



# **INNOVACIÓN EN SALUD DIGITAL: INICIATIVAS COLABORATIVAS PARA CONSTRUIR UN ENTORNO FAVORABLE**

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# European Institute of Innovation and Technology (EIT)

## Multiple Knowledge Innovation Communities (KICs)

- Training a new generation of entrepreneurs
- Developing innovative products and services
- Powering start-ups and scale-ups

# About EIT Health

**EIT Health is a vibrant community of some of the world's leading health innovators supported by the EU.**

- Working across borders, we harness the brightest minds from business, research, education and healthcare delivery to answer some of Europe's biggest health challenges.



Strengthening healthcare systems in Europe



Promoting better health of citizens



Contributing to a sustainable health economy in Europe

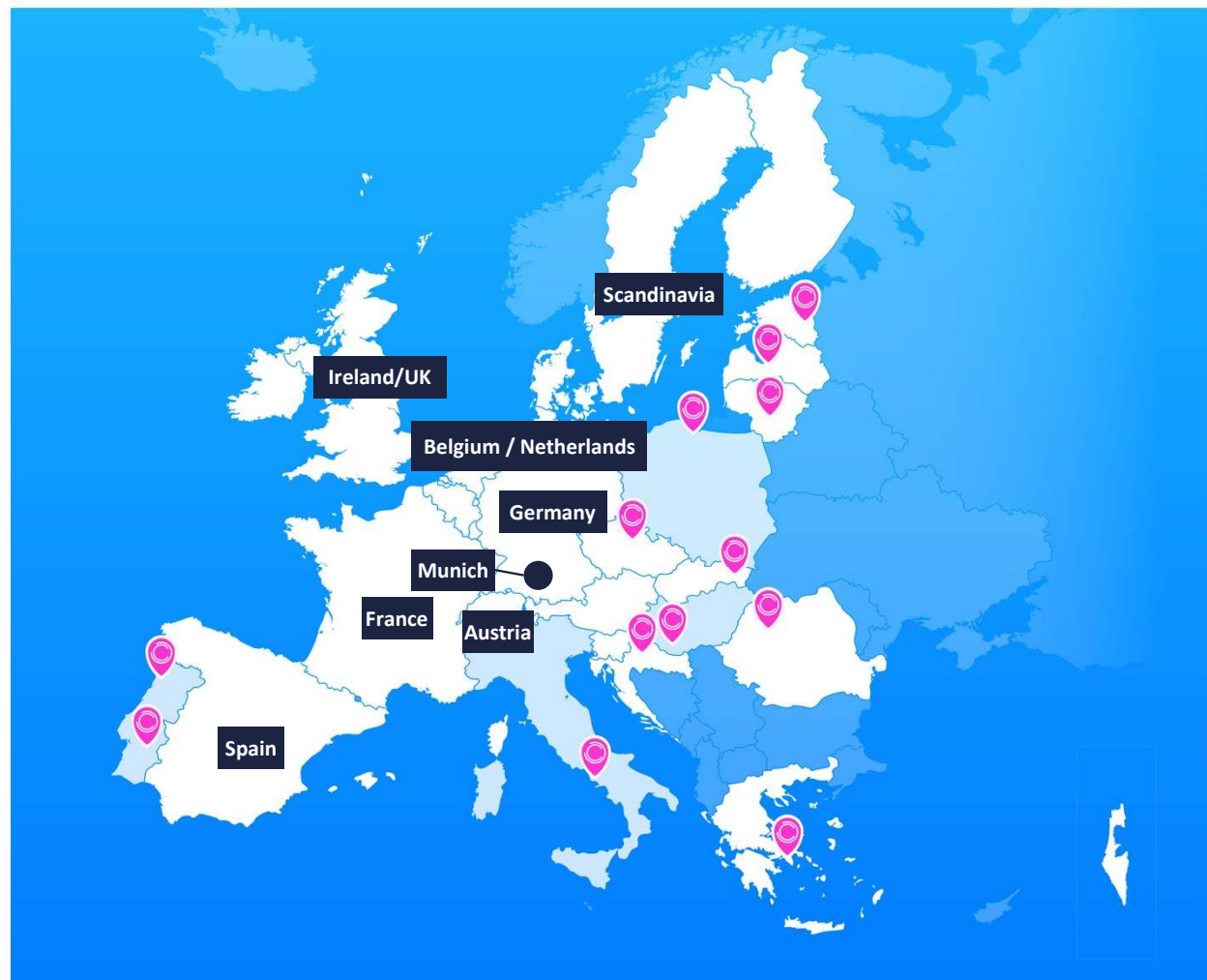


Co-funded by the  
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# Our presence

Co-funded by the EU, we promote innovation by supporting the creation of health innovation ecosystems in different countries and regions, operating as public private partnership



## Our programmes: funding and supporting innovation transfer



### Accelerator

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.



### 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.



# EIT Health Partners

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

## Core partners



## Associate partners



# EIT Health Spain



UNIVERSIDAD  
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DE MADRID

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Business School  
University of Navarra

SaludMadrid  
Servicio Madrileño  
de Salud

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managing technologies

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Salut/ Agència de Qualitat i Avaluació  
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Biomed

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Science and Technology

Associate  
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ítemas isciiii  
Plataforma de dinamización e innovación de las capacidades  
industriales del Sistema Nacional de Salud

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## EIT Health impact

We're transforming the way healthcare is delivered in Europe, changing lives, making new leaps in healthcare that put the patient front and centre.

### Innovation



280

innovation projects supported



76

products or services brought to market

### Accelerator



1,683

supported start-ups



>€1BN

start-ups have attracted over €1BN investment

### Education



>224K

citizens and patients trained and empowered to foster healthier living and prevent disease



>40K

students and professionals trained



## Refocusing on flagships



# Think Tank

**World-class ideas are wasted if the world isn't ready for them.**

Think Tank – our thought leadership forum – brings healthcare leaders together to prepare the ground for life-changing innovation and identify the next opportunity for a step-change in delivery.

We collaborate across disciplines, time-zones and sectors to explore and assess the most pressing topics.



# Salud digital después de la Covid-19: Impulso de los agentes, estrategias y fondos

- Impulso en la demanda por pacientes y profesionales de soluciones digitales y respuesta rápida de los innovadores durante la Covid-19.
- Inyección de fondos sin precedentes en Europa para fortalecer los sistemas sanitarios (NextGen, EU4Health)
- Planes estratégicos a nivel nacional: PERTE de Salud de Vanguardia, Plan de Salud Digital, Estrategia Nacional de Inteligencia Artificial
- PERTE Salud de Vanguardia: transformación digital (específicamente en Atención Primaria) y creación de un espacio de datos de salud como áreas de acción prioritaria.
- Digitalización solo es transformadora **si hay una “ordenación” de las iniciativas y si el entorno, especialmente el regulatorio, allana y agiliza el camino de la innovación**



# Beneficios de las soluciones de salud digital

- Favorecer los cambios de comportamiento que pueden mejorar la **adherencia**
- Mejorar la **accesibilidad** en la atención, este el paciente donde esté e independientemente de la hora a la que necesite la atención.
- **Monitorizar** al paciente y su tratamiento, con la oportunidad de recoger **información** de calidad que ayude al profesional sanitario a adaptar el tratamiento a las necesidades específicas del paciente
- Recoger indicadores o marcadores que contribuyan a una **medicina personalizada**
- Adecuar la atención sanitaria poniendo las necesidades de los **pacientes en el centro** y ayudar a las decisiones compartidas médico-paciente.
- Contribuir a la **resiliencia y sostenibilidad de los sistemas sanitarios**, con impacto tanto en los diferentes niveles asistenciales como en los diferentes sistemas sanitarios, estatal o autonómicos.



# Salud Digital: ¿estamos preparados en España?

- Las aplicaciones de salud digital, validadas clínicamente y de calidad, que pueden recomendarse o prescribirse por un profesional sanitario se consideran **tecnologías sanitarias, en concreto, dispositivos médicos**, cuyos procesos de evaluación, autorización y financiación están establecidos en España.
- Pero ¿están estos procesos realmente adaptados en España a este tipo de tecnologías de salud digital y a su rápida evolución?



# Challenges in German HC System



## HEALTH STATUS & DISEASE BURDEN

**81.1**

Life expectancy at birth (years)

**23.6%**

Obesity prevalence

**8.3%**

Diabetes prevalence

**17%**

Adults with multiple chronic conditions (2 or more)

- Aging population
- Shortage of Health care professionals, e.g. over 100.000 caregiver missing already today in Germany
- Access to health care in rural areas
- Increasing number of patients with chronic diseases

Source: [https://www.commonwealthfund.org/sites/default/files/2020-12/2020\\_IntlOverview\\_GER.pdf](https://www.commonwealthfund.org/sites/default/files/2020-12/2020_IntlOverview_GER.pdf)

# DiGA: Digitale Gesundheitsanwendungen

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

- Medical device of the risk class I or IIa (according to the Medical Device Regulation (MDR))
- The main function of the DiGA is based on digital technologies.
- The medical purpose is mainly achieved by way of its digital function.
- The DiGA supports the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment, alleviation or compensation of injuries or disabilities.
- The DiGA is used by the patient alone or by patient and healthcare provider together.

# DiGA vs. Health apps

## 2,779\* Health apps

Not BfArM-approved,  
Not necessarily a medical device

Positive effect on health care system not controlled

No proof of benefit required

Usually self-payer

Patient safety and functional capability not regulated

Data protection only regulated by the GDPR, no regulation on data security

## 28\*\* DiGA

**BfArM-approved**, class I or IIa medical device, CE-marked or certified

Must provide **medical benefit** or **patient-relevant procedural** or **structural improvement**

Proof of benefit through **comparative clinical study**

**Costs covered** by statutory health insurance

Patient safety and functional capability meets BfArM requirements

**Data protection and data security** meets BfArM requirements, these go beyond the DSGVO

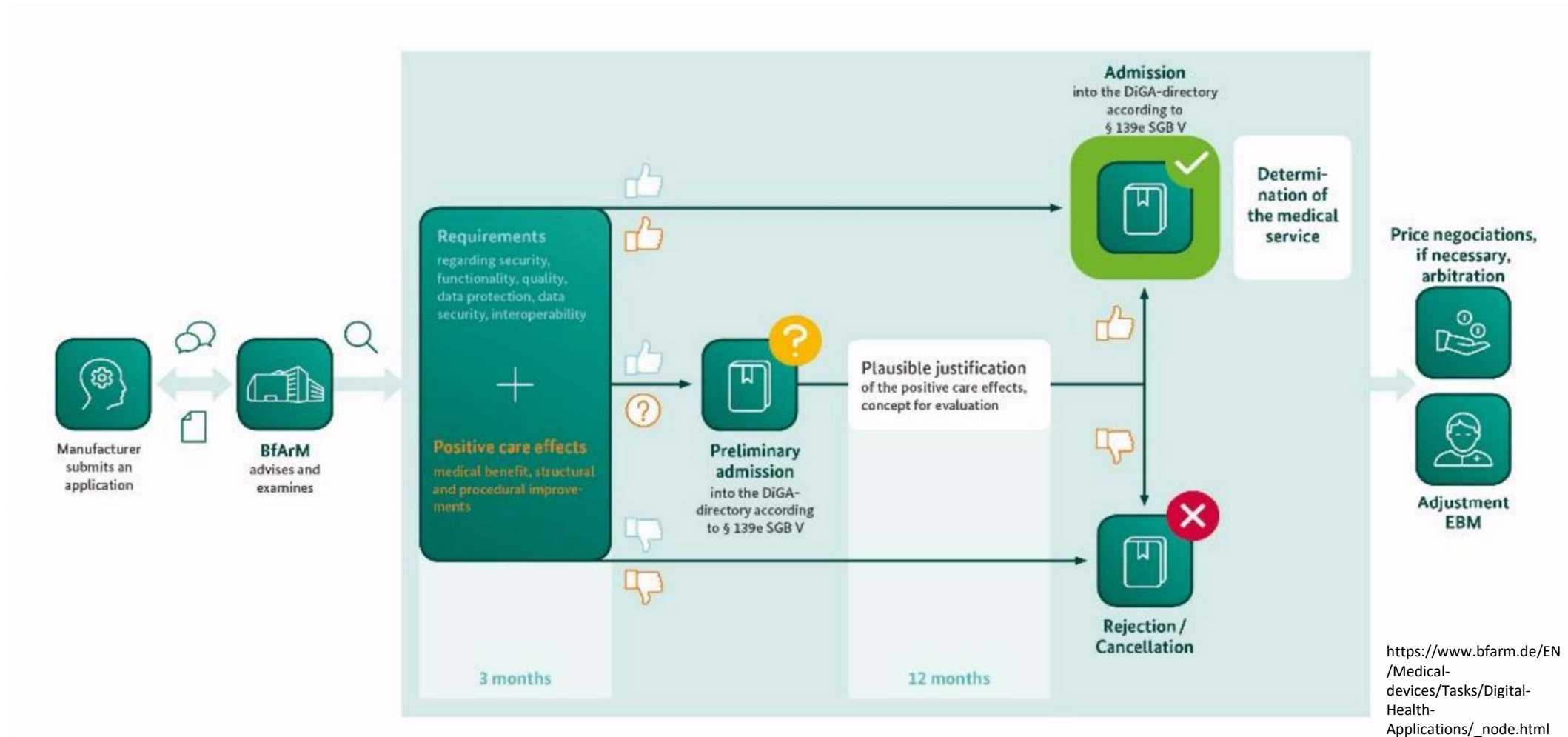


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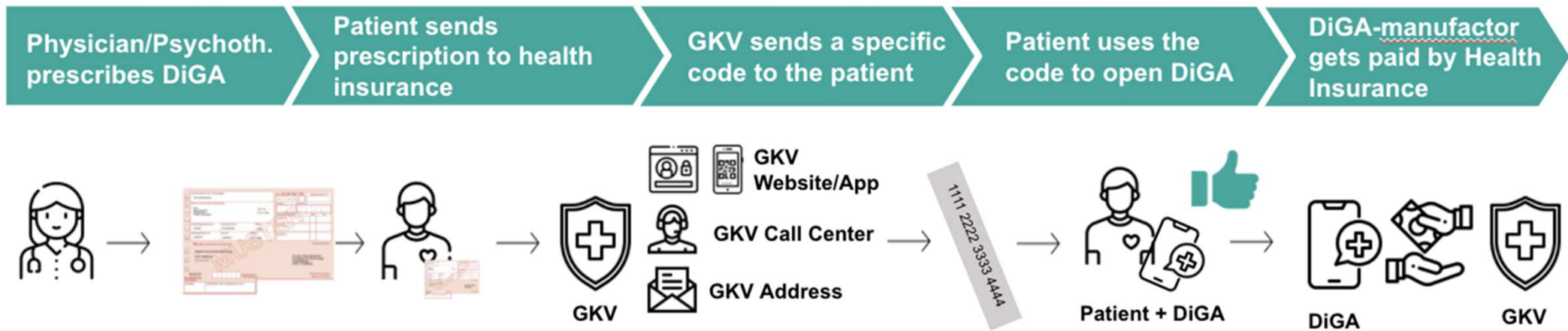
\*Number of German-language health apps in Germany, Austria, Switzerland, App Market Explorer, 06 June 2019

\*\* Number of DiGA in the BfArM list, 21.2.2022

# Assessment process for DiGAs in Germany

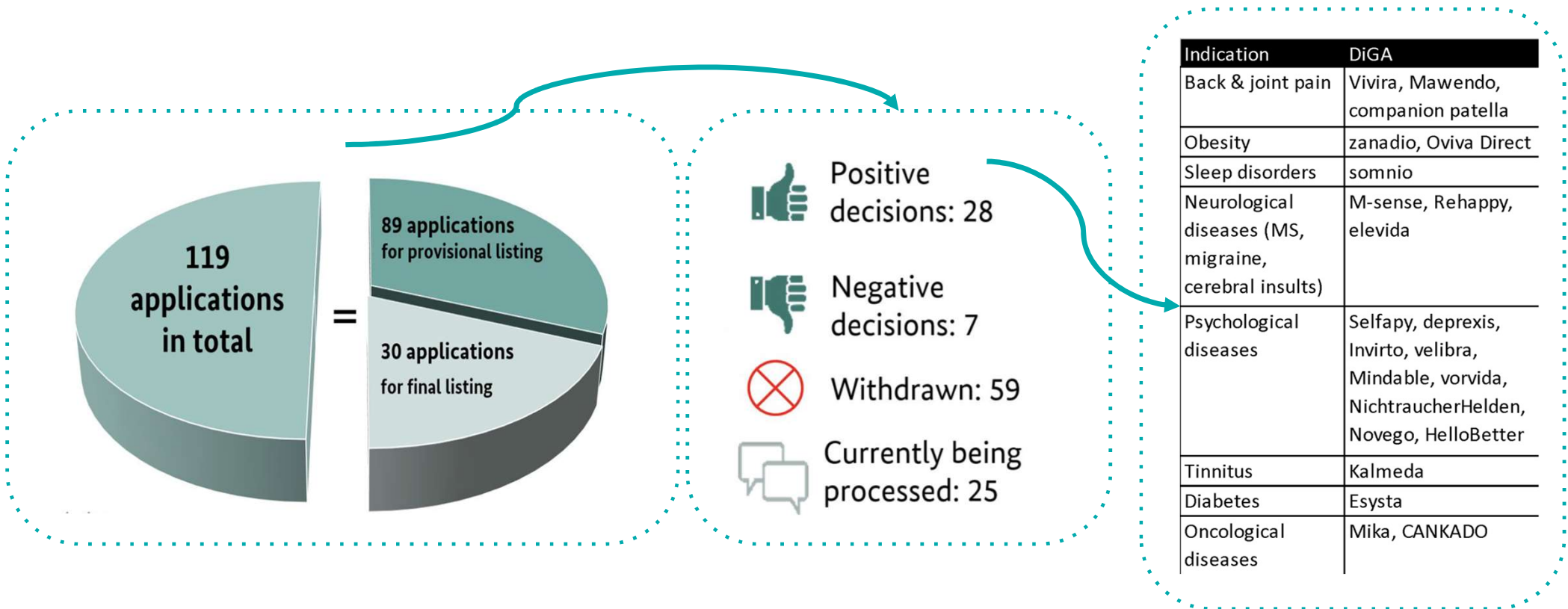


# DiGA prescription process 2020



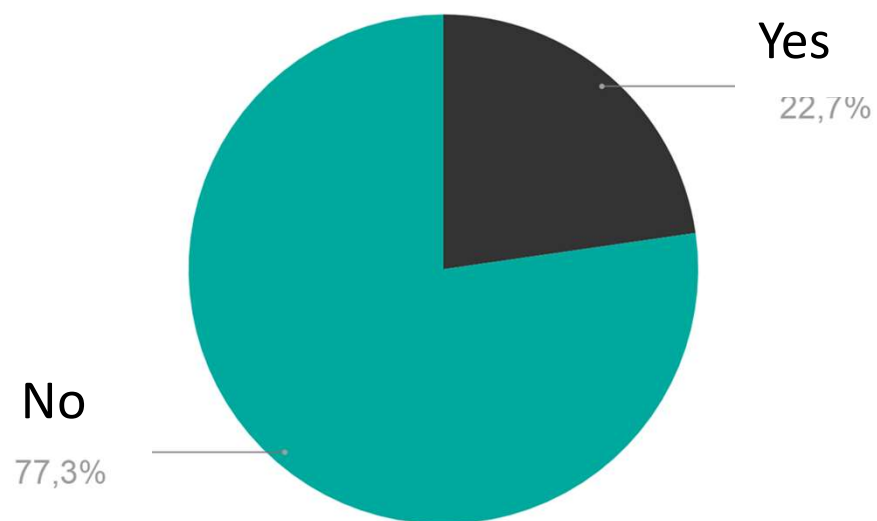


## Facts & figures app. 1 1/2 years after launch

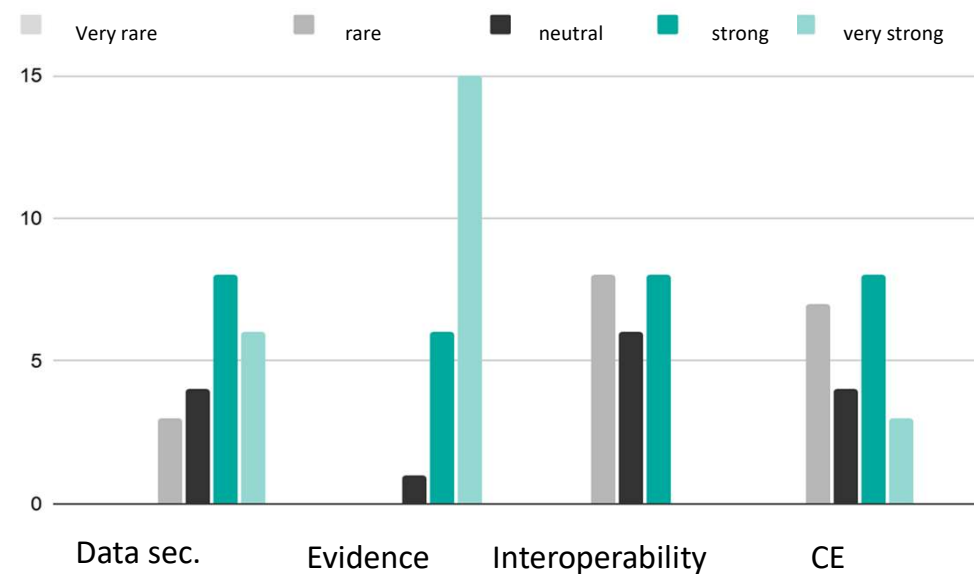


## Feedback from DiGA manufacturers

Could you bring your DHA to the market without the opportunity of preliminary listing?



In which areas are the biggest challenges to bring DHA to the market?



## Learnings of first year of DiGA in Germany: the challenge of adoption

- **Reliable conditions for listing and reimbursement**
- **Communication effort to all stakeholders** (insurance companies, pat.)
- **Training for Health care professionals**
- **Easy processes for patients and Health care professionals** - electronic prescription
- **New ways of reimbursement**, e.g. value based approaches
- **Integration of DHA in a larger digital eco system** with e.g. electronic patient files

## Context : Early access to DMD reimbursement in EU Member States

**Digital medical devices (DMDs)** are subject to clinical evidence-based requirements and reach a new level of regulatory challenges linked to market access and reimbursement of digital supported patient care. Germany, France, and Belgium do already have national HTA and reimbursement systems for DMDs in place.



**DiGA Fast-Track  
(mobile health apps)**



**mHealthPyramid  
(mobile health apps)**



**DMD Fasttrack  
(several DMD types)**



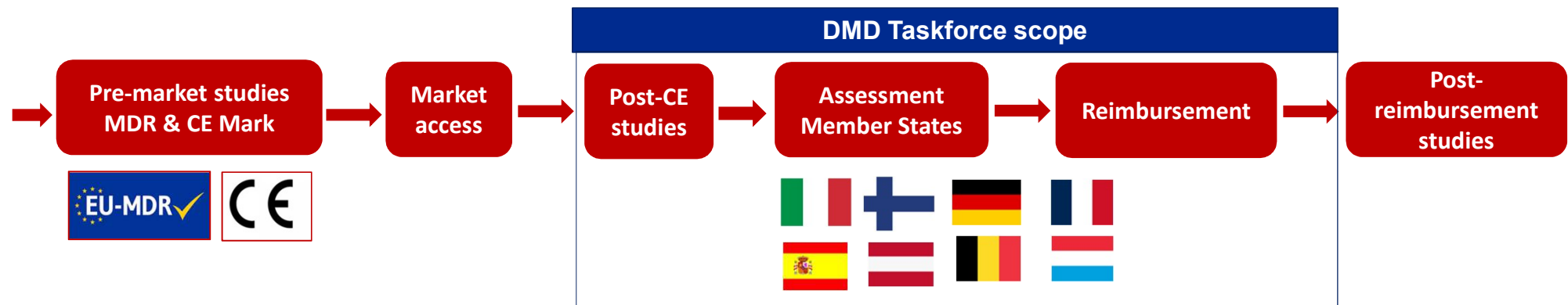
Other European countries are actively working on the implementation of similar procedures

➡ The **differences between EU Member States** lead to different categorisations of DMDs and different clinical evaluation requirements, hence the need for **harmonisation of the evaluation of DMDs** to facilitate their integration in HC systems and move towards **equitative access**

## French initiative: Towards a common European market for digital health



Framework of the **Regulation on Health Technology Assessment (HTA-R)**



- ➡ By developing a **joint approach** producing concrete outputs that can be used in the Member States, duplication of assessments can be avoided, patient access to innovative and proven digital health solutions can be accelerated, and health systems improved.



# Mission: Accelerate European market access through clinical evaluation criteria harmonisation for Digital Medical Devices (DMDs)

**Mission:** To classify innovative DMDs and align their EU-level health technology assessment procedures in the view of harmonizing national assessment informing reimbursement process 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

Harmonize the taxonomy of DMDs based on their application scope and evaluation categories

## Work package 2

Consensus on determining quantity, quality and the type of evidence that is needed for assessing DMDs

## Work package 3

Propose a societal health evaluation and health system implementation framework

## External Advisory Board

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

## Taskforce Members



**Magali Boers**  
Luxemburg Health  
Directorate



**Enrico Caiani**  
Biomed Alliance



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- Johannes Ahlqvist



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- Shannon Thor
- Anindita Saha



### Canadian Women's College Hospital

- Ibukun Abejirinde



### NICE, UK

- Mark Salmon

**Disclaimer:** All members of the Taskforce have disclosed any potential conflicts of Interests.

# Spain

EIT Health Spain conducted in 2022 several roundtables and consultations to experts to gather insights on how to accelerate the access of patients/citizens in Spain to the most beneficial and innovative digital health solutions, including those related to prevention and health promotion.

A first report with 20 keys for a roadmap was generated





Agilizando la adopción de aplicaciones de salud digital en España:

## 20 claves para una hoja de ruta

**1** Los profesionales sanitarios necesitan credibilidad a la hora de prescribir soluciones de salud digital. Para ello es preciso **integrar a los clínicos en el proceso**, superando la resistencia al cambio en los modos de trabajo. También es fundamental mejorar las competencias digitales de los profesionales y hacer pedagogía de los beneficios de la transformación digital en salud.

**2** Los profesionales necesitan **evidencias sólidas** para adoptar y prescribir este tipo de soluciones. De ahí la importancia central de establecer unos criterios de validación clínica rigurosos y **adaptados** a este tipo de soluciones

**3** La desigual aceptación por parte de los pacientes de las transformaciones digitales puede superarse por la propia dinámica de transformación en otros ámbitos sociales. No obstante, **la pedagogía y la evidencia clínica necesarias en los profesionales también lo es para los pacientes**, si queremos agilizar la adopción de los cambios. Para pacientes menos digitalizados debería existir un soporte, bien en el ámbito asistencial, bien en el desarrollador.

**4** Es necesario **integrar a profesionales y pacientes desde la misma definición de las necesidades** a las que deben dar solución las aplicaciones digitales. Si se responde mejor a las necesidades será más fácil que las aplicaciones encajen con las necesidades del sistema sanitario

**5** Facilitar la **toma de decisiones de los pacientes** en aplicaciones de salud digital además de autoregular el mercado podría evitar colapsar al personal médico.

**6** Para una más amplia y rápida adopción de soluciones de salud digital es preciso **incorporarlas a las guías y prácticas clínicas, a las rutas asistenciales, a la gestión clínica**; también es preciso evaluar los dominios organizacional, económico, de salud, de usabilidad, de aceptación...

**7** Solo evaluando el impacto que conllevan estas tecnologías y las mejoras que introducen en sistema será posible que el sistema se plantee su **financiación**.

**8** La financiación de estas soluciones permitirá **escalar** la mayor parte de las soluciones digitales que se están usando en la actualidad en el sistema sanitario español y que, normalmente proceden de dentro de las propias organizaciones.

Agilizando la adopción de aplicaciones de salud digital en España:

## 20 claves para una hoja de ruta

**9** La **colaboración entre entidades evaluadoras de países con sistemas sanitarios y economías parecidas** podría reducir el nivel de fragmentación a nivel europeo.

**10** Es preciso incorporar **procesos con fast track** que se adapten al rápido ciclo de actualización de las soluciones de salud digital.

**11** Los **gobiernos deben establecer una hoja de ruta con procesos y sistemas de financiación** para que la implantación y adopción de aplicaciones de salud digital sea una realidad.

**12** El **DiGA alemán puede ser un punto de partida**, no para centralizar procesos pero sí para establecer modelos semejantes y homologables, que permitan también compartir más datos, dentro de España y Europa. Otros modelos pueden ser el desarrollo de *sandbox* de evaluación y financiación, o el de *coverage with evidence development*.

**13** Es urgente establecer un modelo de financiación que permita que **España sea un lugar atractivo para innovadores y emprendedores en salud digital** y que les de la seguridad de que es posible superar los procesos de evaluación y acceso al sistema.

**14** Es preciso **establecer marcos de valores y acordar qué queremos evaluar**. No todas las apps tienen que pasar por los mismos criterios de evaluación ni por las mismas metodologías.

**15** Es urgente **dotar a las agencias de evaluación de tecnología del conocimiento y los recursos humanos y econó-**

**micos** necesarios para abordar la evaluación de este tipo de aplicaciones.

**16** Para que las agencias de evaluación tengan una capacidad de decisión vinculante, deben **incorporar perfiles poco habituales en este campo, como el del ingeniero de telecomunicaciones**, cuyos conocimientos van a ser fundamentales para enfrentarse a la evaluación de tecnologías que se basan en algoritmos de inteligencia artificial.

**17** España cuenta con un **gran potencial** para ofrecer un servicio de evaluación de soluciones de salud digital y sus beneficios para el sistema: el gran lago de datos donde somos líderes.

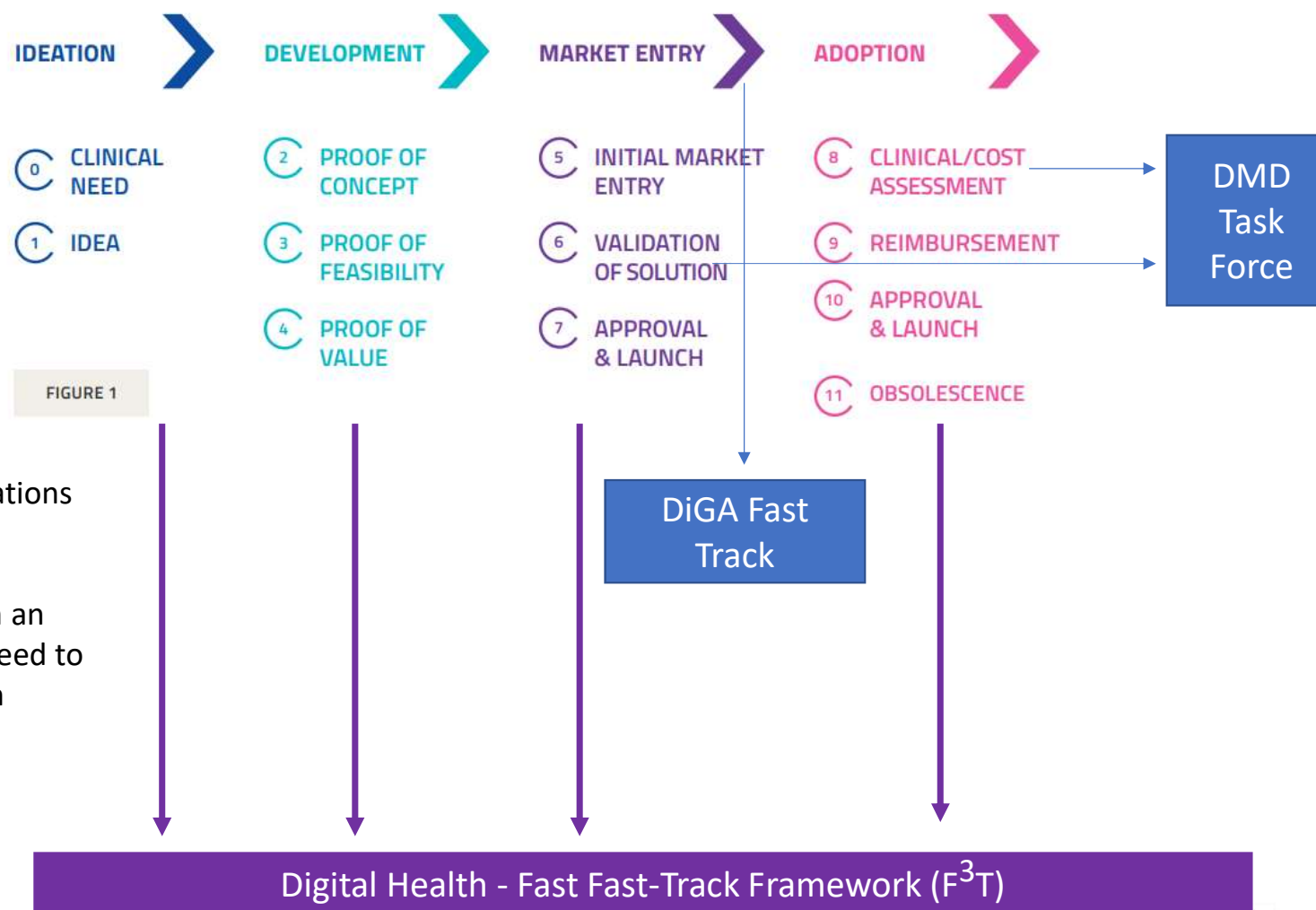
**18** Las aplicaciones de salud digital son tecnologías que van aprendiendo y cambiando, idealmente mejorando, por lo que **incorporar datos de vida real en la evaluación de las aplicaciones es indispensable**. Y para ello deben poder acceder al sistema de manera ágil y anticipada.

**19** La validación de las aplicaciones debe incorporar no solo criterios clínicos, sino organizativos, económicos, éticos, sociales y también poblacionales, de edad... Por eso se observa de gran utilidad el **uso del big data en la evaluación de aplicaciones digitales**.

**20** Para un mayor éxito en la validación de estas aplicaciones, serían útiles **servicios de asesoría temprana a startups**, no solo directa sino también a través de clústeres o agencias.



# Optimizing the Digital Innovation Pathway



A fast-track process for digital health applications aims at accelerating patient's access to the benefits they can provide. But a fast-track regulatory process is just one piece –though an important one- to speed up adoption. We need to intervene in several points of the innovation pathways in parallel

From the perspectives of both innovators **and** adopters

# About the F<sup>3</sup>T project

The **F<sup>3</sup>T project - Framework for Fast Fast-Track of Digital Health Solutions** is an initiative that aims to bring together experts, healthcare innovation agents and decision-makers to define a framework that streamlines the adoption of digital health applications in Spain, while facilitating the path for innovators and entrepreneurs. The ultimate goal is to establish a roadmap and explore a possible scalable pilot for Spain.

The F<sup>3</sup>T project emerged as a result of the consultations and meetings that EIT Health held in 2022 to identify obstacles in the path of innovation for digital health applications and the areas where it is key to intervene in a priority way. The conclusions of these meetings are reflected in the report [“Streamlining the adoption of digital health applications in Spain”](#)



# Project kick off meeting (Feb 2023)



# Strategic group

The F<sup>3</sup>T Strategic Group is made up of representatives from healthcare administration and institutions, hospitals, HTA agencies, industry, and healthcare startups, convened by EIT Health Spain, which acts as a facilitator and coordinator of the initiative to bring together the healthcare innovation ecosystem.

The project aim to include other relevant stakeholders in the subsequent steps of the project

- **Enrique Arjonilla** - IT Strategy Coordinator. Andalusian Health Service
- **Eva Aurín** - eHealth Manager. Telefónica
- **Lluís Blanch** - Coordinator. ITEMAS-ISCIH
- **Robert Fabregat** - CEO. Biocat
- **María José Faraldo**. Head of Service. Avalia-t
- **Francesc Iglesias** - Director of the Office of Innovation and Deputy Director of the Catalan Institute of Health
- **Ramón Maspons** - Chief Innovation Officer. AQUAS
- **Ana Miquel** - Responsible for Innovation and International Projects. Ministry of Health of Madrid
- **Aurora Nieto** - Director of Market Access. InsulCloud
- Jaume Ribera. Director IESE - CRHIM (Center for Research in Healthcare Innovation Management)
- **Laura Sampietro** - Deputy Director of Innovation. Hospital Clinic Barcelona
- **Elena Torrente** - Director DKV InnoLab for Digital Health
- **César Velasco** - Head of Innovation. AstraZeneca Spain



# Extended Group- representatives of key stakeholders' groups

- Farmaindustria – Spanish Association of Pharmaceutical Industry
- FENIN – Spanish Association of MedTech Industry
- FACME–Federation of Scientific Medical Societies
- POP–Patients' Groups Platform
- SEDISA–Society of Health Care Managers
- ASD–Digital Health Association
- BSC–Barcelona Super Computing Center
- Spanish Association of Health Law
- ITACA. Universidad Politécnica de Valencia
- Instituto Aragonés de la Salud
- IDIVAL

# F<sup>3</sup>T Project objectives

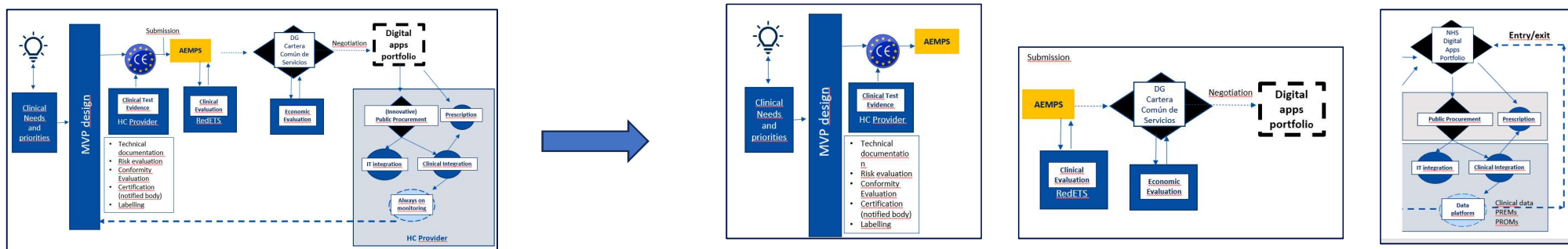
- Promote reflection and guidance from experts
- Gather the knowledge and experience of Spanish and European ecosystems
- Bring together public and private sector stakeholders and decision makers, to map the process, its pains and bottlenecks
- *Co-create feasible solutions that speed up the idea to adoption process*
- Raise awareness and urgency on the need for this framework towards decision makers while offering feasible, ready to implement solutions.



# A unique co-creation project

- Collaborative process from the very inception
- Including all the relevant stakeholders of the healthcare value chain
- Connections to EU initiatives (DMD Task Force, Procure4Health, DiGA...)
- Territorial diversity
- Openness and transparency
- Neutrality
- Commitment to change

# Collaborative process of analysis and co-creation



- Draw current innovation pathways and select the one we want to streamline
- Tear the process in 3 pieces:
  - From idea to submission
  - From submission to validation
  - From validation to purchase- to adoption
- Collaborative analysis of pains and bottlenecks
- Co-creation of solutions
- Iteration of the “to-be” process

# Identifying bottlenecks & “pains”

The objective of the first stage of the F<sup>3</sup>T initiative is

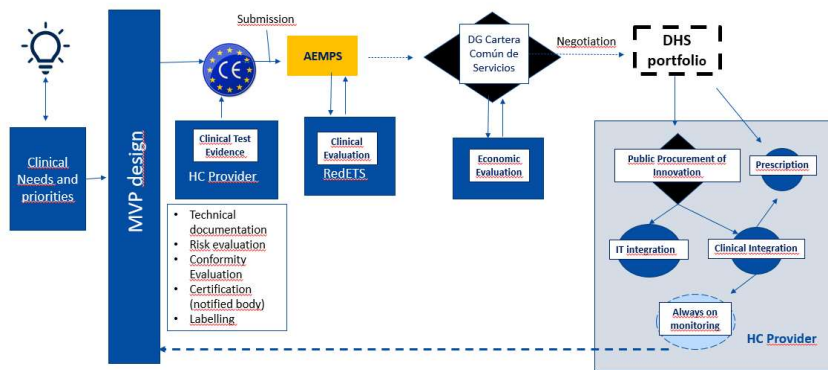
- identifying bottlenecks in the digital health applications adoption process,
- specific pains of the different stakeholders that imply delays or blocks

The analysis is intended for Digital Health Solutions (DHS) clasified as **digital medical devices class I or IIa**, according to the EU Medical Devices Regulation (MDR).

# Basics for the co-creation

- Must have: a portfolio of value based highly beneficial digital health solutions available for all patients and healthcare systems
- Avoiding multiple (un-needed) pilots to evaluate/validate digital Health solutions
- Focus on practical, actionable (even small) changes in the process to accelerate it
- EU, national and regional inspiration
- Commitment of all the stakeholders participating in supporting feasible changes and advocate for them

# The F<sup>3</sup>T general co-creation objective



What do we, as expert group recommend as practical and viable ideas to :

- speed up the process towards a common digital apps portfolio for the National Health Systems
- than can be financed (purchased, reimbursed...)
- to ensure patients and health systems benefits from the best digital apps in a safe way
- and best ideas and innovators are successful

# Thank You!

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Agilizando la adopción de  
aplicaciones de salud digital en  
España



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