DIGITAL HEALTH

REIMBURSEMENT

Current practices and challenges.

“

MONEY

MAKES THE WORLD GO ROUND.

Reimbursement of digital health technologies is still in its infancy.

Without a clear route to revenue, HealthTech innovations are stifled.

In This Carousel,

We will explore the current status quo in **5 major countries** to gain a better understanding of how HealthTech is reimbursed.

GERMANY

DiGA

Digitale Gesundheitsanwendungen

Federal Institute
for Drugs
and Medical Devices

A DiGA is a digital health application eligible for reimbursement under Germany's DVG Law.

Germany classifies DTx as digital health apps, and the **The Federal Institute for Drugs and Medical Device** (BfArM) provides assessments for access to national reimbursement.

A DiGA is a **CE-marked medical device** that has the following properties:

Medical device of the **risk class I or IIa**

Main function is based on **digital technologies.**

Medical purpose is mainly achieved by way of its **digital function.**

Supports the **recognition, monitoring, treatment or alleviation** of diseases

Used by the patient alone or by patient and healthcare provider together

To achieve the reimbursement status in Germany, DTx companies need to:

. **Provide CE marking** as a medical device and GDPR compliance.

. **Provide proof of general requirements** (including data protection, information security, interoperability and ease of use.

. **Provide a scientific evidence evaluation** through clinical trials by improving the user's health.

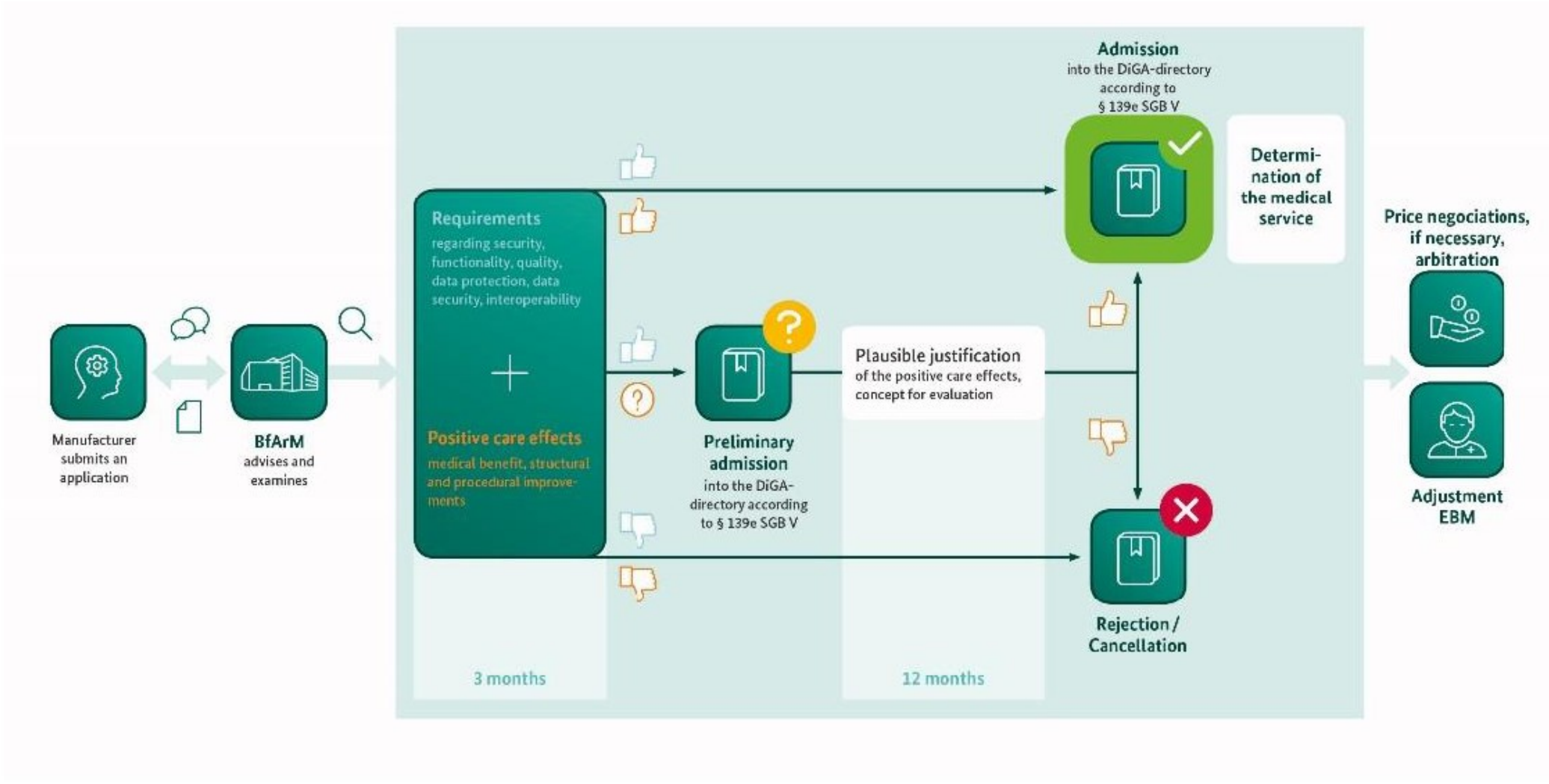


Figure 1: Sequence of the Fast Track procedure.
Source: BfArM.

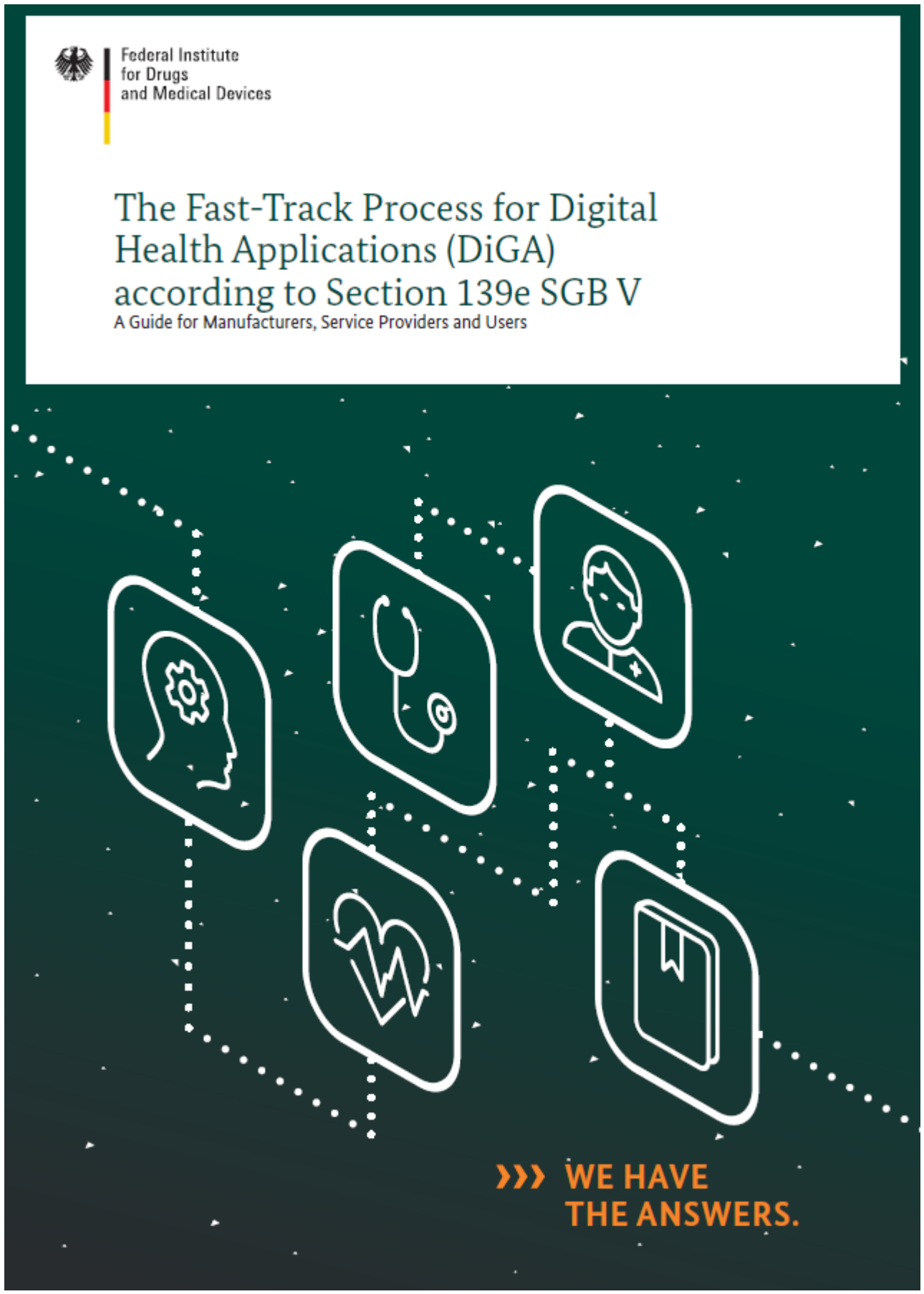
Currently, applications can be listed on the directory via **a Fast-Track scheme**.

Once in, the DVG allows for its release on the market for a temporary period of 12 months to **gather scientific evidence** to prove its safety and efficacy in the real world setting.

Once a DiGA have successfully completed the assessment of the BfArM, **they will be listed in a directory of reimbursable digital health applications.**

This means that **approximately 73 million persons** covered by the German Statutory health insurance are entitled to use a DiGA.

They can be prescribed by doctors and can be **reimbursed by the health insurance**.



There is a 128 page guide for DiGA if you are interested in the process. Available here:

https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html

FRANCE

PECAN

(Prise En Charge Anticipée Numérique)

The new PEC-AN a **transitional one-year reimbursement pathway** that provides rapid patient access to digital health solutions at a temporary one-year reimbursement rate to a more permanent listing.

Early access to reimbursement for digital devices (PECAN)

Learn what steps you should take to secure early access so you can be ready right away.

3 services

FINANCING

Early access to reimbursement for digital devices (PECAN)

2 MIN →

Checking to see if you're eligible for early access to reimbursement (PECAN)

2 MIN →

DISCOVER

How to demonstrate the clinical and/or organizational benefits of your solution

1 MIN →

To be qualified for a new temporary pathway, solutions must have the following:

CE marking as a medical device under the MDR.

Technical certification on cybersecurity, compliance, and GDPR norms.

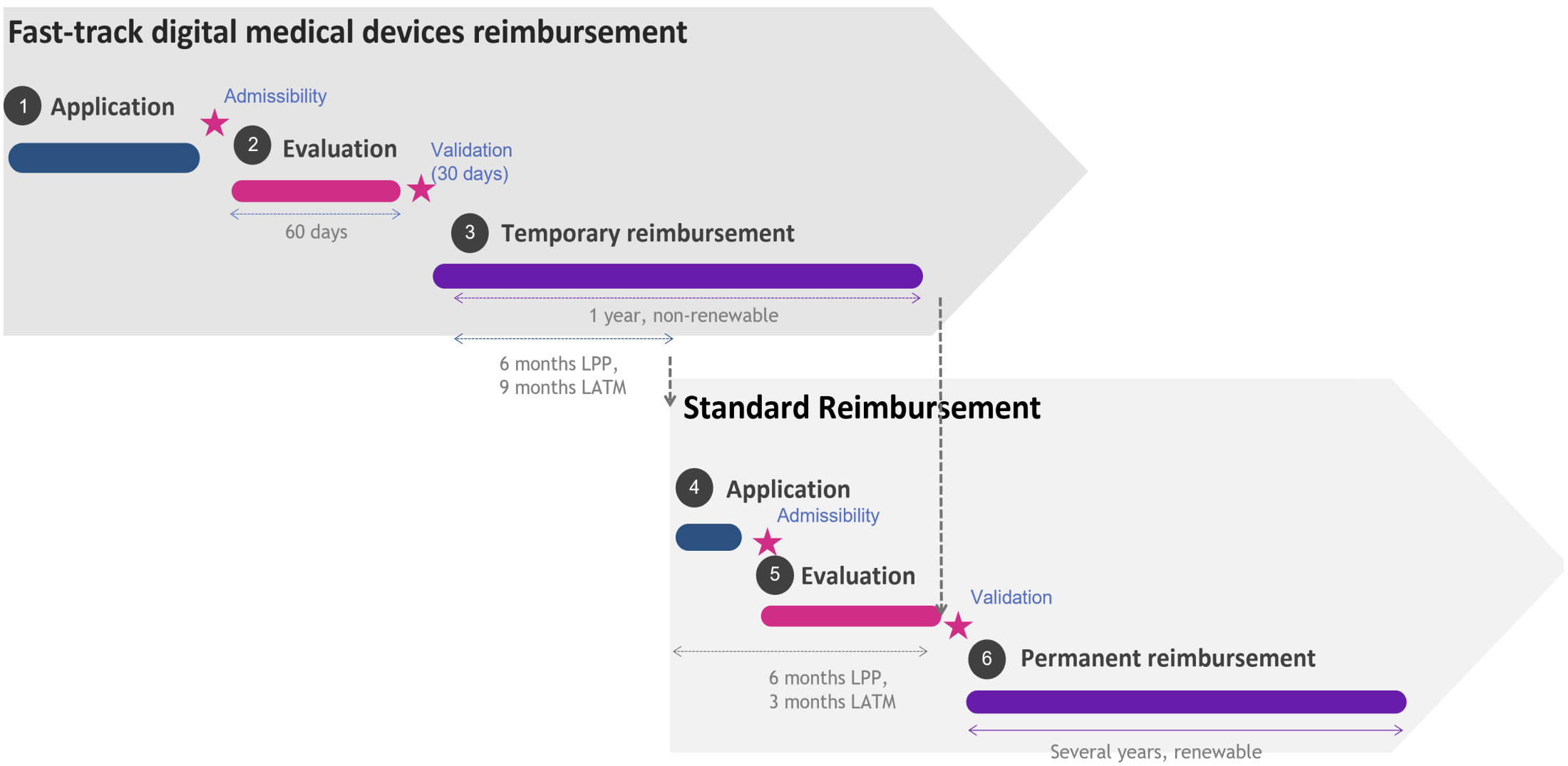
Clinical evaluation (until the end of one year term);

Information about medical usefulness or improvement in care arrangements.

After obtaining approval from the:

- **CNEDiMTS** (National Commission for the Evaluation of Medical Devices and Technologies) established on the first available clinical data.
- **National Digital Health Agency** for compliance with interoperability and security measures, the solution will be reimbursed for one year.

The company then has **several months to finish its evidence file**, which would authorize it to obtain a common law reimbursement.



If your solution is approved, it added to the list of **reimbursed products** (LPPR or LATM) for a **period of several years**, renewable.

This application **must be renewed** before the end of each period.

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1 MIN

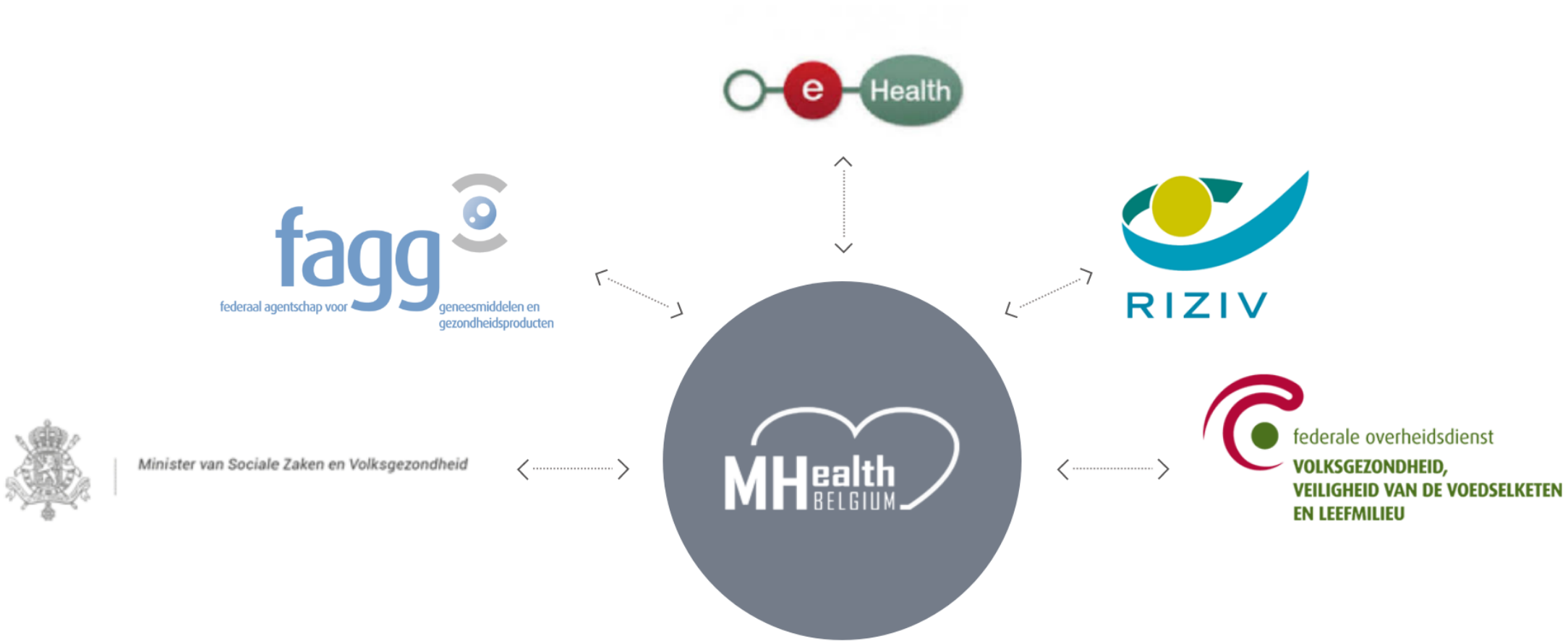
→

More information can be found here at their official website:

https://gnius.esante.gouv.fr/en/early-access-reimbursement-digital-devices-pecan

BELGIUM

mHealthBelgium

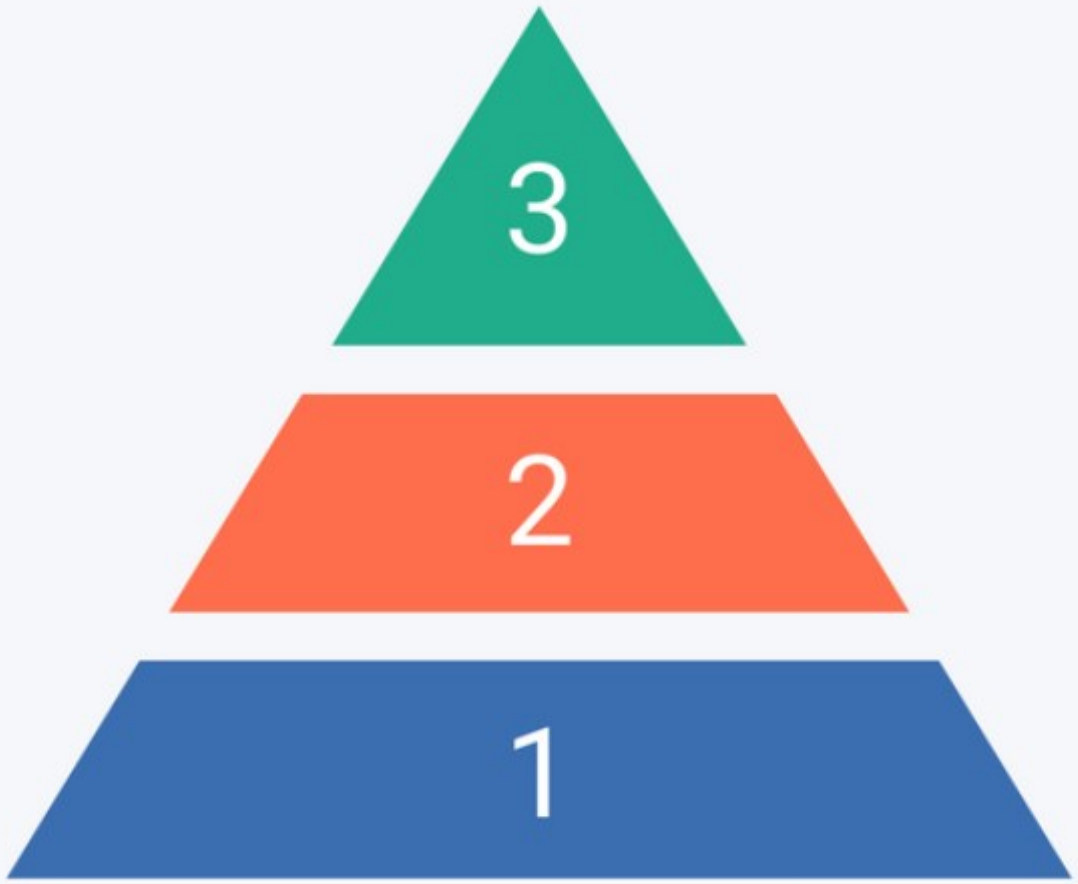


The **NIHDI** (National Institute for Health and Disability Insurance) launched a framework to **approve digital therapeutics for reimbursement**.

mHealthBelgium, also known as mobile health Belgium, is the Belgian platform for **mobile apps that are CE-marked as a medical device**.

CHINO.IO

Belgium
Validation Pyramid



Level 3: is for DTx whose socio-economic added value has been demonstrated and which are financed after positive advice from INAMI/RIZIV on their reimbursement request.

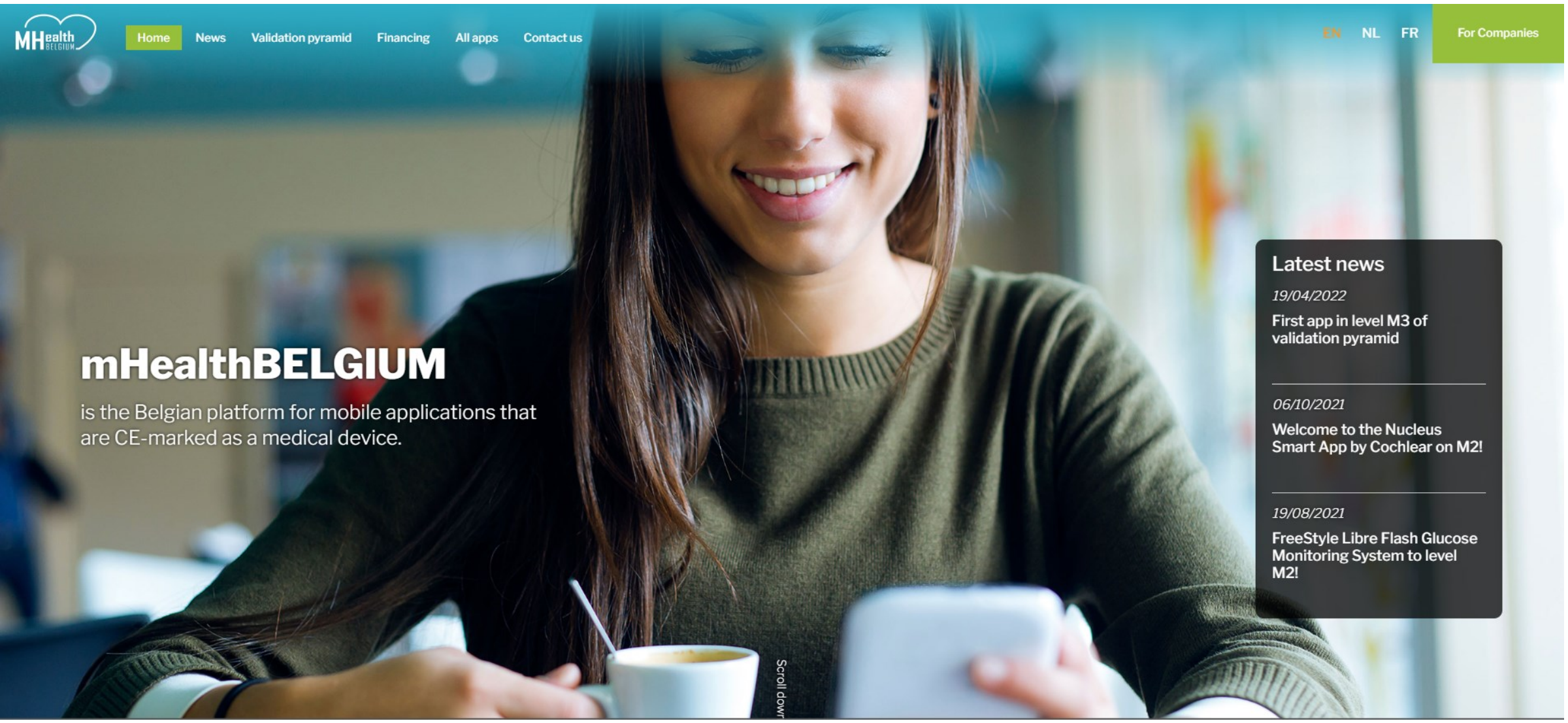
Level 2: includes level 1 requirements, plus interoperability with other mobile/ICT services, connection with the eHealth platform and risk assessment related to authentication/security.

Level 1: requires DTx to meet basic requirements (e.g. CE-marking, compliance with GDPR and product notification in the FAMHP database)

However, to get the approval, they must reach the top level of **Belgium's mobile health (mHealth) validation pyramid** and pass the evaluation by the Federal Agency for Medicines and Health Products (**FAMHP**).

When the integration and reimbursement is temporary, it will be displayed as **'M3 light'**.

When the use of mobile medical applications has been definitely integrated in the financing of the care process, it is referred to as **'M3 plus'**.



More information can be found in the official website here:

https://mhealthbelgium.be/

UNITED KINGDOM

Integrated Care Systems

Reimbursement in the National Health Service (NHS) in the UK, the provision of healthcare is devolved, with distinct health systems in England, Scotland, Wales and Northern Ireland.

Procurement decisions are **made primarily at a local level.** This is the main route to reimbursement for digital solutions.

In England, commissioning has been delegated to **42 Integrated Care Systems (ICSs).**

Integrated Care Systems Network
NHS Confederation

DTx products in the UK require a **CE mark and/or UKCA mark**, in addition to being **GDPR compliant** and meeting **Digital Technology Assessment Criteria** (DTAC) requirements.

DTx are recognised as Digital Health Technologies (DHT) under the **National Institute for Health and Care Excellence's** (NICE) Evidence for Effectiveness framework.

NICE National Institute for Health and Care Excellence

NICE has published an **evidence standards framework (ESF)** for digital health technologies.

This is designed to **assist health system decision makers** in analysing whether a solution is likely to benefit its users and the wider health system.

The ESF is not tied directly to any reimbursement process. Therefore, **there is no strong incentive for innovators to comply**.

NICE is also trialing the **Early Value Assessment (EVA)** for HealthTech. This aims to rapidly identify solutions addressing unmet needs in the NHS.

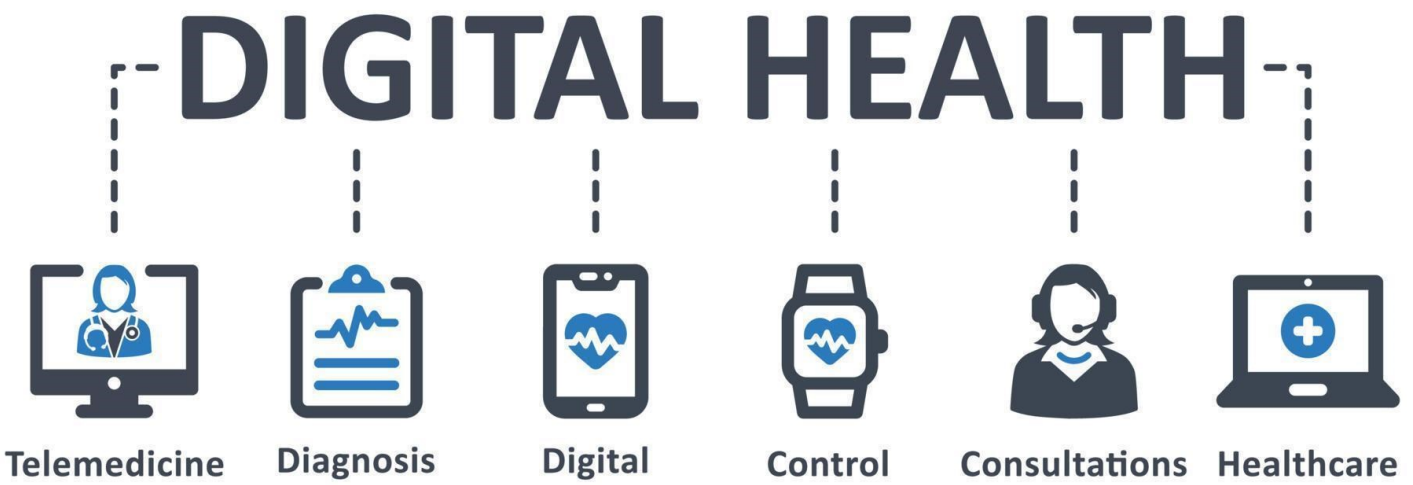
However, there remains no concrete connection between **NICE recommendations and reimbursement**, and strong evidence generation does not guarantee adoption at scale.

UNITED STATES OF AMERICA

Public vs Private Insurance

The US defines DTx as “mobile software applications used to **diagnose, treat, alleviate and prevent diseases** or other issues affecting the human body," with most DTx applications labelled as **class II medical devices** in the United States.

Based on this fact, DTx products are subject to regulation by the **Food and Drug Administration (FDA)** and classified according to the product's intended use, and level of risk and subject to different degrees of oversight.



New DTx are reviewed by the **Medical Technology or Digital Formulary Committees** who consider:

. **FDA submission data** - is a prerequisite but does not guarantee coverage.

. **Peer-reviewed clinical data** - reliable clinical data to achieve coverage and thus justify the pricing.

. **HEOR data** to show cost offsets or cost savings.

In addition to FDA approvals, digital health applications must be **HIPAA compliant** to exchange Personal Health Information (PHI) with covered entities (hospitals or insurances).

. **Medicare** currently does not pay for software products due to no existing appropriate benefit category for this type of solution.

. **Medicaid programs** and care plans can consider fee-for-service product coverage via specific benefit programs on **a state-by-state** basis.

. **The Department of Defence** (i.e., Veterans Affairs) is beginning to cover some digital therapeutic products with a hardware component.

Private health insurance plans have taken the initiative in the adoption of digital solutions including therapeutics.

Larger health plans have started to develop their own standardized evaluation frameworks for digital products and services, and to look at how to integrate these into their offering.

Ultimately however, the reimbursement landscape for digital health **remains fragmented**, and from the perspective of innovators, somewhat uncertain.

REFERENCES:

1. **Chino.IO Blog** - https://blog.chino.io/

2. **Bekey.IO Blog** - https://bekey.io/blog/articles

3. **New approaches to evaluate digital solutions with clinical value** - Prova Health/Roche

4. **DiGA** - https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html

5. **MhealthBelgium** - https://mhealthbelgium.be/

6. **PECAN -** https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/early-access-reimbursement-digital-devices-pecan

Hope you found this helpful!

This is a series we are making to help HealthTech Innovators access better resources.

Just our small way of helping!