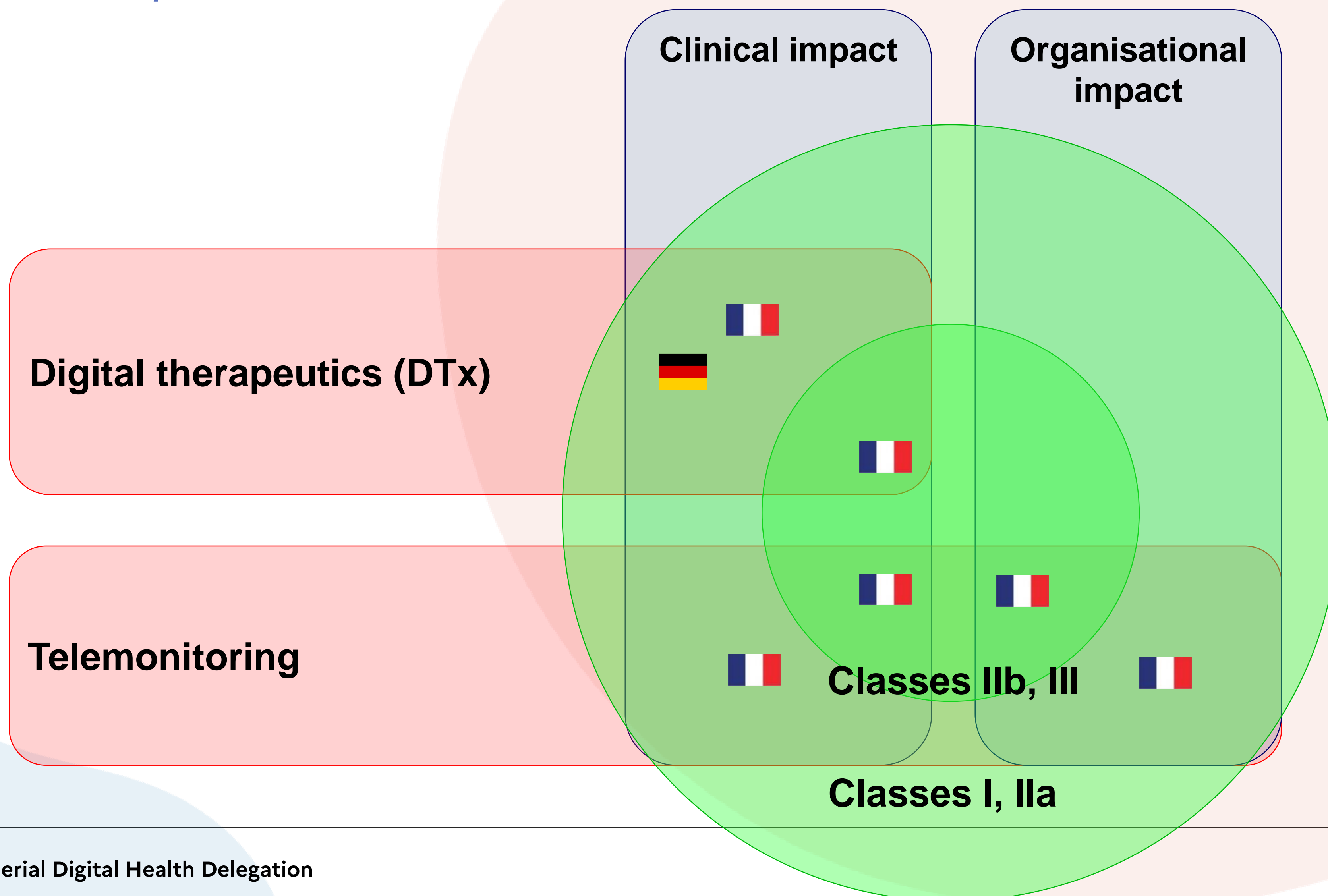
## Guidelines by the National eHealth Agency (ANS):

- Repository of Interoperability and Security of Digital Medical Devices [Link](#)



# Different approaches for fast track access for DMDs in the EU

BOTH GERMAN AND FRENCH NATIONAL REGULATIONS SUPPORT BROADER PATIENT ACCESS TO INNOVATIVE DMDs, USING DIFFERENT SCOPES





# #PFUE2022: An opportunity for digital health

## A European way of using 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.

**STRATEGY FOR DIGITAL HEALTH in EUROPE**  
A single market approach empowered by the European Health Data Space

European ethical  
principles for digital  
health

Develop European use  
cases

Technical standards

Market access



# 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



**More to come**



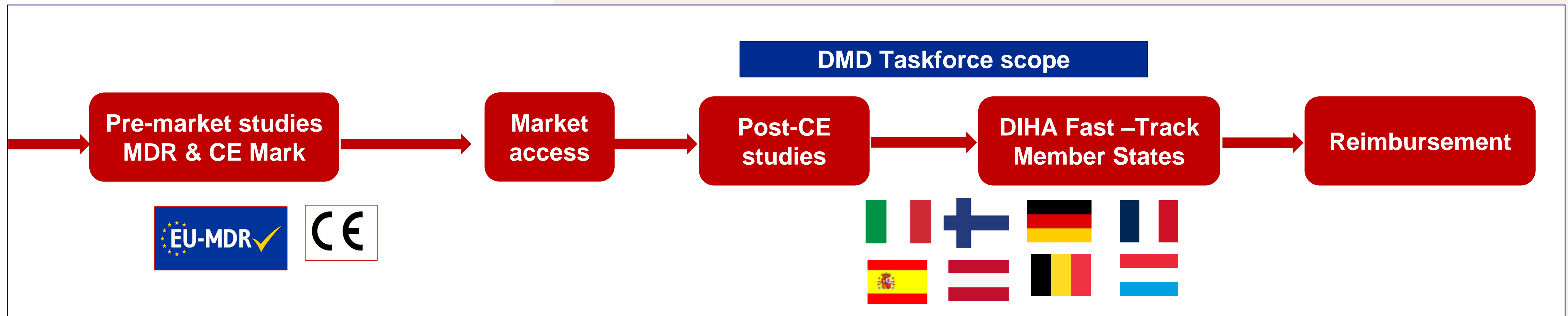
**Initial steps**



# Towards a common European market for digital health



Framework of the **Regulation on Health Technology Assessment (HTA) regulation**, a deliverable of the EU Pharmaceutical Strategy, applicable from January 2025.



- ➔ 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.**

# Launch of a European Taskforce for Harmonised Evaluation of DMDs

- The final recommendations for harmonizing clinical criteria and methodologies for evaluating DMDs results from three work packages.

| Work package 1  | Work package 2  | Work package 3 & 4  |
|---|---|---|
| <ul style="list-style-type: none"> <li>Harmonize the taxonomy of DMDs based on their application scope and evaluation categories</li> </ul>   | <ul style="list-style-type: none"> <li>Consensus on determining quantity, quality and the type of evidence that is needed for assessing DMDs</li> </ul>   | <ul style="list-style-type: none"> <li>Propose a social health evaluation framework based on pre-requirements (technical, technological, ethical)</li> </ul>  |
| Definition/Selection of the DMDs  | Joint Evaluation Criteria   | Socio-Economic Acceptance   |
| <ul style="list-style-type: none"> <li>Compare definition by national HTA-R (Germany/France/other)</li> <li>Harmonize with MDR</li> <li>Extract similarities</li> </ul> <p><u>Propose a joint definition/taxonomy</u></p> <ul style="list-style-type: none"> <li>Therapeutic Application purpose</li> <li>Diagnostic Application purpose</li> </ul> <p><i>Linked to WP2 evaluation criteria</i></p> | <ul style="list-style-type: none"> <li>Analyse existing Evaluation Criteria                             <ul style="list-style-type: none"> <li>Clinical evidence categories</li> <li>Outcome/ study methods + design</li> </ul> </li> <li>Compare to international evaluation concepts (e.g. EU, UK, USA, etc.)</li> </ul> <p><u>Recommend Joint Evaluation Concepts</u></p> <ul style="list-style-type: none"> <li>Patient-centric effects</li> <li>Service-relevant measures</li> </ul> <p><i>for the different DMD types (WP1)</i></p> | <ul style="list-style-type: none"> <li>Assess social acceptance criteria (patient engagement, HCP integration, health economic evaluation)</li> <li>Ethical, Legal and Social evaluation</li> <li>regional integration into healthcare services</li> </ul> <p><u>Suggest socio-economic evaluation tailored to DMDs</u></p> |
| External Advisory Board   |   |   |
| Contribute to the final suggestions by sharing perspectives of different stakeholders and experiences from real-world examples  |   |   |



# DMD Taskforce Member Institutions



-  Austrian Institute for Health Technology Assessment, AIHTA (Austria)
-  Belgian Health Care Knowledge Centre, KCE (Belgium)
-  BioMed Alliance
-  Bocconi University (Italy)
-  Catalan Agency for Health Quality and Assessment AQuAS (Spain)
-  EIT Health (France)
-  EUnetHTA
-  European Observatory on Health Systems and Policies
-  European Patients' Forum, EPF
-  Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) (Germany)
-  FinCCHTA (Finland)
-  Finnish Innovation Fund Sitra (Finland)
-  French Ministry of Solidarity and Health (France)
-  Luxembourg Health Directorate (Luxembourg)
-  Medical University of Vienna (Austria)
-  National Health Authority, HAS (France)
-  University of Liège (Belgium)
-  Universtiy of Luxemburg (Luxembourg)



# Towards a progressive harmonisation of market access

## Digital medical devices

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

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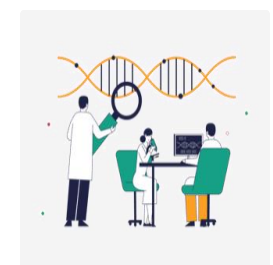


**Initial steps**

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

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**



**A podcast**  
100 days to succeed



**Follow your healthcare pathway** (MonEspaceSanté, Ségur numérique, National Health Identity (INS)...) •



**Decipher funding keys and trends**



**Commercialize a digital medical device**



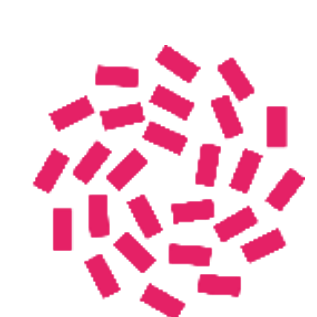
**Identify e-health events**



**Discover eHealth news**



**New:** map of EU-level markets and hubs



# G\_NIUS Key figures



**+ 235 000**

page views since its opening

**+ 90 000**

visitors since its opening

**51%** of

repeat visitors

**2 800**

community members



**9** institutional partners...



The **6** health competitiveness clusters, accompanied by clusters and living labs





## 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



#### Germany

[Access to the country sheet](#)

#### 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 players, although they operate within a legal framework set by the federal state and implemented by the **16 regions (Länder)**.
- It is the first country to have implemented a **"fast track"** for reimbursement of mobile applications (DIGA)

#### Belgium

[Access to the country sheet](#)

#### Several initiatives to drive the digital transformation of healthcare

- At the European level, the country is very actively involved in major health information projects
- Healthdata.be is **the platform to facilitate and standardise the registration of health data**



### Country fact sheets

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

#### eHealth in Germany

##### Key figures

**83M**  
people

**2nd**  
a global player in MedTech

**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 proposes draft laws, regulations and administrative provisions and the Länder are responsible for implementing them. The health system is financed by a compulsory insurance system, **87.7% public and 10.5% private**, organised around public health insurance funds. Physicians bill 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!



# Way forward at the French Ministerial Digital Health Delegation





**merci.**

**Obrigada.**





# To go further

OVERVIEW OF ACHIEVEMENTS OF THE NATIONAL DIGITAL HEALTH STRATEGY 2019 - 2022 - [LINK](#)

STUDY ON DIGITAL HEALTH IN THE EU - [LINK](#)

DIGITAL HEALTH ACCELERATION STRATEGY [LAUNCH PRESS KIT](#) AND NOVEMBER 21 ANNIVERSARY [PRESSKIT](#)

G\_NIUS WEBSITE : [HTTPS://GNIUS.ESANTE.GOUV.FR/](https://gni.us.esante.gouv.fr/)

ARTICLE ON DMD TASKFORCE:

EN: [HTTPS://EITHEALTH.EU/NEWS-ARTICLE/PRESS-RELEASE-DIGITAL-MEDICAL-DEVICES-LAUNCH-OF-A-EUROPEAN-TASKFORCE/](https://eithealth.eu/news-article/press-release-digital-medical-devices-launch-of-a-european-taskforce/)

FR: [HTTPS://ESANTE.GOUV.FR/ESPACE-PRESSE/VERS-UN-CADRE-COMMUN-DEVALUATION-DES-DISPOSITIFS-MEDICAUX-NUMERIQUES-EN-UNION-EUPEENNE-LANCEMENT-DUNE-TASKFORCE-EUPEENNE](https://esante.gouv.fr/espace-presse/vers-un-cadre-commun-devaluation-des-dispositifs-medicaux-numeriques-en-union-europeenne-lancement-dune-taskforce-europeenne)