

Towards

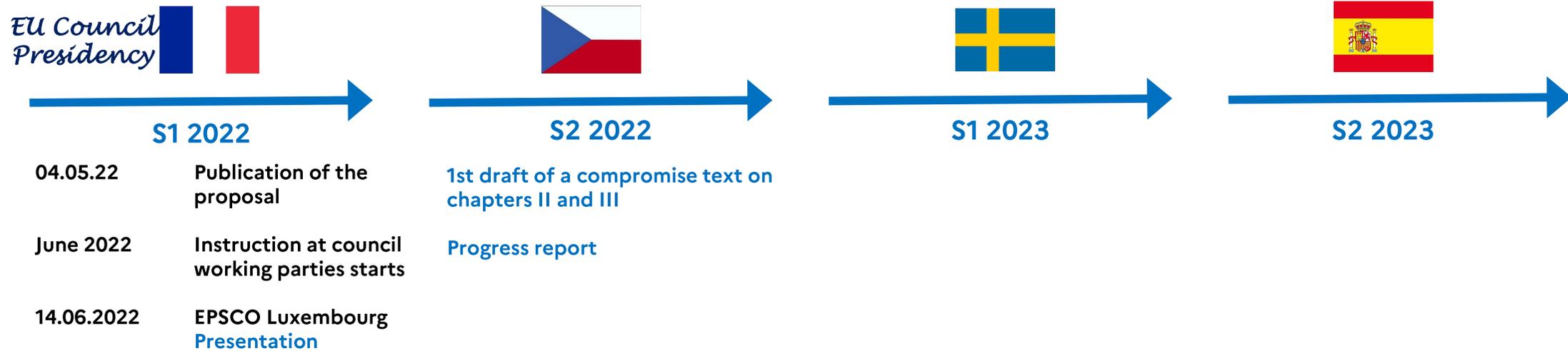


November 28, 2022 – EHTEL SYMPOSIUM

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

Current status of EHDS proposed regulation





**MINISTÈRE
DE LA SANTÉ
ET DE LA PRÉVENTION**

*Liberté
Égalité
Fraternité*

Délégation ministérielle
au numérique en santé

France has been supporting the concept from start

To meet European challenges in health



Health



Sovereignty



Digital



Services for
citizens



Trust &
security





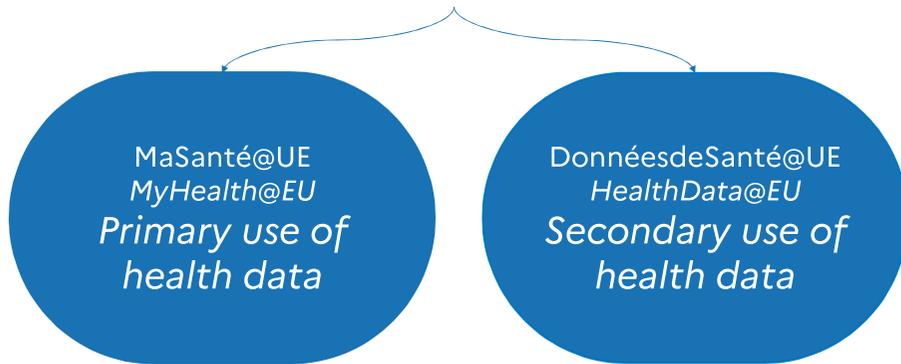
**MINISTÈRE
DE LA SANTÉ
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France has been engaging on both sides of EHDS from start

European Health Data Space (EHDS)



MaSanté@UE
MyHealth@EU
Primary use of
health data

DonnéesdeSanté@UE
HealthData@EU
Secondary use of
health data

Sesali

mon
ESPACE
SANTÉ

HEALTH
DATA HUB

Comment contribuer ?
Participez à la concertation !

participez.esante.gouv.fr/themes/europe



Besoin de plus d'informations ?

Accédez aux 4 webinaires de présentation de chaque chapitre de la réglementation

06 octobre 2022

L'espace européen de données de santé - cadre général et calendrier

11 octobre 2022

Espace européen des données de santé - Partage des données de santé en UE dans le cadre du

20 octobre 2022

Espace européen des données de santé - Future auto-certification des dossiers médicaux

23 octobre 2022

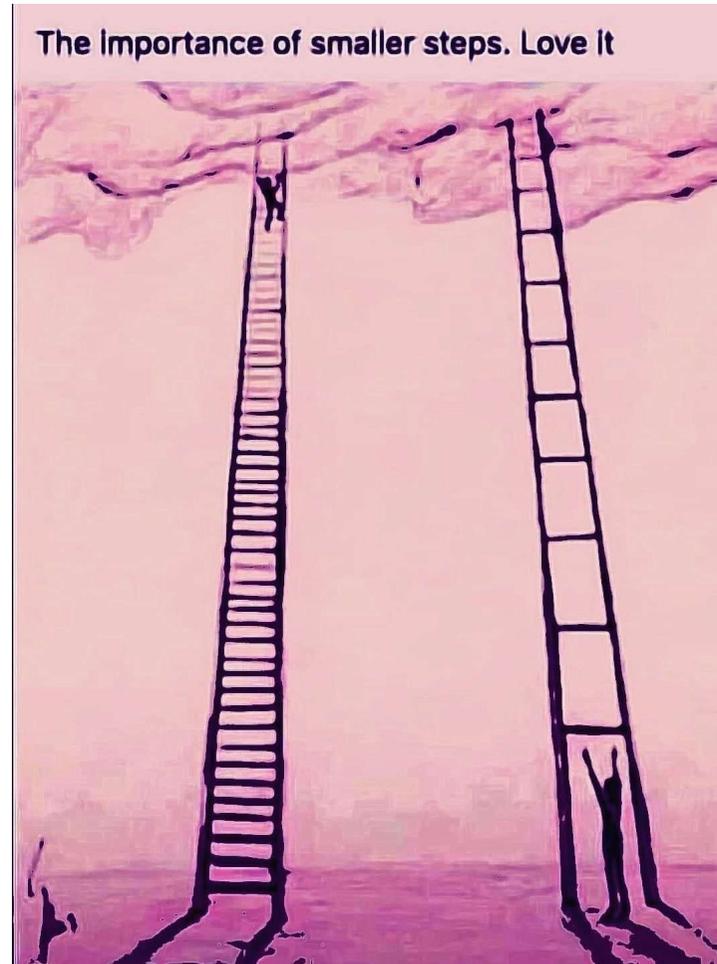
Espace européen des données de santé - Réutilisation des données de santé en Union Européenne



Accéder aux webinaires



Way forward at the French Ministerial Digital Health Delegation



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



AGENCE
DU NUMÉRIQUE
EN SANTÉ

Health Insurance
CNAM



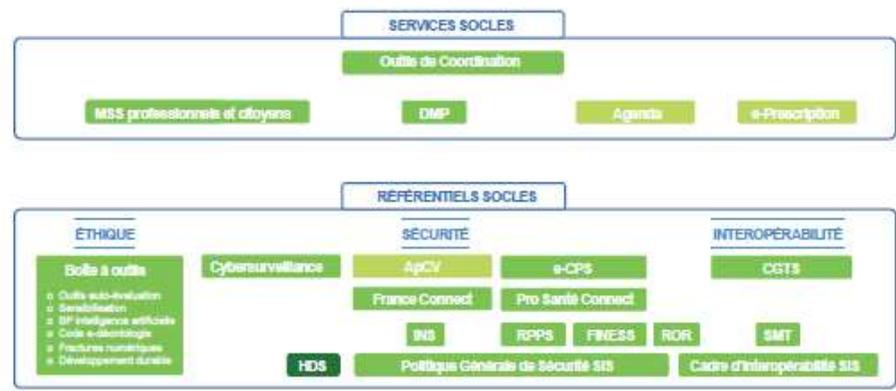
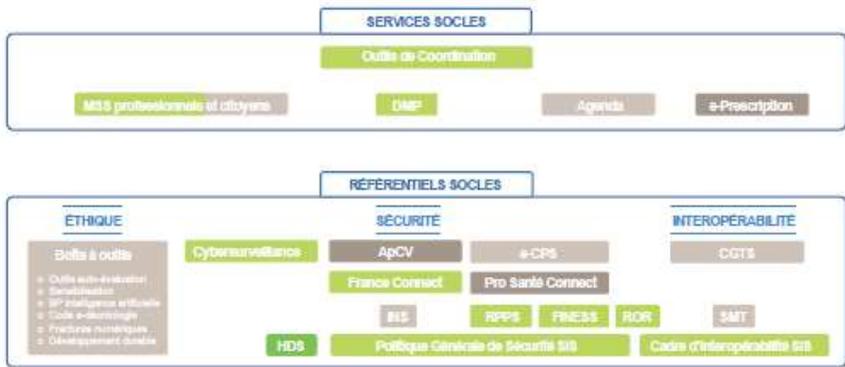
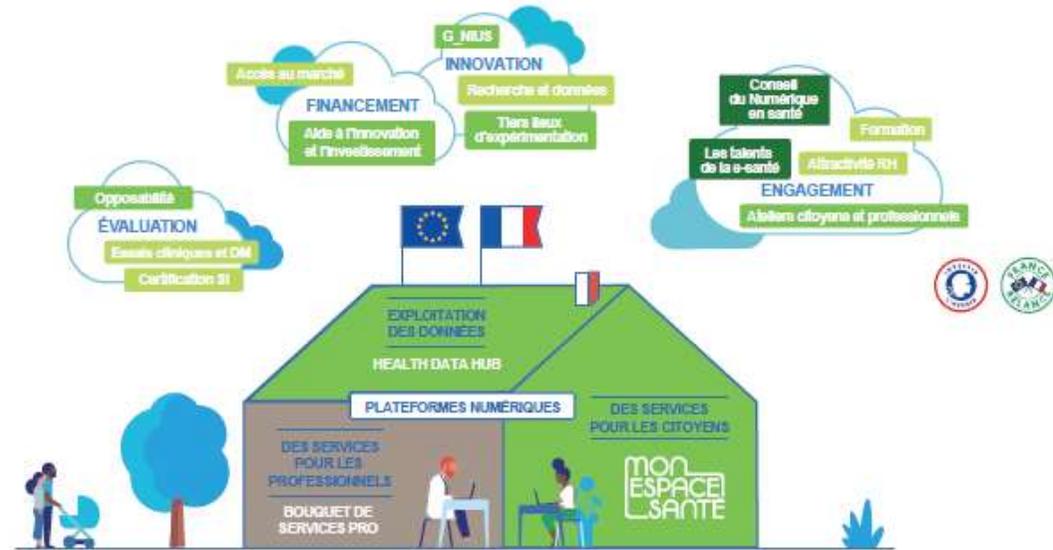
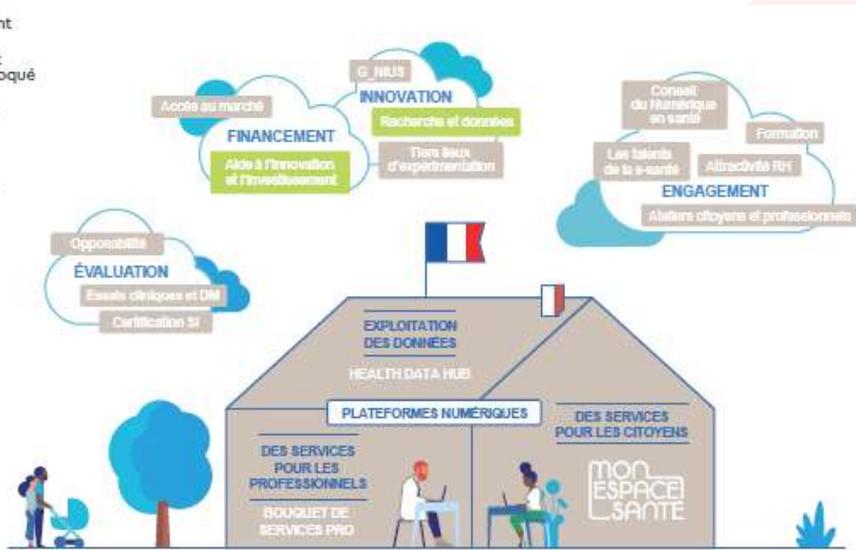
Health Data Hub



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

- Inexistant
- Naissant et/ou bloqué
- Entamé
- Avancé
- Abouti*



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



#MaSanté2022

Ministerial eHealth
Delegation
Ethics Council



Dominique Pon
& Laura Létourneau

Ministerial Digital Health Delegation



MyHealthSpace



France National digital health strategies and funding programs

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



Sécur 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

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

France 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)

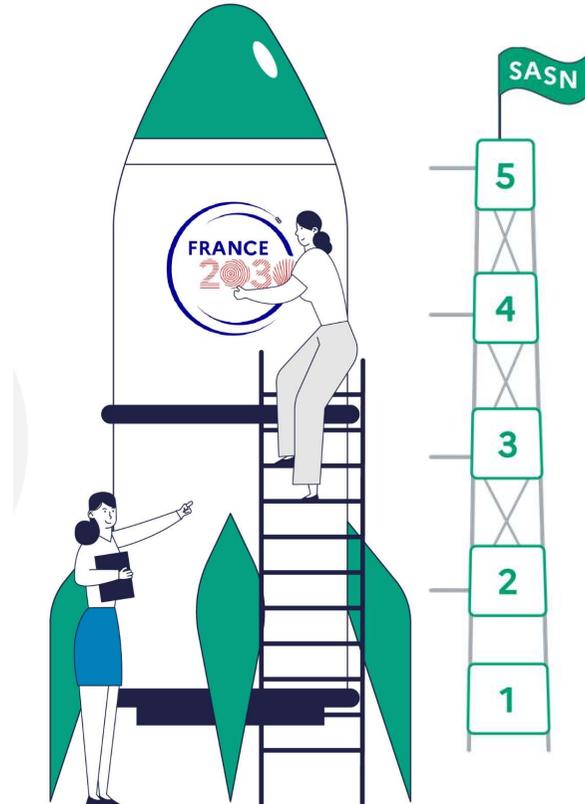
More than **500**
candidates to all digital
health calls

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**

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)

#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

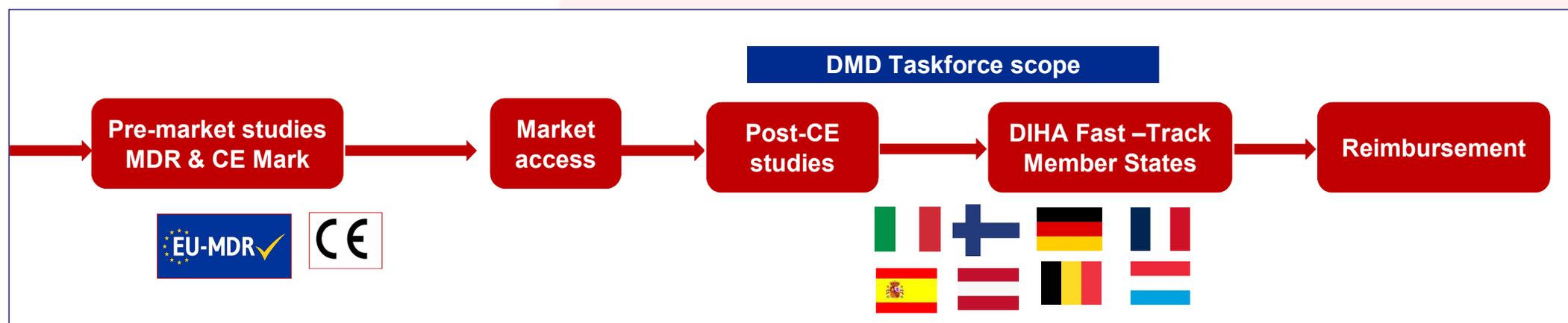


Initial steps

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.**

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



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



Identify e-health events



Identify actors of the digital health ecosystem



Decipher funding keys and trends



Discover eHealth news



A podcast
100 days to succeed



Commercialize a digital medical device



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

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.

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



Scan to access the service!





thank you.
merci.

