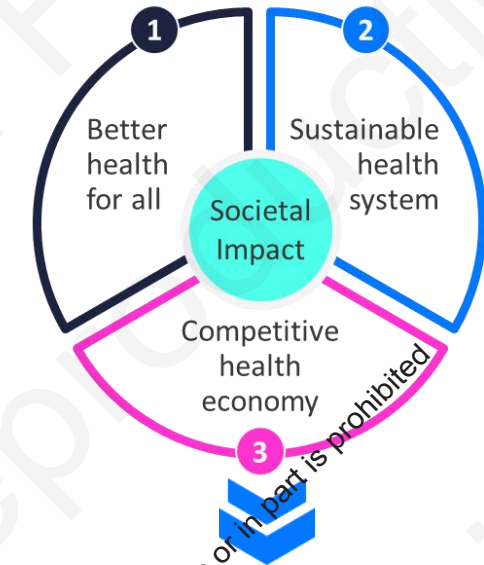5ᵗʰ May 2022

Facilitating fast adoption of digital medical devices in Europe

Dr. Cristina Bescos
Director of Innovation
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The EIT Health **Societal Impact Model**

- EIT Health was established to tackle the EU 'health, demographic change and well-being' **societal challenge** by means of powered innovation & technology

- **EIT Health Goals** acknowledge the primary health-related **societal needs** of
  - citizens & patients - for better health (well-being and quality of life)
  - health entrepreneurs - for sustainable health economies
  - health innovators, educators, payers and providers - for stronger healthcare systems

- EIT Health aims to deliver **societal impact** understood as the implementation of widespread, demonstrable **socio-economic improvements to society**

- EIT Health believes that societal impact is
  - constructed from the connection between innovation and society (**Citizen & Patient Engagement**)
  - measured against what really matters to people (**High-Value Care**)
  - assessed on **Ethical, Legal & Social principles**

Goals

Strategic objectives

Directly improve quality of life of 4.8 million Europeans	**1**
Educate 30,000 change-agents that can scale sustainable and systemic solutions	**2**
Attract € 1.3 billion of investment to start-ups	**3**
All funded activities address health challenges co-creatively and collaboratively with strong European regional inclusion and mitigate the fragmented health market (RIS objective: at least 15% of impact can be brought back to RIS regions)	**1** **2** **3**
Drive appropriate diversity (such as gender and ethnic equality) ensuring an inclusive culture and solutions that are built reflect the society they aim to serve	**1** **2** **3**

EIT Health's goals translate into 5 strategic objectives which focus on different combinations of these goals

![eit Health logo]

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The EIT Health **Operating Model** is composed of 8 co-operating bodies and hinges on a pan-EU **Partner Network**

KIC LE is a non-profit organization operating as an official legal body responsible for all relations with EIT
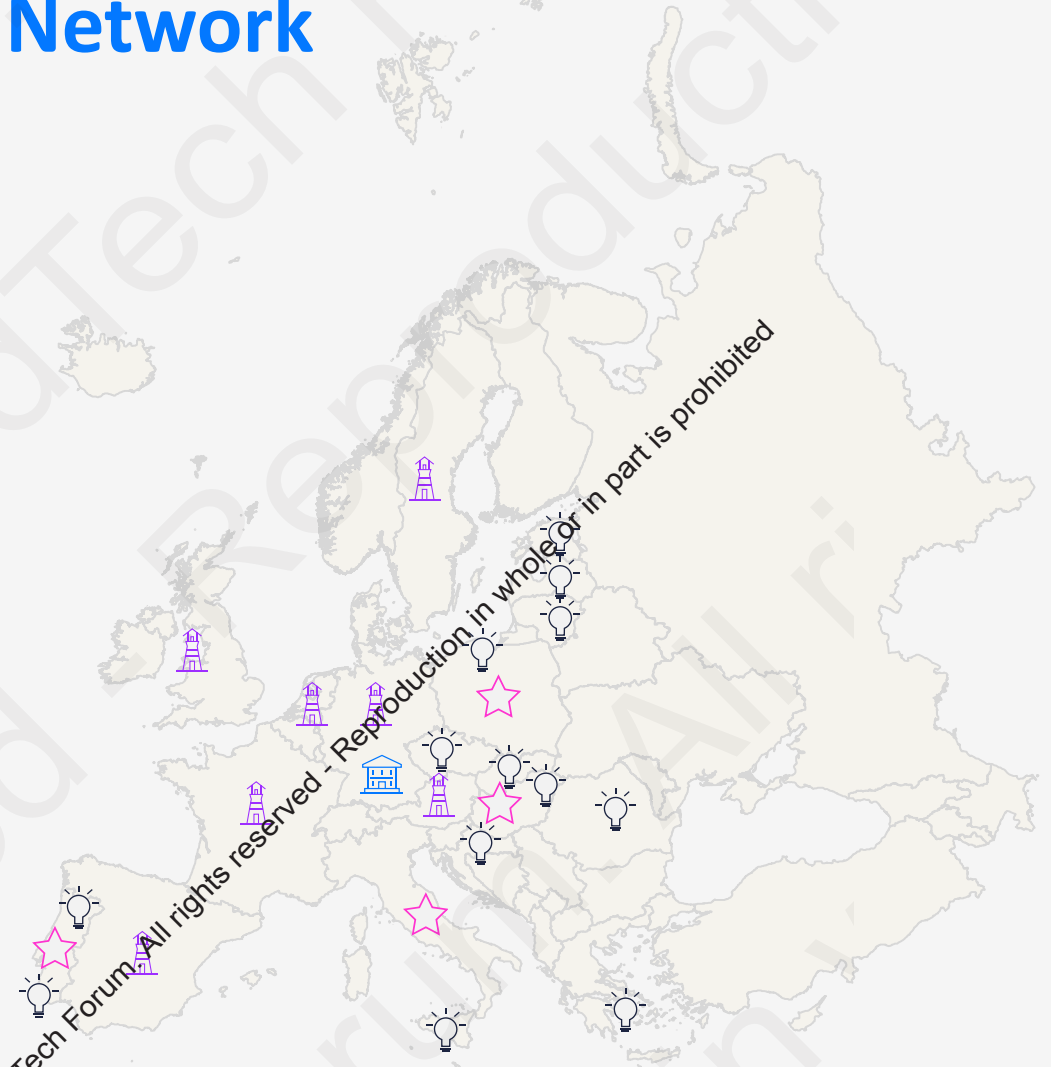
Seven regional Co-Location Centers act as innovation hubs of relevant actors

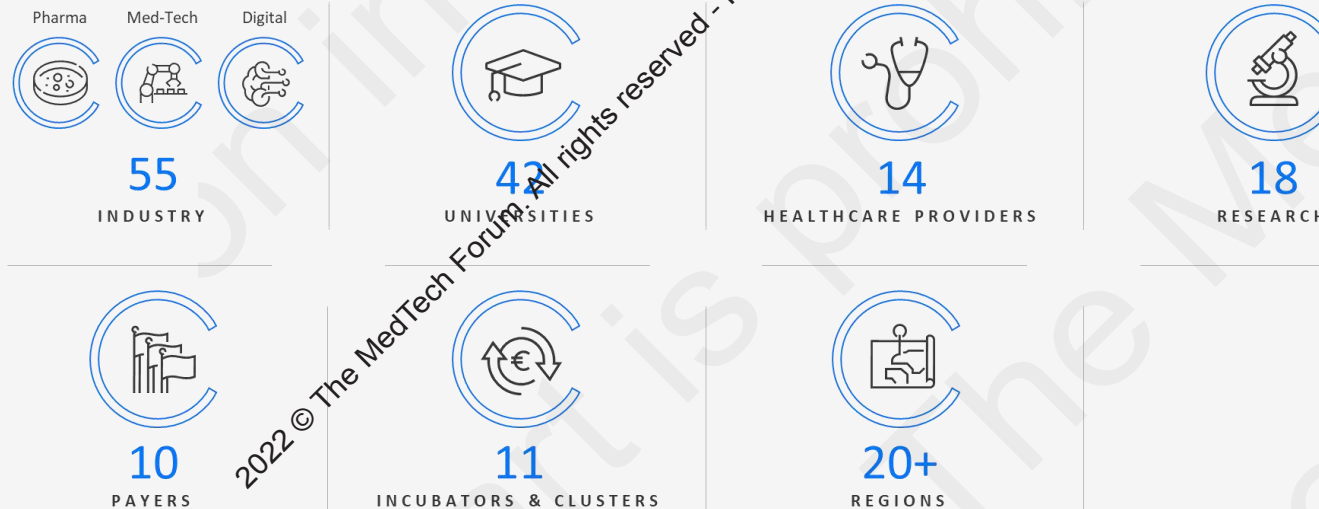InnoStars represents countries quickly developing their innovation capabilities

Regional Innovation Schemes are an effort to expand regional outreach of EIT Health

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EIT Health has a broad focus, with a wide-ranging **Partner Network**

We work with world-leading academic institutions, businesses and innovators to drive health innovation forward.

Pharma   Med-Tech   Digital

55
INDUSTRY

42
UNIVERSITIES

14
HEALTHCARE PROVIDERS

18
RESEARCH

10
PAYERS

11
INCUBATORS & CLUSTERS

20+
REGIONS

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Core partners

Associate partners

EIT Health Activities are structured along the **3 "Pillars" of the Knowledge Innovation Triangle**

Innovation

Connects bold approaches to the people who can make them a reality by turning them into a commercially-viable product or service.

Builds a task force of world-class experts from business, research and education.

Business Creation

A catalyst to business growth to deliver transformative products and services.

Shortens the time-to-market for entrepreneurs, start-ups and SMEs, while creating new jobs and contributing to a thriving health economy.

Education

Bridges the gap between academia and enterprise to upskill professionals on new innovative techniques, providing the practical knowledge and inspiration to deliver future innovation.

Engages learners across society, from citizens to established healthcare professionals.

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Digital Health Transformation

Digital innovation has the potential to transform every aspect of health care and the care delivery pathway, delivering better value to patients but some barriers remain

- **Regulatory** e.g.
    - implementation of the MDR
    - HTA and reimbursement frameworks
    - including **Ethical and legal compliance** (data security, confidentiality, liability and safety=

- **Technical** e.g.
    - interoperability
    - Education + Training (digital literacy, digital upskilling, talent creation..)

- **"Societal"** e.g.
    - Patients' limited involvement in the digital innovation pathway
    - Virtual transfer of 'traditional' health care reducing potential to achieve more value via a true digital transformation

The crisis has shown that much can be achieved in unprecedented ways at fast speeds, without compromising necessary standards and principles. We should not back off from progress made, but rather invest in establishing long-lasting change.

Market Adoption

European markets are beginning to finance the adoption of Digital Health solutions

Germany

- DTx in Germany has been financed for 3-5 years through private insurance funds
- German government approved a law proposed by the Ministry of Health to finance Class I & II digital health products nationally in 2019
- Implementation is currently in progress
- BfArM is the evaluator for deciding which products are allowed into the scheme

Belgium

- The "pyramid" developed by mHealth Belgium serves as a filter for product segmentation
  1) CE marked
  2) interoperable within the Belgian medical record system
  3) can demonstrate HEOR for Belgian patients
- 1 product has reached level 3
- Financing for products is not yet included

France

- France has four possible pathways to reimbursement of DTx to date
- For the Etapes program, only five disease areas are covered, and the program is limited in duration
- HAS is, however, developing a new digital health strategy which may open new avenues with new requirements

UK

- UK has no national reimbursement through NHS, but certain CCGs are using funds for DTx products
- Localized NHS programs wherein certain health apps are financed for citizens of that locality
- London GoodThinking program for mental wellbeing, includes a reimbursed DTx product

Health
eit
GSD Health
Grow Scale Deliver

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Germany: Pathway

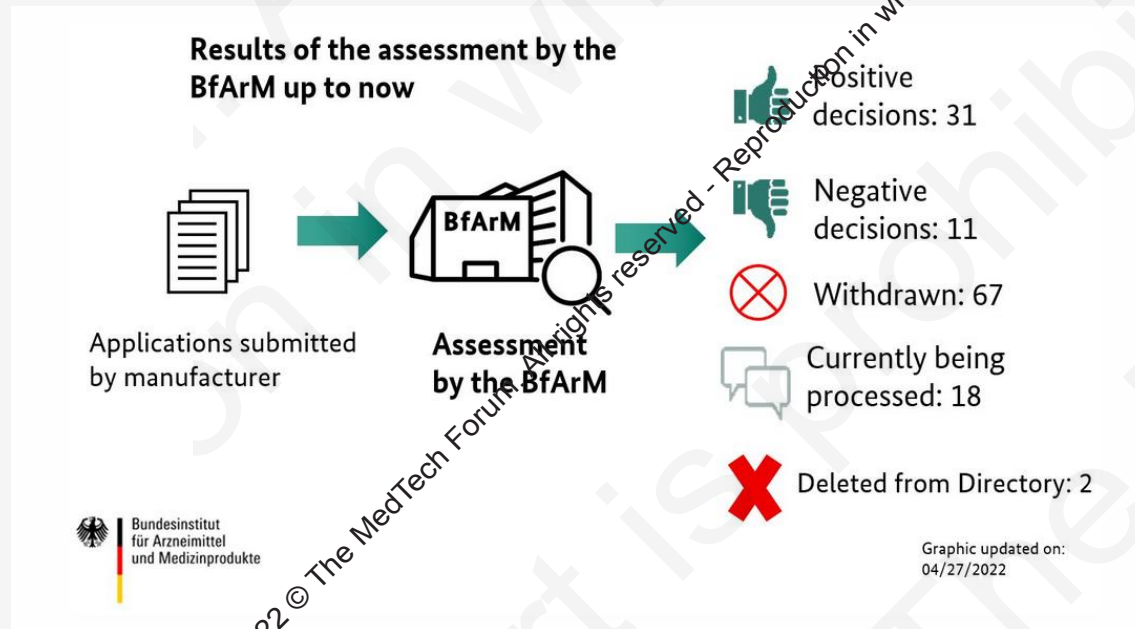| Pre-Requisites	Validation	Market Access	Reimbursement

Medical Product Certification

1. MD Class I or IIa only (MDR)
2. Fulfill requirements on data security, safety, quality and functionality

Application for listing BtArm decides within 3 months

Enough evidence regarding security, quality, functionality, QoC — Yes

No

If missing, evidence must be generated within 12 months

Enough evidence regarding quality, security, functionality, QoC — Yes

No

Official listing & temporary reimbursement*

During the first 12 months: reimbursement is based on app publishers price

Price negotiations between app publishers & GKV

Reimbursement

After the first 12 months: agreed price between GKV and publishers applicable for all public insurers

Health
GSD Health
Grow Scale Deliver

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From the Diga Fast Track Procedure to EIT Health DigInnovation

Results of the assessment by the BfArM up to now

Applications submitted by manufacturer → Assessment by the BfArM →

- 👍 Positive decisions: 31
- 👎 Negative decisions: 11
- ⊗ Withdrawn: 67
- 💬 Currently being processed: 18
- ❌ Deleted from Directory: 2

Graphic updated on: 04/27/2022

Bundesinstitut für Arzneimittel und Medizinprodukte

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

- Based on the learnings from two years of DiGA implementation in Germany, the following challenges and pain points can be identified:
  - Not appropriate study design
  - German-specific evidence needs to be provided
  - Skepticism and resistance from healthcare providers mainly due to concerns regarding data protection, lack of information and trust on DiGAs
  - Pricing and business models are unclear or can be changed after the full registration (prices decreased)
  - No sustained growth in app downloads after approval
  - Logistically difficult to reach providers and users spread across the country
  - Challenges in alignment with the data protection and data security requirements

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Overview : 2021 achievements
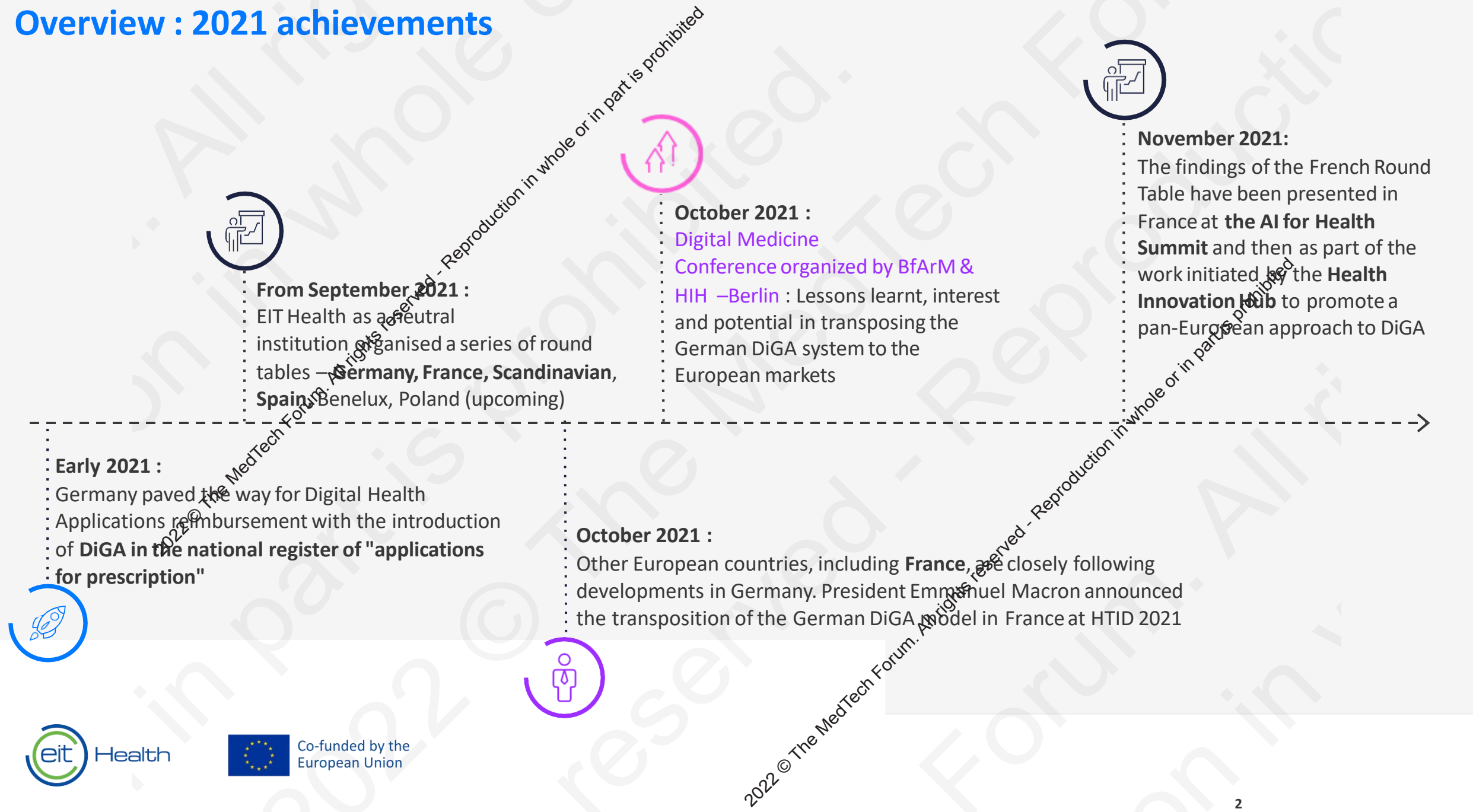
From September 2021 :
EIT Health as a neutral institution organised a series of round tables – **Germany, France, Scandinavian**, **Spain**, Benelux, Poland (upcoming)

October 2021 :
Digital Medicine Conference organized by BfArM & HIH –Berlin : Lessons learnt, interest and potential in transposing the German DiGA system to the European markets

November 2021:
The findings of the French Round Table have been presented in France at **the AI for Health Summit** and then as part of the work initiated by the **Health Innovation Hub** to promote a pan-European approach to DiGA
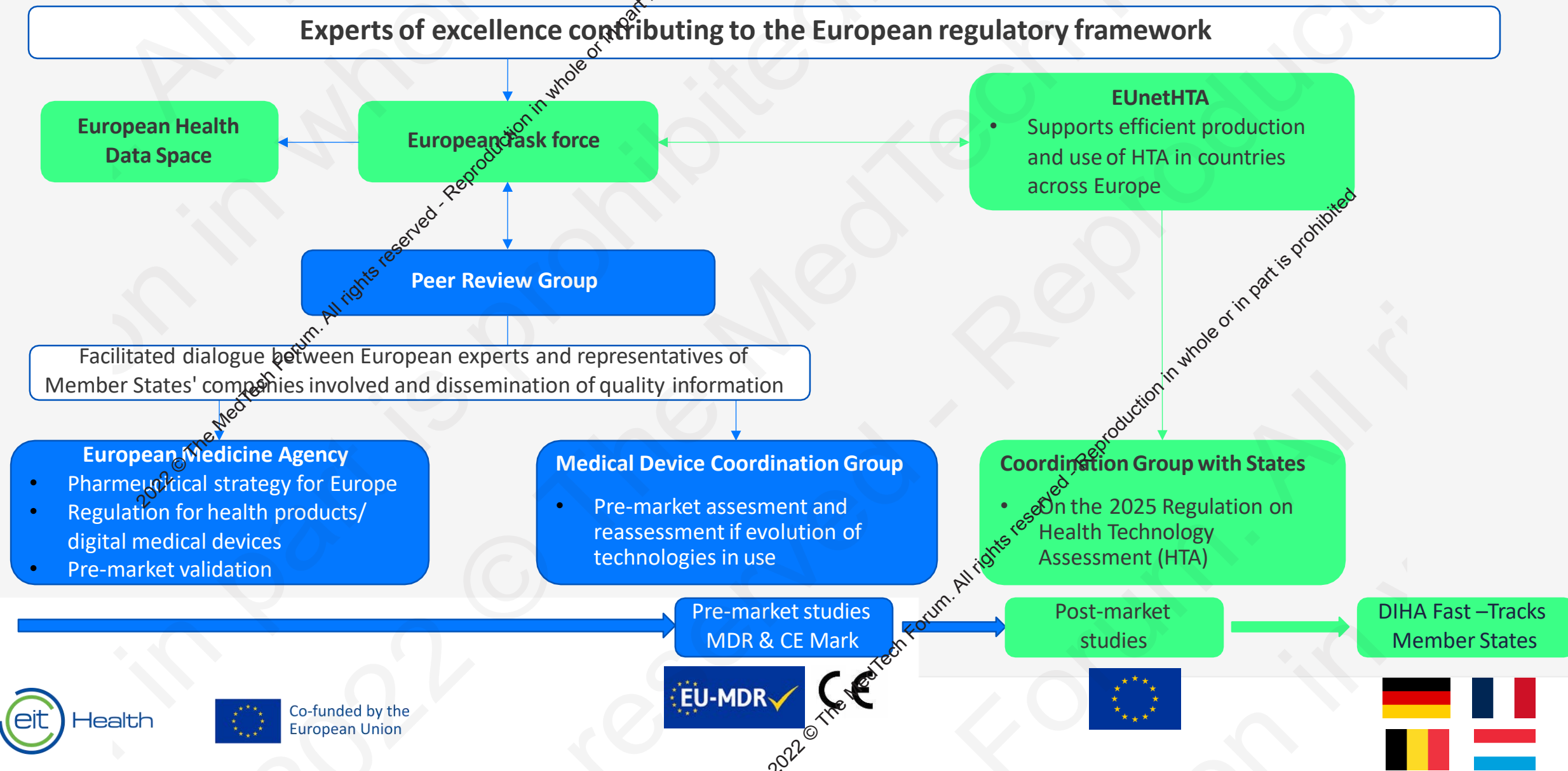
Early 2021 :
Germany paved the way for Digital Health Applications reimbursement with the introduction of **DiGA in the national register of "applications for prescription"**

October 2021 :
Other European countries, including **France**, are closely following developments in Germany. President Emmanuel Macron announced the transposition of the German DiGA model in France at HTID 2021

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Dissemination Strategy : MDCG / EMA/ EUnetHTA

Experts of excellence contributing to the European regulatory framework

European Health Data Space ← **European Task force** ⟷ **EUnetHTA**
- Supports efficient production and use of HTA in countries across Europe

Peer Review Group

Facilitated dialogue between European experts and representatives of Member States' companies involved and dissemination of quality information

European Medicine Agency
- Pharmeutical strategy for Europe
- Regulation for health products/ digital medical devices
- Pre-market validation

Medical Device Coordination Group
- Pre-market assesment and reassessment if evolution of technologies in use

Coordination Group with States
- On the 2025 Regulation on Health Technology Assessment (HTA)

Pre-market studies MDR & CE Mark → Post-market studies → DIHA Fast –Tracks Member States

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EU-MDR ✓ CE

To obtain the best initiative and build the most effective and concrete pan-European consensus

Peer review group

European Task Force

- Pan European approach analysis

- Drafting a Consensus Paper based on scientific iteracy

- Design and share the conclusion

Peer review group

- Testimonies of start-ups, use case and pilots

- Review of the conclusions of the Taskforce
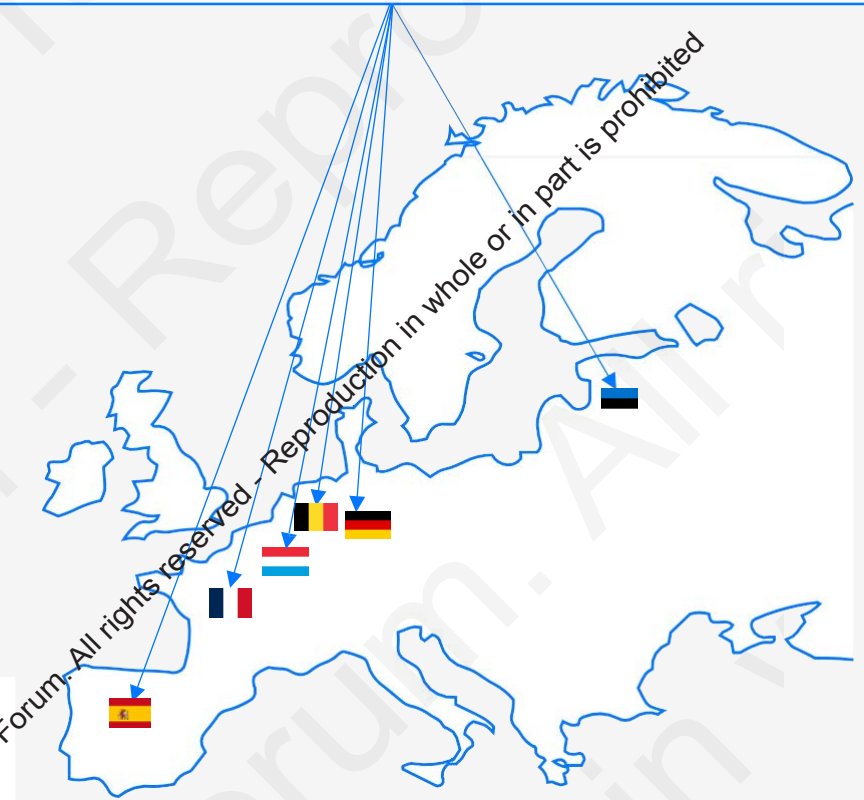
Learnings from DiGA in Germany

CHALLENGES AND OPPORTUNITIES FOR DIGITAL HEALTH COMPANIES ENTERING THE GERMAN MARKET

Focus Area	GENERATING EVIDENCE	PRICING AND BUSINESS MODELS	SELECTING DISTRIBUTION CHANNELS	PROVIDER EDUCTATION
Challenge	DiGA apps must be supported by Germany-specific evidence	• Competition will inevitably lower price points • Data and advertising revenues are restricted for DiGA apps	Logistical difficulty in reaching providers and users spread across the country	Providers unfamiliar with digital tools will be hesitant to prescribe and use them
Opportunity	High quality clinical evidence distinguishes solutions from competitors amongst potential B2B clients and end users	Push towards digitalization may open up new business models for employer and health plan market	Using innovative partnerships with telehealth providers, etc. to reach established networks	Providing clear benefits for HCPs and ease of workflow will encourage adoption

THESE FOUR PILLARS ARE CRUCIAL FOR ALL COMPANIES, REGARDLESS OF DiGA LISTING OR STATUS

Source: Research2Guidance Report
Reference

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Further Learnings from DiGA in Germany

I'd like to note that the manufacturers which didn't make it into the fast track were mostly rejected because their **study design was not appropriate**. Thus, the way they wanted to generate initial evidence was simply not sufficient. To me, it's a very thorough argument that BfArM is making sure non-scientific evidence doesn't infiltrate the health care sector.

Henrik Matthies
Managing Director of **health innovation hub (hih)**
Reference

DiGA manufacturers see an immediate growth in downloads after DiGA listing, but **the growth does not appear to be sustained in the mid-term**

Research2Guidance Report
Reference

53% of doctors want **a central platform where they can learn about the DIGAs**. Should this be created, developers should reflect how they can stand out on this platform.

Bitkom survey

One in four physicians said they would like to prescribe DiGAs, but **so far only two percent have done so...** Many physicians remain hesitant, around **28% do not want to prescribe DiGAs, mainly due to concerns regarding data protection, lack of information and trust on DiGAs**

Bitkom survey

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DiGinnovation: a grant-for-option collaborative programme supporting the faster reimbursement pathway for digital health apps in Europe

What you get

- Partners:
  Ability to **join and support** the best digital health start-ups in getting reimbursed at certain European markets.

- Start-up:
  - grant up to **€250,000** for a start-up and **€350,000** in total for a project
  - access to **EIT Health network** and possibility to cooperate with top-notch healthcare organizations
  - support from EIT Health **highly qualified staff** in matchmaking, proposal preparation etc.
  - **marker of EU support** and framework for international cooperation
  - **learning opportunities** and **expert advice** through the Pitch Day, due diligence and valuation process, monitoring review

What you give

- Partners: **sharing leadership** and **grant** with a start-up.

- Start-up: **Option** for EIT Health to assume shares in defined activating events (asset and share deal exits, IPO, liquidation).

Intended impact

Innovations **entering new markets** and **getting reimbursed**
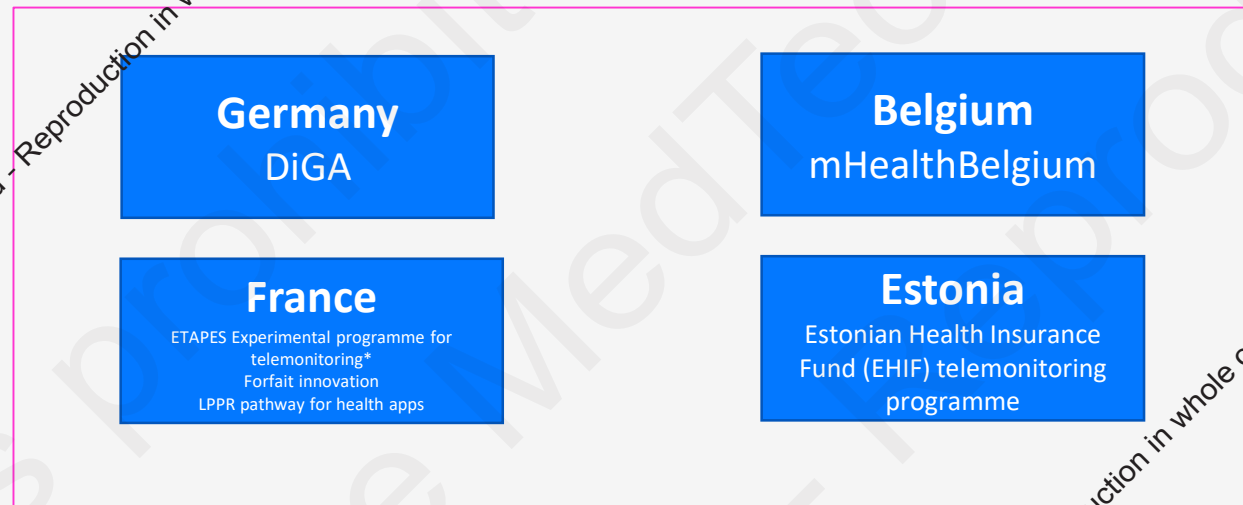
More **patients benefitted**

Healthcare professionals trained

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Geographical Focus of the Call

Primary markets

- Where the fast-track reimbursement pathways for digital health apps already exist (fully or partially). Mandatory to plan reimbursement in one of these markets in the framework of the Call OR show that there is a reimbursement pathway available in the secondary market

Germany
DiGA

France
ETAPES Experimental programme for telemonitoring*
Forfait innovation
LPPR pathway for health apps

Belgium
mHealthBelgium

Estonia
Estonian Health Insurance Fund (EHIF) telemonitoring programme

England
NHS Apps Library**

Secondary markets

- Where the fast-track reimbursement pathways for digital health apps do not readily exist but could potentially be implemented in 2022. Can be offered as additional markets by the start-ups in the proposal OR shown that there is a reimbursement pathway available

Other EU markets

Spain

Netherlands

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*Was planned to be discontinued at the end of 2021
***Outside of the scope of a Call, discontinued at the end of 2021

Sources:
Position Paper 'Recognising the value of digital health apps: An assessment of five European healthcare systems', Medtech Europe, 2021
DTx Alliance https://dtxalliance.org/understanding-dtx/dtx-by-country/

The EIT Health **Approach**

Delivering outcomes that matter to people

Innovation

**People
Payers
Providers**

**People
Payers
Providers**

Business Creation

Education

We **identify** unmet societal (socio-economic) needs

We bring together the brightest minds from **education, business, and research**

We **deliver solutions that address the needs** of the market and society.

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New European Innovation Agenda

European Commission intends to develop potential Flagship actions to address the below-mentioned weaknesses.

It is expected that the EIT Community could play an important role in addressing the talent gap, the innovation divide as well as strengthening the European innovation ecosystem.

- Access to finance
- Framework conditions, including legislation
- Fragmentation of the EU innovation ecosystem
- Innovation performance: differences among EU regions
- Talent: developing and attracting entrepreneurial talent

The Commission has published a brief summary of the initiative at this link, which is now open for feedback.

Innovation is critical to navigate the twin green and digital transitions and to secure the EU's open strategic autonomy. This initiative builds on strong foundations to address the scale-up financing gap; need for regulation to enable innovation in rapidly evolving fields; to better interconnect innovation ecosystems and bridge the innovation divide between regions and Member States; and to harness the potential of all innovation ecosystems' players while developing and attracting talents.

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Thank you

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