## How is EIT Health supporting Al integration into the health innovation eco-system

Jérôme Fabiano ESC Workshop 13-14 of November 2024 Zurich





### Agenda

- Introduction to EIT Health
- InHeart: Example of an EIT Health supported project
- Presentation of EdiHTA project in the context of the HTA Regulation
- Testing and experimenting Facilities in Health programme in the context of the AI Act
- Shaiped project with HDABs in the context of EHDS Regulation
- Collaboration with Hospitals buyers.









## EIT Health – who we are

## Our mission is to drive healthcare innovation and create positive societal impact in Europe

EIT Health is a **community of world-leading health innovators** and one of 9 **Knowledge and Innovation Communities** (KICs) of the **European Institute of Innovation and Technology** (EIT), an EU body.

**EIT Health has been established in 2015** based on the principle that when experts from **business**, **research and education work together as one**, an optimal environment for innovation is created.

To achieve this, we facilitate innovative solutions to:



Contribute to a sustainable health economy in Europe

Strengthen healthcare systems



Promote better health of citizens

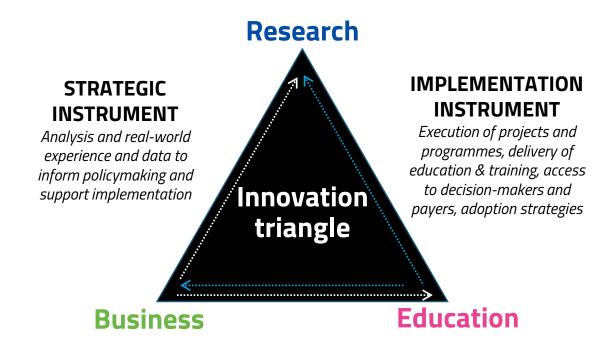






### **EIT Health** | Transforming Healthcare

**Strategic & Implementation instrument** around the Innovation Triangle







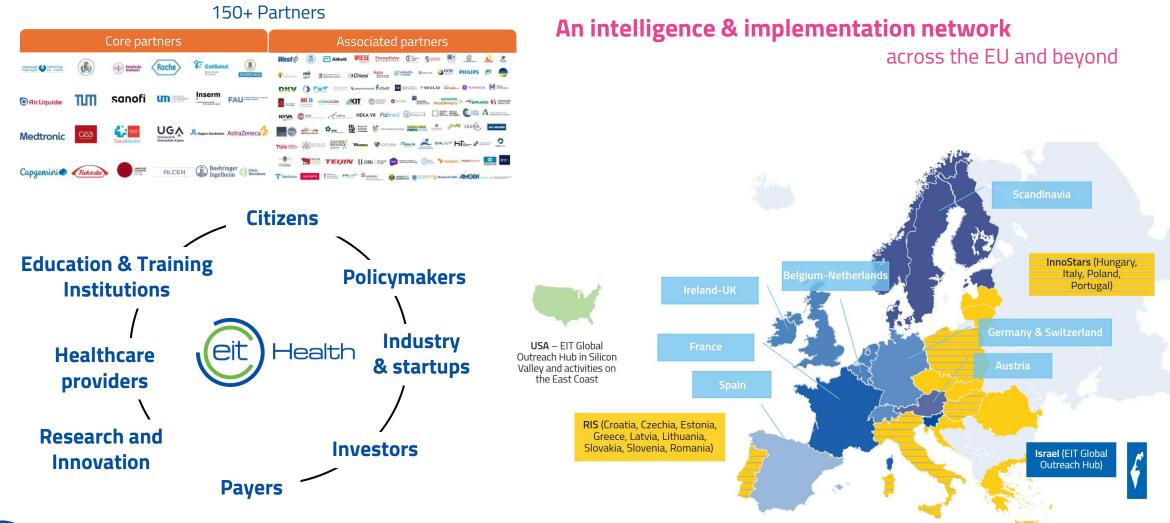


- Alignment with EU Health agenda
- Support policymaking & best practices exchanges at EU, MS and regional levels
- Think Tank (roundtables, reports)
- Workshops & events
- Market intelligence, tech radar
- Business support services
- Access to investors, fundraising
- Innovation support & adoption
- EU large-scale initiatives (TEF Health, EP PerMed, IHI, Cancer mission...)
- Grants (EIT funding)
- EIT Health Academy (capacity building)
- Healthcare Industry Pact4Skills
- WorkinHealth Skills Observatory & skills gaps (AI-based SkillSync)
- Talent pools access (Career fairs, matchmaking)
- Grants (EIT funding)





### **EIT Health** | Multi-stakeholder pan-EU Community

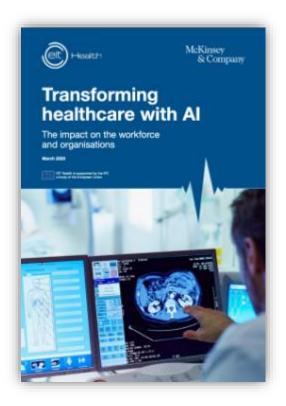






### **EIT Health Think Tank**













### **EIT Health alliances and collaborations**



The MOU between EITH and IHI creates a collaborative innovation ecosystem that promotes entrepreneurship and innovation in healthcare, benefiting patients and society.

**COLLABORATION**: Collaborative workshops and events, coordinating calls between both organisations to contribute to each other's initiatives.



The MOU between EITH and EUREGHA utilizes regional and local health authorities, along with Co-Location Centres connecting with healthcare innovation experts.

**COLLABORATION**: Joint events/ workshops, Facilitating and guiding the regional-level adoption of the EHDS.



The MOU between EITH and the Biomed Alliance ensures a smooth cooperation between EITH activities and health professionals across Europe. **COLLABORATION**: Open and transparent communication between partners and membership.





EIT Health, IHI and EUREGHA are kick starting an initiative to strengthen the initiatives from IHI and EITH with regional health authorities

### <u>Additonal</u> <u>collaborations/networks</u>:

- Member of the HERA Joint Industrial Cooperation Forum (JICF)
- Collaboration with EIC/ EISMEA on streamlining data, Fast Track, Business Accelerator
- Contribute to EFPIA Oncology Platform Sounding Board.
- Observer of the HTA Network





## InEurHeart : Example of an EIT Health supported project

InHeart, INRIA,







## EdiHTA Project in the context of HTA-R





The first European Digital Health Technology Assessment framework co-created by all stakeholders along the value chain

www.edihta-project.eu





EDiHTA EU-project





@EDiHTAproject





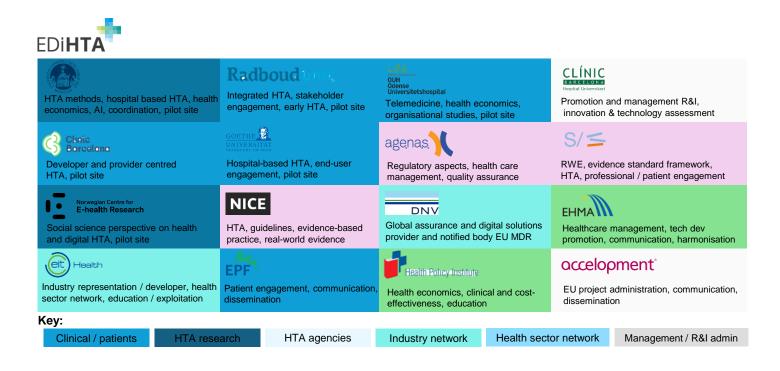


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### Consortium

#### 16 partners from 10 European Countries.

Key expertise in HTA research, 3 **HTA agencies**, 4 **hospitals** as end-users of DHTs, 1 **patient organisation**, 1 NGO specialised in HTA, 1 **global quality assurance** and risk management company and **notified body** for MDR certification, as well as the European **Institute of Technology**, the **European Patients' Forum** and the European Health Management Association (**EHMA**).





## Road map and impact

#### Short-term within EDiHTA

#### Mid-term (+ 5 years)

### Long-term (+ 10 years)

#### **Expected results**

### ✓ Develop and harmonise a new digital framework for European health technology assessment

- ✓ Define and expand evidence-based HTA domains
- ✓ Improve the research evidence base for HTA
- ✓ Capture real-world feedback through user-centred piloting
- ✓ Develop an agreed multidisciplinary and multidomain HTA framework for all DHTs at all phases of the life cycle/technological maturity and to capture the user learning curve
- ✓ Provide a valuable tool to support HTA doers at any decision-making level with specific regard to hospitals and other HCOs

#### Outcome

### √ A new centralised approach to European digital Health Technology Assessment based on universal standards

- ✓ A framework that equips European HTA agencies (and the EU HTA-Regulation Coordinating Group) to reliably assess new and emerging technologies
- ✓ Resource optimisation and reduced duplication of activities
- Improved quality of decisionmaking processes
- √ Timely and accelerated access to and funding and reimbursement of innovative health technologies

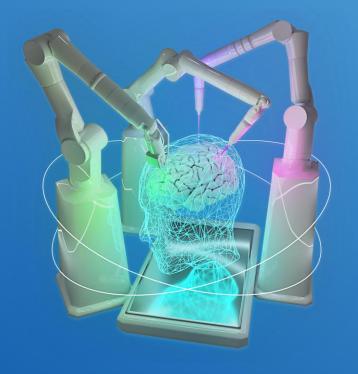
### Impact

- ✓ Creation of a common EU market for digital solutions, facilitating crossborder deployment of digital health services
- ✓ Significant reduction of healthcare costs by a fast and cost-efficient Europe-wide HTA
- ✓ Increasing personal and societal wellbeing through the adoption of safe new health technologies
- ✓ Empowerment of the healthcare sector through direct engagement with and application of new technologies





## TEF Health in the context of the Al Act



## TEF-Health

Testing and Experimentation Facility for Health Al and Robotics

info@tefhealth.eu www.tefhealth.eu





## Testing and Experimentation Facilities (TEF) for Health Al and Robotics

## For producers of Al solutions (start-ups, SMEs, industry)



**Test Al Solutions** in large-scale real –or realistic- environments

Receive **funding** (total 30M€ as reduction in fees)

Support in **market access** for intelligent technologies





## Close the gap in Al Innovation Chain

#### **Grow and scale**

Validate Al solutions in real health environments

#### Match & connect

Facilitate market access for Al solutions in health

#### Train and Attract

Upskilling in Health AI for entrepreneurs & professionals



## For Providers of facilities (virtual or physical)

**Access** to 1500+ international start-ups, SMEs

Privileged and early **access to Al solutions** as well as data networks

Receive **funding** (total of 30M€)

**Optimize investments** and avoid duplication of facilities





### **TEF-Health Al: facts & figures**

Aim

**Consortium** 

**Funding** 

**60 M€** in total

**Timing** 

1.

**Validate** Al

solutions in real health environments **51 partners** from Germany, France, Sweden, Slovakia, Portugal, Belgium, Finland, Czech Republic, Italy

**30 M€** 

Commission

30 M€

Member States

2023-2028 **(5 years)** 

2.

Facilitate market
access for Al
solutions in health

Labs at Notified hospitals, bodies

universities

(medical

imaging,

digital

medical

devices ...)

certification

EU-wide connectors

EIT Health (connect offer & demand) E-Brains (transact data)

30 M€ **Offer** Side 30 M€

Demand Side

(discount
fees for

SMEs to use
facilities)

Status:
selected for
funding (draft
grant
agreement)



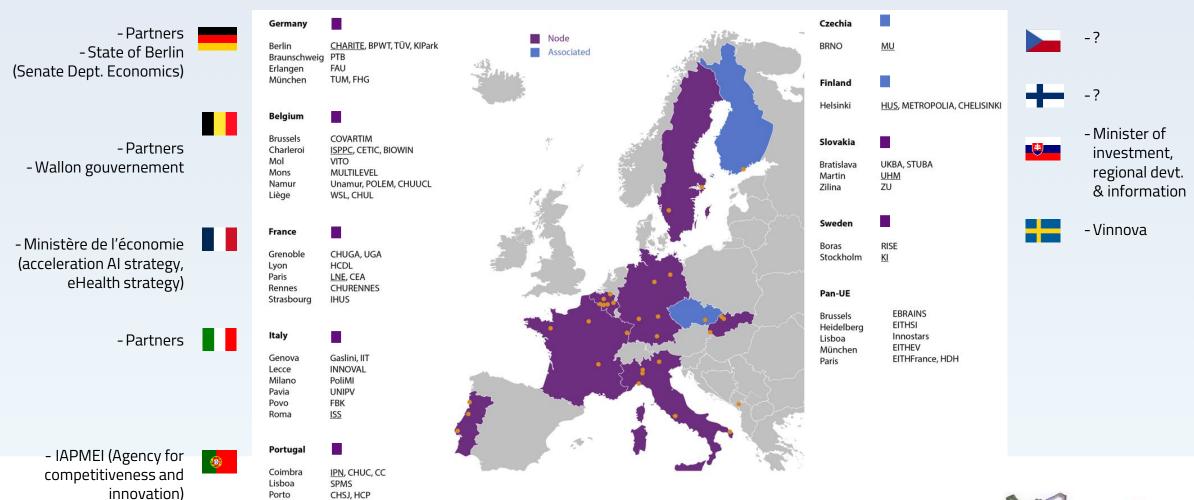




### **TEF-Health Al: consortium**

**Partners** 

Co-funding (MS)



Co-funding (MS)

**Partners** 

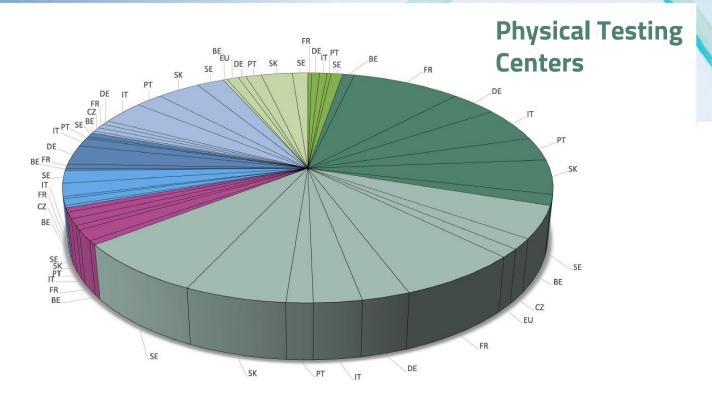
Lead: Charité-BIH, Berlin, Germany





### TEF Health Al: services across nodes

Ethics, Legal & Society
Physical Testing Centers
Virtual Testing Centers
Education & Dissemination
Standards & Quality
Certification
Clinic, AI & Robotics
Business dev & Integration













### TEF-Health AI - KPIs

#### 500 TEF users served

- 80% TEF users are SMEs
- 70% cross border participation

### 500 solutions tested

- At least 50% started CE marking or in agile certification process
- 2% adopted by health providers
- 2% brought to market
- Long term Business Plan: fee-based services available to Industry











# Shaiped project in the context of the EHDS regulation

### 30 European players join forces to form a "European space for AI in healthcare"

With the adoption of the regulation for a European Health Data Space - EHDS - due at the end of 2024, the SHAIPED consortium is a concrete expression of the European Commission's ambition to foster a network of dynamic players to exploit data on a European scale while complying with the highest standards of data protection.

With 30 partners from 11 Member States, the SHAIPED consortium is the largest to date to include the future Health Data access Bodies of the EHDS. This project is a continuation of the pilot project for the EHDS, which was entrusted to the HDH by the European Commission and which aims to build a European infrastructure for the secondary use of health data.

The Health Data Hub (HDH) and its consortium have won a European call for projects with the SHAIPED project, aimed at developing artificial intelligence (AI) solutions for medical devices. With a total budget of €4 million, this selection is the 10th of the HDH for European calls for projects, confirming its commitment to the development of digital health in Europe.





## Meeting the challenges of AI in healthcare in Europe

In the age of artificial intelligence, a major challenge for medical devices (MDs) is access to real world data to train, test and validate these tools. Integrating these devices into healthcare information systems (HIS) and proving their clinical effectiveness are also major challenges. The SHAIPED consortium is addressing these issues through several working groups, seeking to:

- Facilitating access to health data for AI-based medical devices,
- •Validate the clinical effectiveness of these devices on a large scale,
- •Integrating medical devices into European healthcare systems.

Three use cases will provide a framework for testing and validating the solutions developed by the consortium. These examples show the potential of AI to improve patient care and boost the efficiency of European healthcare systems.

- •The first use case will focus on chronic kidney disease. Led by Aarhus University Hospital (Denmark), this project will explore the ability of existing AI models to adapt to cohorts of data from several European countries.
- •The second will focus on the detection of metastases. In collaboration with the Centre Léon Bérard and the Health Data Hub (France), this use case will analyse cohorts of patients to assess the performance of AI in detecting lung metastases and mammograms.
- •Finally, the third will focus on the prevention of heart failure. Led by Implicity (France), this last use case will evaluate AI software for preventing Heart failure hospitalizations in patients with Cardiac Implantable electronic devices (CIED).







## **THANK YOU**



