Presentation of the Digital Health Acceleration Strategy

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Ministerial Digital Health Delegation
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Agenda

1. **Digital health acceleration strategy**
2. G_NIUS - platform for digital health entrepreneurs
3. Fast-track reimbursement in France for digital medical devices (« PECAN »)

French Digital Health Acceleration Strategy

Alignment with other national digital health funding strategies

Digital Health Ministerial Roadmap 2018-2022

Accelerate the digital shift

Ségur de la santé —2020-2025

€ 2 billion, including € 600 M for medico-social sector*
Modernization, interoperability, security of health information systems,...

SÉGUR DE LA SANTÉ

PariSanté Campus

2020-2028

€ 400 M - Digital Health Campus

ParisSanté campus

Digital Health Ministerial Roadmap 2023-2027

Putting digital services at the service of health

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

Digital Health Acceleration Strategy

2021-2025

€ 718 M to make France a leader in digital health

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Medical Devices Plan

2022-2026

€ 400 M to develop and deploy innovative medical devices and digital and disruptive digital health solutions

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Health Innovation Plan 2030

FRANCE 2030

*medico-social sector: institutes caring for children, medico-psychological teaching centres, medical education institutes, nursing homes for the dependent and elderly etc...

Digital Health Acceleration Strategy

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

An interministerial strategy for 2021-2025

Making France a leader in digital health

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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
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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

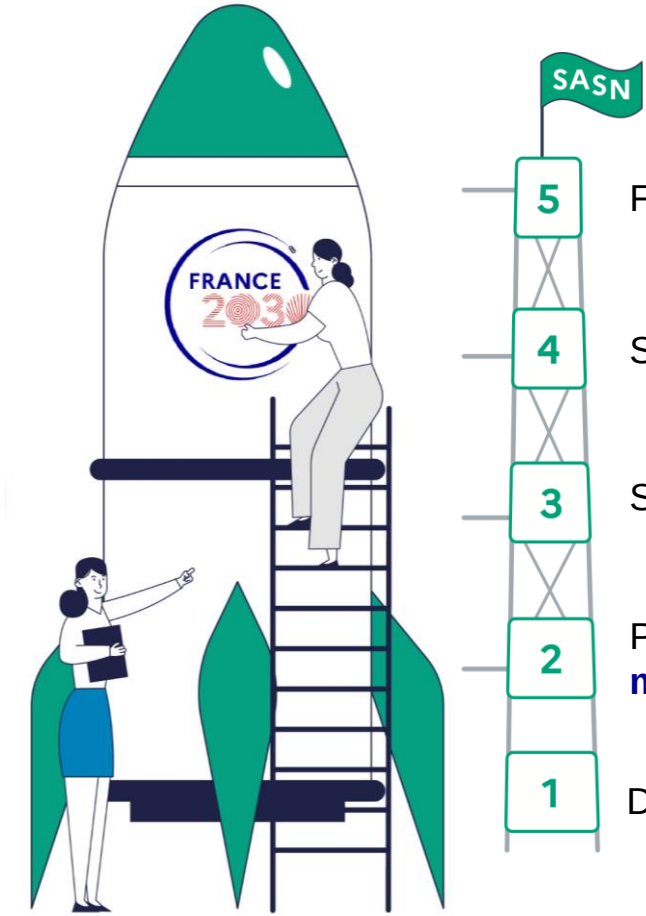
A national portal to save time for entrepreneurs

G_NIUS

A « Tour de France» to meet digital health actors

Digital Health Acceleration Strategy

A strategy with € 738 M 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 the implementation of **experimentations in real-life conditions** and **first industrial steps**

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

Digital Health Acceleration Strategy

First assessment: an encouraging first year

First semester 2022: SASN "Tour of France"

- 9 stages to meet local digital health actors all over France
- 27 roundtables and workshops with more than 600 actors involved

2nd semester 2022: One-year SASN celebration

- > 500 participants
- Featuring Minister of Education and Research, Minister of Health and Prevention, European Commission and General Secretary for Investment

€152 M committed in 2022

- at 31/12/2022, i.e. 1/3 of the France 2030 budget spent since the launch of the strategy

31 actions launched

- including 9 call for projects

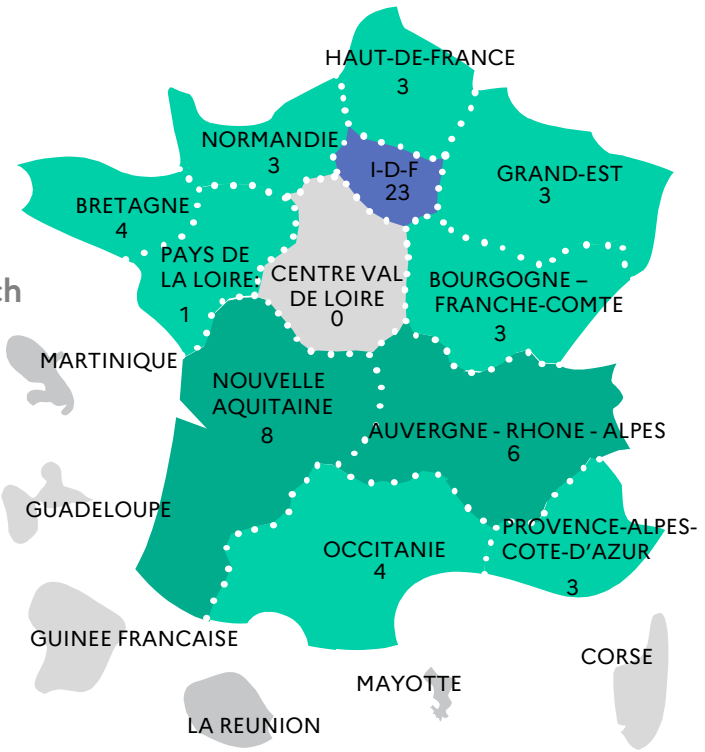
61 winners of call of projects

- More than 500 applicants for digital health call for projects

More ambition, more openness, more funding for digital health so far. ***A major component*** *of France Santé 2030,* ***to prepare the future of our healthcare system and the ecosystem of digital healthcare companies.***

Agnès Audier, ***Ambassador France 2030***

Places of successful project leaders



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G_NIUS

https://gnius.esante.gouv.fr

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

Discover eHealth news

Decrypt national digital health regulation

Identify actors of the digital health ecosystem

A podcast
100 days to succeed

G_NIUS services

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

New: funding search engine for eHealth projects Link

New: map of EU-level markets and hubs Link

8

G_NIUS Key figures

> 460K
page views since its opening (+71% since 2022)

> 150K
visitors since its opening

10M results in Google in 2022

3 000
community members

9 institutional partners...

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

G_NIUS

International Service: Decoding digital health abroad

One single «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.

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Fast-track reimbursement in France for digital medical devices (« PECAN »)

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 TELEMONITORING IN FRANCE

Innovation package (« Forfait innovation »)
Since 2015
Innovative MDs with clinical studies and medico-economic assessments to be collected

« Article 51 »
2018 – June 2023
Organisational impact experimentations

Transitional Reimbursement (« Prise en charge transitoire » - PECT)
Since 2021
Innovative MDs that meet a need that is insufficiently covered, i.e. for serious or rare diseases, or to compensate for a disability

« ETAPES «
2018 – June 2023
Remote monitoring experimentation for five chronic diseases

Anticipated Reimbursement (« Prise en Charge Anticipée » - PECAN)
March 30, 2023
Remote monitoring for other diseases than those included in ETAPES
Individual use of DTx
Remote monitoring « ETAPES »

“PECAN” - the new French DMD reimbursement process that accelerates the deployment of digital health solutions

IMPLEMENTED AS PART OF THE “DEPLOYMENT AXIS” OF THE DIGITAL HEALTH ACCELERATION STRATEGY

Launch of digital medical devices (DMD) reimbursement (“PECAN”)

- **Objective: to accelerate reimbursement by the French National Health Insurance for innovative DMDs**
- Provision for “PECAN” (Prise en charge anticipée numérique) by French 2022 Social Security Funding Law (Art. 58)
- Implementation through ministerial order of March 30, 2023 by means of service desks offered by the French Digital Health Agency (ANS) and HTA agency (HAS)
- This fast-track enables the manufacturer to **finalize the clinical trials while already being reimbursed during one-year** (non-renewable)
- **Scope :** Digital medical devices for therapeutic purposes or innovative medical remote monitoring solutions

More information on the application process on the G_NIUS website

Which types of DMDs are in the scope of “PECAN” ?

Categories

- **Digital Therapeutics** (DTx), before registration on the *List of Reimbursable Products and Services (LPPR)*
- **Telemonitoring solutions**, before registration on the *List of Telemonitoring Activities (LATM)*

DMD with CE mark

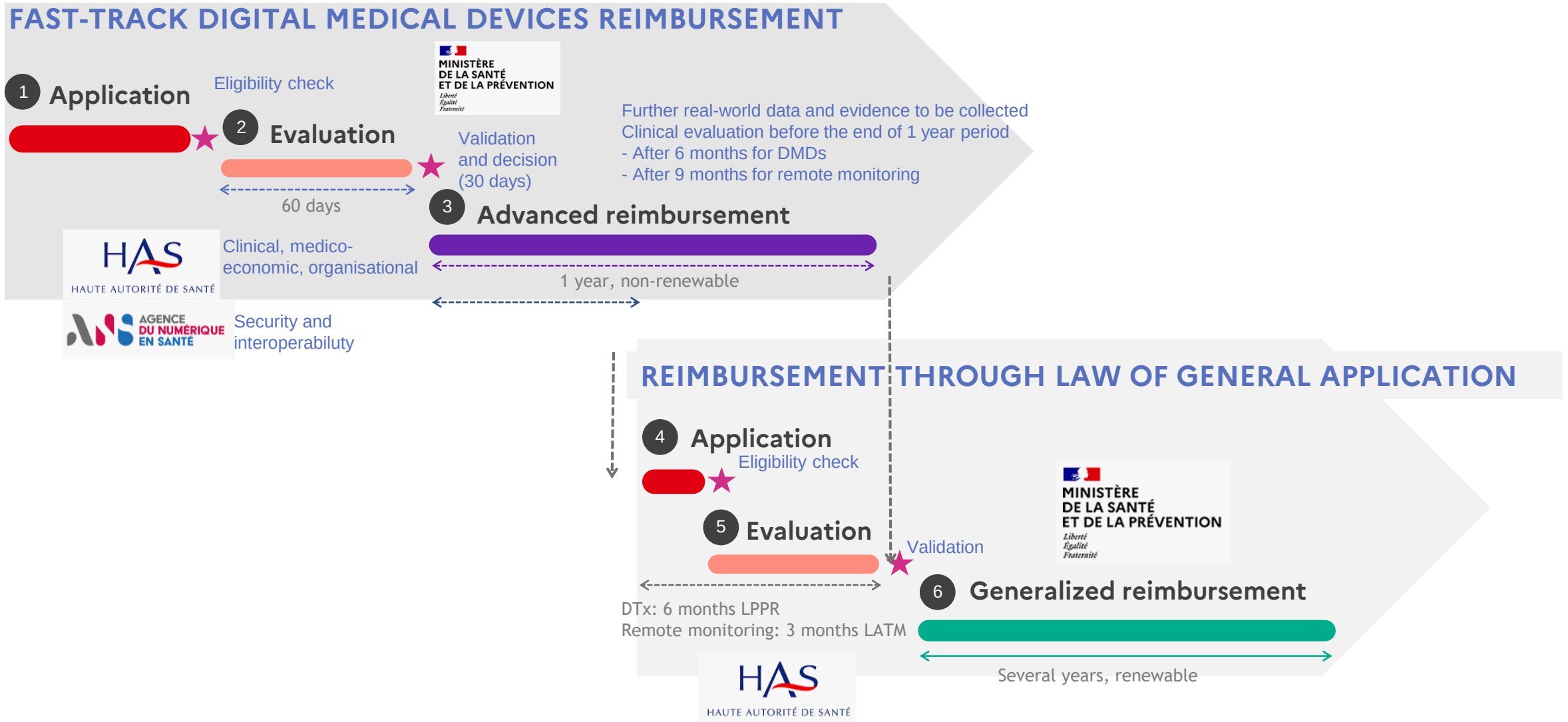
Existing preliminary clinical evidence*

The solution is “mostly digital”

Compliance with data interoperability and security standards requirements

*Completed clinical study or ongoing study with intermediate results

What are the steps to access DMD reimbursement in France?



Fast-track reimbursement in France for digital medical devices (« PECAN »)

*No CNEDiMTS sessions between mid-July and September, 2nd half of December

Different approaches for DMD fast track access in the EU

BOTH GERMAN AND FRENCH NATIONAL REGULATIONS SUPPORT BROADER AND FASTER ACCESS FOR PATIENTS ACCESS TO INNOVATIVE DMDS, USING DIFFERENT SCOPES AND CATEGORIES OF DIGITAL HEALTH APPLICATIONS

German Digital Healthcare Act

DiGA Fast Track :

- DMD **for therapeutic uses** (DTx)
- DMD **class I and IIa**

- BfArM **evaluates** DiGA applicants on their potential **positive health effects**
- One year transitional rebate at **manufacturer's rate**
- Possibility of additional **clinical studies** during provisional listing

Social Security Funding Law 2022 + March 2023 order

PECAN :

- DMD **for therapeutic uses** (DTx) or telemonitoring
- DMD **class I, IIa, IIb and III**

- DMD presumed to be innovative, especially in terms of **clinical benefit or improvement for the organization of care,** as assessed by HAS (CNEDiMTS)
- Need to pursue data collection throughout deployment

One year transitional reimbursement period, predefined price **package**

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

European Taskforce for Harmonised Evaluation of Digital Medical Devices

A **European digital medical device (DMD) taskforce** has been launched in April 2022, chaired by the Ministerial Digital Health delegation of the French Ministry of Health and Prevention and co-chaired by the European Network for Health Technology Assessment (EUnetHTA), coordinated by EIT Health and supported by contributors of other European Ministries of Health and/or national responsible authorities and agencies.

Mission: To **classify innovative DMDs and align their EU-level health technology assessment procedures** in the view of harmonizing national assessment in the view of reimbursement by national health insurance organisations for distinct subclasses of DMDs.

➔ By developing a **joint approach** duplication of assessments can be avoided, patient access to innovative and proven digital health solutions can be accelerated & health systems improved.

The recommendations for harmonizing clinical criteria and methodologies for evaluating DMDs will result from several work packages

Work package 1	Work package 2	Work package 3 & 4
Harmonize the taxonomy of DMDs based on their application scope and evaluation categories	Consensus on determining quantity, quality and the type of evidence that is needed for assessing DMDs	Propose a social health evaluation framework based on pre-requirements (technical, technological, ethical)

External Advisory Board

Contribute to the final suggestions by sharing perspectives of different stakeholders and experiences from real-world examples

Links to go further

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):

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

Way forward at the French Ministerial Digital Health Delegation

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merci.