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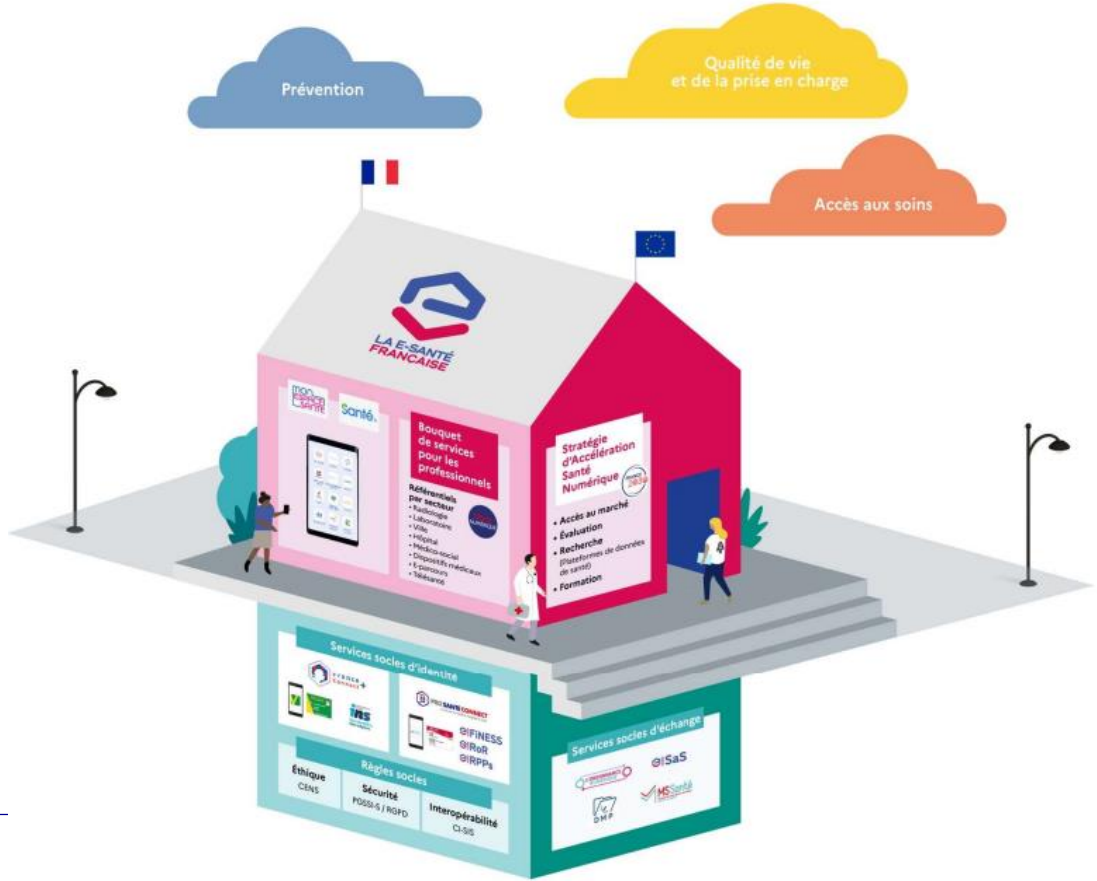
Early Access to Reimbursement for Digital Medical Devices (PECAN) in France

November 15th, 2023
10:45-11:45 - Revolutionising Healthcare: Leveraging Reimbursement Models For Uptake Of Digital Health Solutions

Digital Health Delegation (DNS)
French Ministry of Health and Prevention

The Digital Health Roadmap 2023-2027



Click here to have a look at the new digital health roadmap 2023-2027 launched the 17th May 2023

The Digital Health Roadmap 2023-2027 in 4 axes, 18 priorities and 65 objectives

This roadmap is the result of several months of **consultation**, resulting from a **18-stage tour of French regions**. The roadmap is based on the values of **ethics**, **sovereignty** and **sustainability.**

Axis 1 – Develop prevention services and allow patients to control their own health

Axis 2 – Use the benefits of digitlization to optimize daily work of healthcare professionals and enhance the quality of patient care

Axis 3 – Improve access to healthcare

Axis 4 - Deploy an enabling environment to foster digital health deployment and innovation

The French Digital Health landscape at a glance

Digital Health Delegation (DNS)

*Oversees all **digital healthcare transformation projects** in France on the **national level**, based on three fundamental pillars: **ethics**, **security** and **interoperability***

MINISTÈRE DE LA SANTÉ ET DE LA PRÉVENTION
Délégation ministérielle au numérique en santé

National Digital Health Agency (ANS)

*The agency is **supervised** by the **Digital Health Delegation** and acts as its "operational arm". The ANS ensures the deployment and respect of **digital health standards and referentials.***

AGENCE DU NUMÉRIQUE EN SANTÉ

National Health Insurance Fund (CNAM)

*Defines the national **health insurance policy**. Its role is to monitor, coordinate and advise actions of primary health insurance funds (CPAMs) and the 5 general social security funds.*

L'Assurance Maladie

Health Data Hub (HDH)

*Unique gateway to facilitate access to French **health data for public interest research and innovation.***

HEALTH DATA HUB

15 Regional Support Group for the Development of e-Health (GRADeS)

Collège des GRADeS

*Ensures the **urbanization**, **interoperability** and **security** of **health information systems***

18 Regional Health Agencies (ARS)

Provides **unified management** of health care in the regions

ars Agence Régionale de Santé

Regional/ local actors: *hospitals, universities, healthcare professionals, actors of the digital health ecosystem*

National digital health strategies and pluriannual 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.

SÉGUR DE LA SANTÉ

PariSanté Campus

2020 – 2028

400 Mio. €
Birthplace of tomorrow's digital health

PariSanté campus

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

Digital Health Acceleration Strategy

2021 – 2025

734 Mio. € to make France a leader in digital health

FRANCE 2030

Medical Device Plan

2022 - 2026

400 Mio. €. to develop and produce innovative medical devices and digital and disruptive healthcare solutions

FRANCE 2030

Plan Innovation Santé 2030

FRANCE 2030

Ministerial digital health roadmap

2023 – 2027

Digital tools at the service of health

Digital Health Acceleration Strategy 2021-2025

A national funding program co-constructed by and for the health digital ecosystem

An interministerial strategy for 2021-2025

To make France a leader in digital health

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MINISTÈRE DE L'ÉCONOMIE, DES FINANCES ET DE LA SOUVERAINETÉ INDUSTRIELLE ET NUMÉRIQUE
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Co-constructed with the digital health ecosystem

The result of a broad public consultation

429 replies **50** qualitative interviews **6 months** of inter-ministerial work

Collective preparation for calls for projects and expressions of interest

12 webinars **More than 120** meetings

Support the actors with useful tools

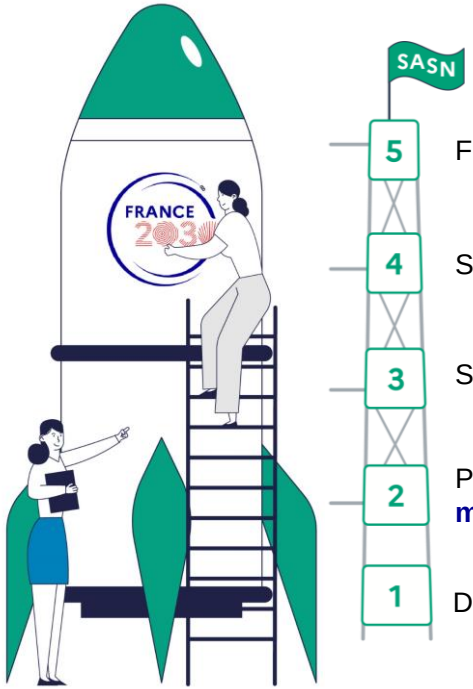
A national portal to support digital health entrepreneurs

G_NIUS

☞ gnius.esante.gouv.fr

Digital Health Acceleration Strategy 2021 - 2025

A strategy with € 734 million to support all levels of a digital health project cycle



Foster the conditions for the **large-scale deployment** of successful digital health projects

Sustain **experimentations in real-life conditions** and **first industrial demonstrations**

Support the **development** of structural projects to strengthen strategic territorial 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

PECAN, an innovative approach to derogatory reimbursement of digital medical devices (DMDs)

Overview

- New **one-year transitional and temporary reimbursement** access scheme
- Launched in April 2023

Scope

- **Innovative DMDs for individual use**
  - for therapeutic purposes (DTx)
  - remote Monitoring (TLS)
- With **initial elements to assess the potential benefits of the solution**
- **Running studies** with results available **before the end** of PECAN

Why?

- **Rapid access** to digital health innovations for patients
- Operational deployment in parallel of procedures **to get a standard definitive reimbursement**

How?

- **Parallel evaluation** process by **HTA Agency (HAS) & Digital health agency (ANS)**
- **Authorisation decision** by the **Minister of Health**
- **Duration: 3 to 4 months** after candidate submission of file

PECAN, a new fast-track to facilitate the launch of digital health innovations

1 year

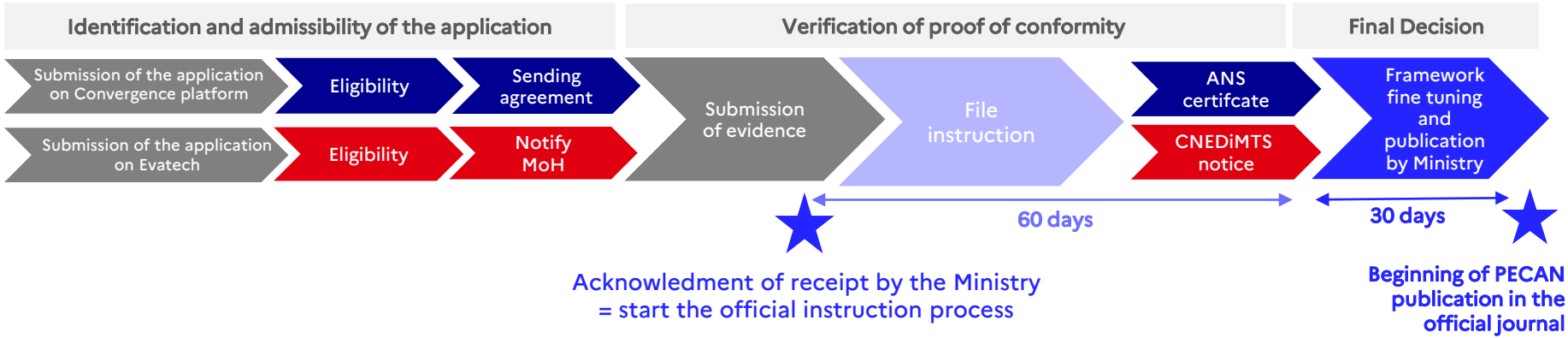
Pre-reimbursement at fixed price and a springboard for innovators to obtain generalized reimbursement

Facilitated application

through two simultaneous applications (medical/scientific and security/interoperability) and simplified evaluations

PECAN – Step by step

Steps to benefit from early reimbursement scheme



Caption:

Candidate | HAS | ANS | ANS/HAS and candidate | Ministry of Health

Focus on the requirements of the DMN Interoperability and Security

The repository is composed of different sections of requirements:

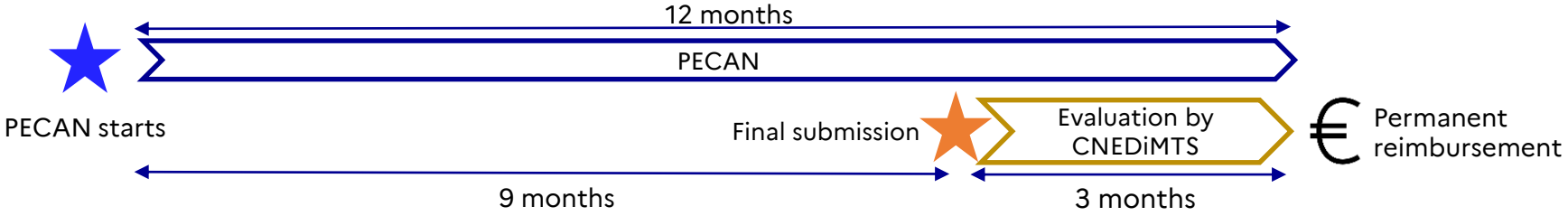
National Health Identity	Pro Health Connect	Health Directory	GDPR	Data portability	Electronic identification
Identité Nationale de Santé ins		rpps répertoire partagé des professionnels de santé	RGPD		PGSSI-S
Securing patient identification	**Securing HCP Authentication**	**HCP directory**	**GDPR data privacy**	**Access to health data (interoperability)**	**HCP access Patient access**

The requirements of the repository are derived from **the doctrine of digital healthcare** and the various ANS **benchmarks**.

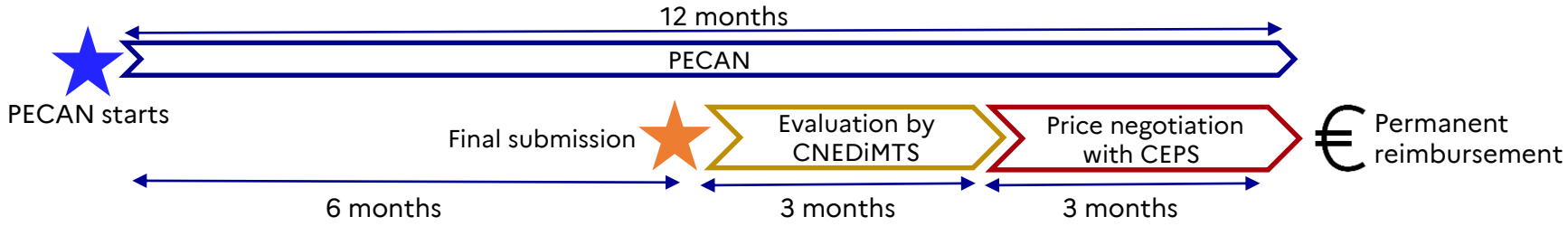
Documents available on the Digital Health Agency portal for industrials:
https://industriels.esante.gouv.fr/produits-et-services/dispositifs-medicaux-avec-des-fonctions-numeriques

PECAN – after a year of reimbursement

- *Towards a permanent reimbursement of **Digital Medical Devices (DMD)***
  - **Inclusion in the List of Reimbursed Telemonitoring Activities (LATM)**



  - **Inclusion in the List of Products and Services qualifying for reimbursement (LPPR)**



PECAN and DiGA, two pioneering mechanisms in the EU

In Germany, the Diga Fast Track has enabled accelerated market access for certain categories of digital health applications

Social Security Funding Law 2022 : Article 58

PECAN:

- **Therapeutic** (DTx) or **telemonitoring activities**
- Class I, IIa, IIb and III **HAS** (CNEDiMTS) and **ANS** evaluate PECAN applications
- **One-year transitional reimbursement**
  predefined fixed compensation
  Negociated final price after 12 months (only for DTx)
  Telemonitoring prices are predefined (no negociation)

German Digital Healthcare Act

DiGA Fast Track:

- **Therapeutic DMD** (DTx)
- Class I and IIa only **BfArM** evaluates Diga candidates
- **One-year transitional reimbursement**
  at manufacturer's price
  Negociated final price after 12 months

Other European countries are actively working to implement similar procedures

G_NIUS, a one-stop shop to save time for digital health entrepreneurs

Set up by the Ministry of Health and Prevention, the purpose of G_NIUS is to **make life easier** for entrepreneurs in the digital health sector and **speed up the development of their solutions**

👉 gnius.esante.gouv.fr

G_NIUS services

Entrepreneurs are directed to the **right contacts** and have access to the **right information**, so that they can better **anticipate** the stages of their development.

- **Find relevant subventions and call for projects**
- **Get reimbursement** from the Health Insurance
- **Find e-health events**
- **Identify the actors of the ecosystem**
- **Decipher DMD regulation**
- **Discover the news on e-health**
- **Understand the regulations**
- **Explore e-health abroad**
- **Listen to the podcasts** 100 jours pour réussir
- **Diagnose the regulatory requirements** of your project
- **Follow your guided tour** My Health Space, Ségur numérique, INS

G_NIUS In figures

562 000 pages viewed [June 2023]

163 000 visitors since its opening in 2020

3 150 members of the community

12 institutional partners

51% of returning visitors

Useful links

More information on PECAN

- PECAN ministerial order of March 30, 2023 Link
- PECAN information sheet on G_NIUS Link
- PECAN Webinar Replay Link (in French only)
- HAS guidance Link (in French only)
- Early stage appointment with the National HTA Agency HAS Link

Guidelines by the National Health Technology Assessment Authority (HAS):

Submission guidelines for medical devices (as of June 1, two different platforms, for clinical evaluation: Evatech) Link

- Evaluation principles by the CNEDiMTS of individual use medical device for their access to reimbursement Link in English / Link in French (May 2019)
- Methodology for the clinical development of medical devices (including digital) Link in English / Link in French
- Real-world studies for the assessment of medicinal products and medical devices Link
- Organisational impact for map for health technology assessment Link
- Analysis grid for the AI component in medical devices Link
- Remote monitiong uses Link in French
- 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
- 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):

- Interoperability and Security standards for Digital Medical Devices (DMDs) Link
- Compliance certification platform Link

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