1. PECAN, in a nutshell

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

PREMIER MINISTRE
Liberté Égalité Fraternité

Secrétariat général pour l'investissement

MINISTÈRE DE LA SANTÉ ET DE LA PRÉVENTION
Liberté Égalité Fraternité

MINISTÈRE DE L'ÉCONOMIE, DES FINANCES ET DE LA SOUVERAINETÉ INDUSTRIELLE ET NUMÉRIQUE
Liberté Égalité Fraternité

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR ET DE LA RECHERCHE
Liberté Égalité Fraternité

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
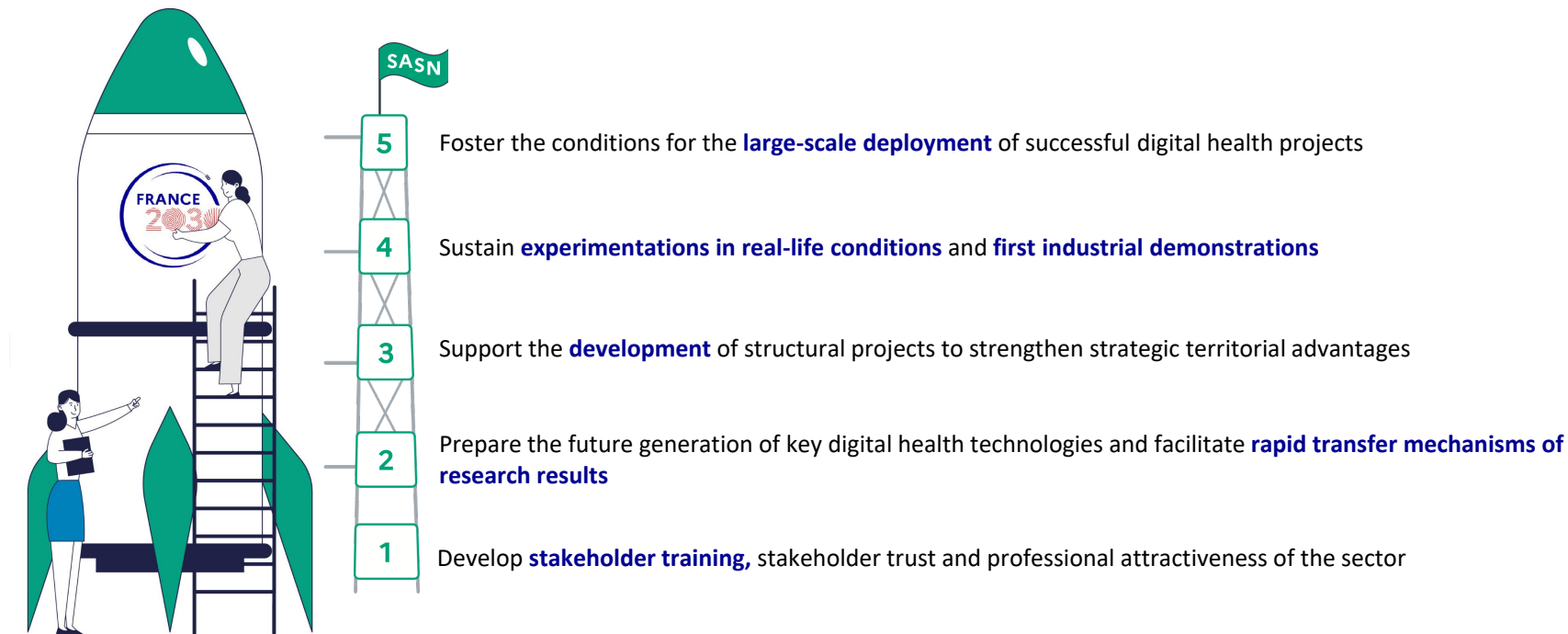
Support the actors with useful tools

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

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

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

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

2 Prepare the future generation of key digital health technologies and facilitate **rapid transfer mechanisms of research results**

1 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** 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

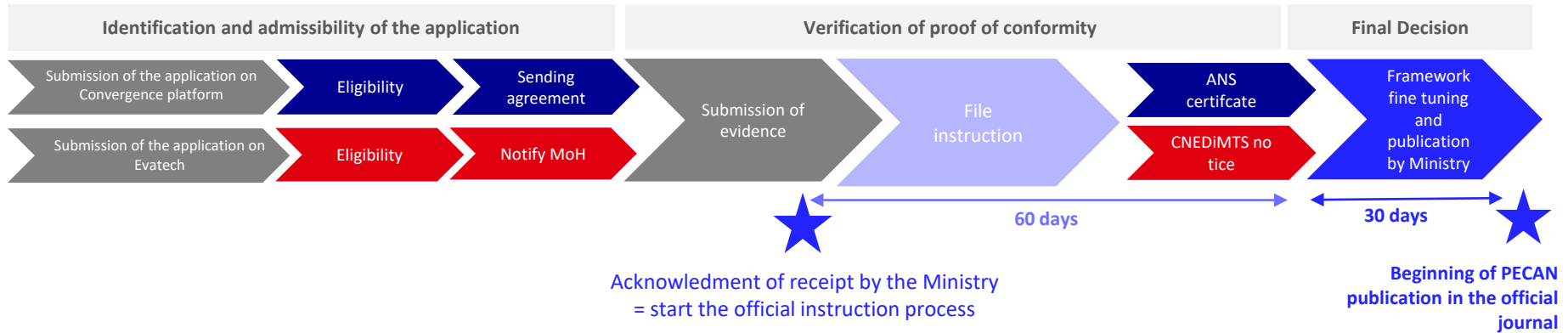Pre-reimbursement at fixed price and a springboard for innovators to obtain generalized reimbursement

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

Identification and admissibility of the application	Verification of proof of conformity	Final Decision

Submission of the application on Convergence platform → Eligibility → Sending agreement

Submission of the application on Evatech → Eligibility → Notify MoH

Submission of evidence → File instruction → ANS certifcate / CNEDiMTS notice → Framework fine tuning and publication by Ministry

60 days **30 days**

Acknowledgment of receipt by the Ministry
= start the official instruction process

Beginning of PECAN publication in the official journal

Caption:

Candidate	HAS	ANS	ANS/HAS and candidate	Ministry of Health

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

GOUVERNEMENT
Liberté
Égalité
Fraternité

FRANCE 2030

PeCAN
Prise en charge
anticipée
numérique

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
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

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

163 000
visitors since its opening

3 150
members of the community

12 institutional partners

ANS AGENCE DU NUMÉRIQUE EN SANTÉ

ansm Agence nationale de sécurité du médicament et des produits de santé

l'Assurance Maladie Caisse Nationale

bpifrance

CNIL

MINISTÈRE DE L'ÉCONOMIE, DES FINANCES ET DE LA SOUVERAINETÉ INDUSTRIELLE ET NUMÉRIQUE

Direction générale des Entreprises

HAS

RÉPUBLIQUE FRANÇAISE
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LA FRENCH TECH

sesam-vitale

FRANCE 2030

AGENCE DE L'INNOVATION EN SANTÉ
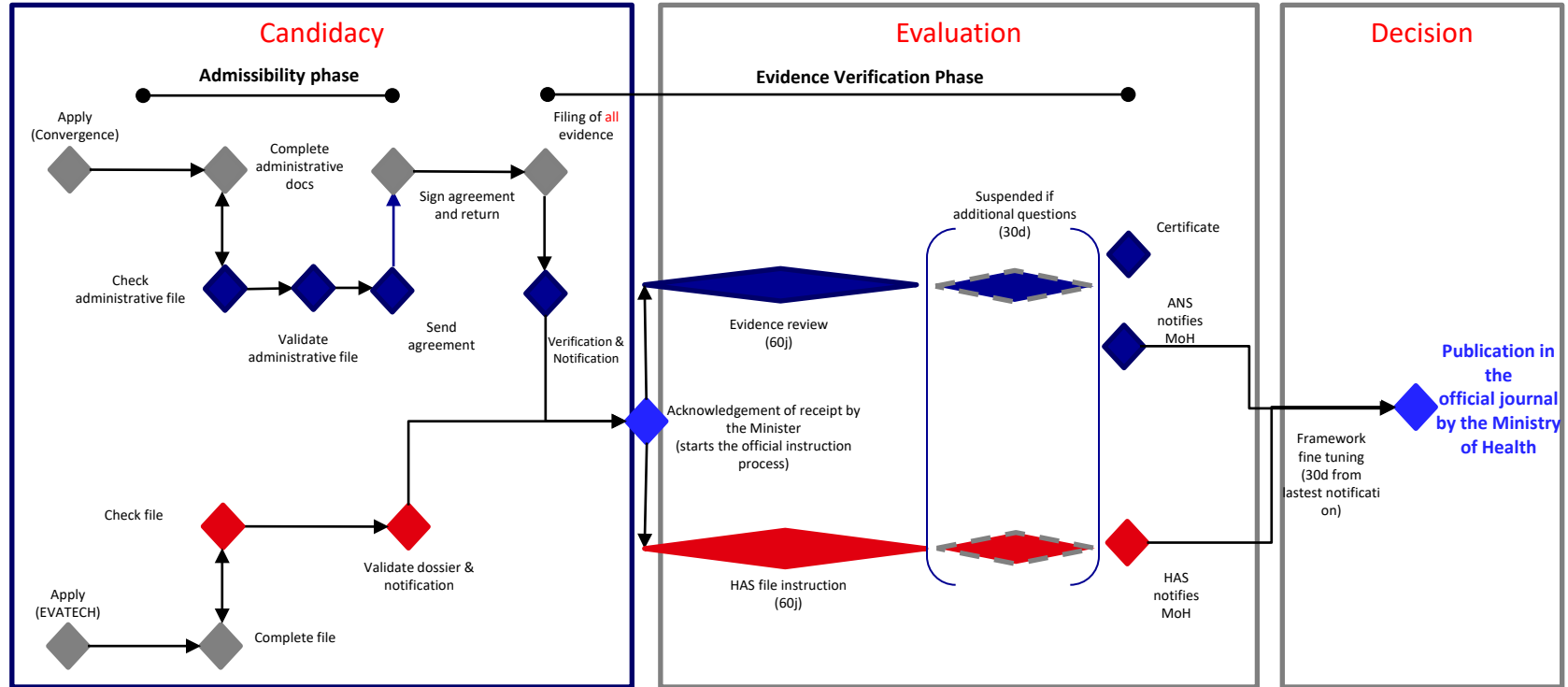
HDH HEALTH DATA HUB

PariSanté campus

51% of returning visitors

MINISTÈRE DE LA SANTÉ ET DE LA PRÉVENTION

Délégation ministérielle au numérique en santé

ANS AGENCE DU NUMÉRIQUE EN SANTÉ

2. PECAN, deep-dive in the process

How to get a derogatory reimbursement

Caption:

| Candidate | HAS | ANS | Ministry of Health |

How to benefit from the derogation reimbursement– Application for PECAN

Candidacy

Admissibility phase

Submission of applications (Convergence)

Candidate

Complete administrative docs

Filing of all evidence

ANS

Check administrative file

Sign agreement and return

Validate administrative file

Send agreement

Verification & Notification

Ministry of Health

Acknowledgement of receipt

HAS

Check file

Validate dossier & notification

Candidate

Submission of applications (EVATECH)

Complete file

- Parallel submission on Evatech platform (HAS) and on Convergence platform (ANS) and possibility of discussion with the instructors

- Possible types of discussion:
  - HAS:
    - Early meeting to discuss a study protocol
    - Pre-deposit meeting to discuss the construction of your file
  - ANS:
    - Contact ANS teams through the industrial contact form

- When the file is complete, Ministry of Health sends acknowledgment of receipt

- Starts the official evaluation process by HAS and ANS

How to benefit from the derogatory reimbursement —
Evaluation for PECAN

Evaluation

Evidence Verification Phase

Filing of all evidence

Suspended if additional questions (30d)

60 days

✓ Start of the evaluation by HAS and ANS

✓ Opinions delivered to MoH and the candidate by the CNEDiMTS of the HAS and the ANS

Evidence review (60j)

Acknowledgement of receipt by the Minister (starts the official instruction process)

HAS file instruction (60j)
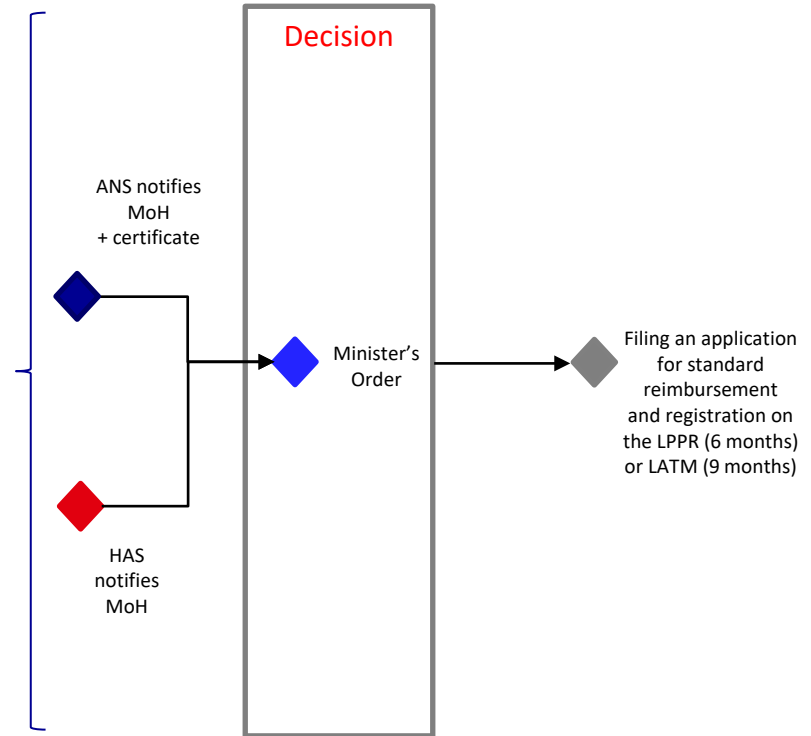
ANS Certificate

ANS notifies MoH

HAS notifies MoH

· The instruction may be **suspended when additional information** is expected

· Every suspension (max 30d) is **notified by the Ministry of Health**

Caption:

| Candidate | HAS | ANS | Ministry of Health |
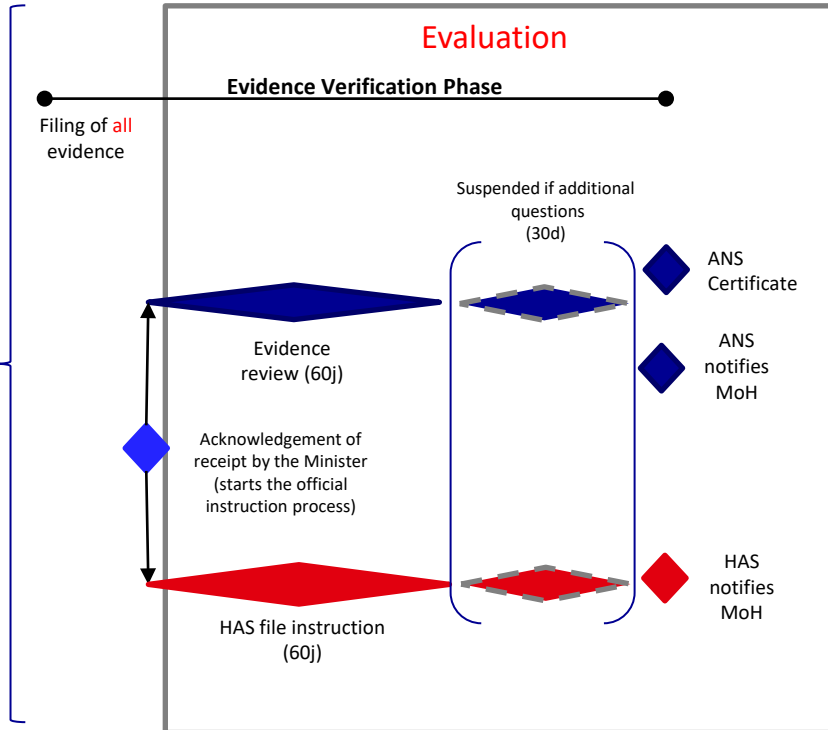
PECAN decision tree towards derogatory reimbursement

> ➤ **PECAN decision for a 1-year reimbursement by the ministers responsible for health and social security**

> ➤ **Commitment of the candidate to file its application for standard reimbursement and registration in the LPPR or the LATM**, within a period of **6 months and 9 months** respectively from the publication of the PECAN's order

Decision

ANS notifies MoH + certificate

HAS notifies MoH

Minister's Order

Filing an application for standard reimbursement and registration on the LPPR (6 months) or LATM (9 months)

Caption: Candidate HAS ANS Ministry of Health

After a year of reimbursement

End of the PECAN

✓

➤ Validation for standard reimbursement

➤ After a year without validation nor refusal

🚫

▢ Absence of final evaluation submission within legal time limits, or withdrawal of the standard reimbursement application

▢ Refusal : Negative decision by the minister

▢ Non-compliance with the legal requirements regading CE marking, interopérability and security ANS conformity

▢ Removal form the market for serious reasons related to patient's safety by MDR competent authority in France (ANSM)

- **Mandatory treatment continuity for the industrial,** depending on the case :
  - 6 months after the end of the temporary reimbursement
  - 45 days after a refusal by the minister in the claimed indication
  - Except for serious reasons related to patient safety

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Useful links

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

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) <u>Link</u>
- Evaluation principles by the CNEDiMTS of individual use medical device for their access to reimbursement <u>Link in English</u> / <u>Link in French</u> (May 2019)
- Methodology for the clinical development of medical devices (including digital) <u>Link in English</u> / <u>Link in French</u>
- Real-world studies for the assessment of medicinal products and medical devices <u>Link</u>
- Organisational impact for map for health technology assessment <u>Link</u>
- Analysis grid for the AI component in medical devices <u>Link</u>
- Remote monitiong uses Link in <u>French</u>
- 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 <u>Link</u>
- Guidelines for telemonitoring on 5 chronic diseases (as in ETAPES) <u>Link</u> (In French)
- Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care <u>Link</u>

Guidelines by the National eHealth Agency (ANS):
- Interoperability and Security standards for Digital Medical Devices (DMDs) <u>Link</u>
- Compliance certification platform <u>Link</u>

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