



How can health technology assessment (HTA) for digital health technologies contribute to the transformation of health and social care systems?

THCS WP10 Shared Learning Webinar

26 March 2025

Funded by the European Union under the Horizon Europe Framework Programme - Grant Agreement N°: 101095654. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.



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Welcome and Introductions

Nessa Barry, Andrea Pavlickova, Scottish Government



The THCS Partnership

THCS started in January 2023 and will last 7 years

63 partners are members of the THCS Consortium:
56 beneficiaries and 7 affiliated entities

THCS is coordinated by IT MOH in cooperation
with other National entities

The total budget allocated for THCS is
305.248.586,63 €
co founded at 30 % by the EC

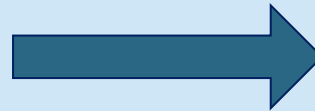


26 countries are involved: 20
Member States + 3 HE
Associated Countries,
together with 3 non-EU
Countries, Switzerland, UK
and the United States



THCS Vision and Objectives

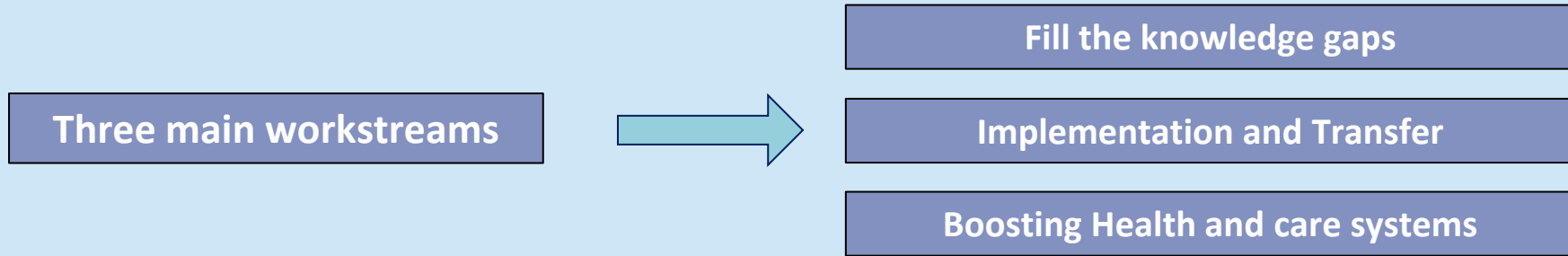
**High-quality, fairly
accessible, sustainable,
efficient, resilient and
inclusive health and care
systems for all**



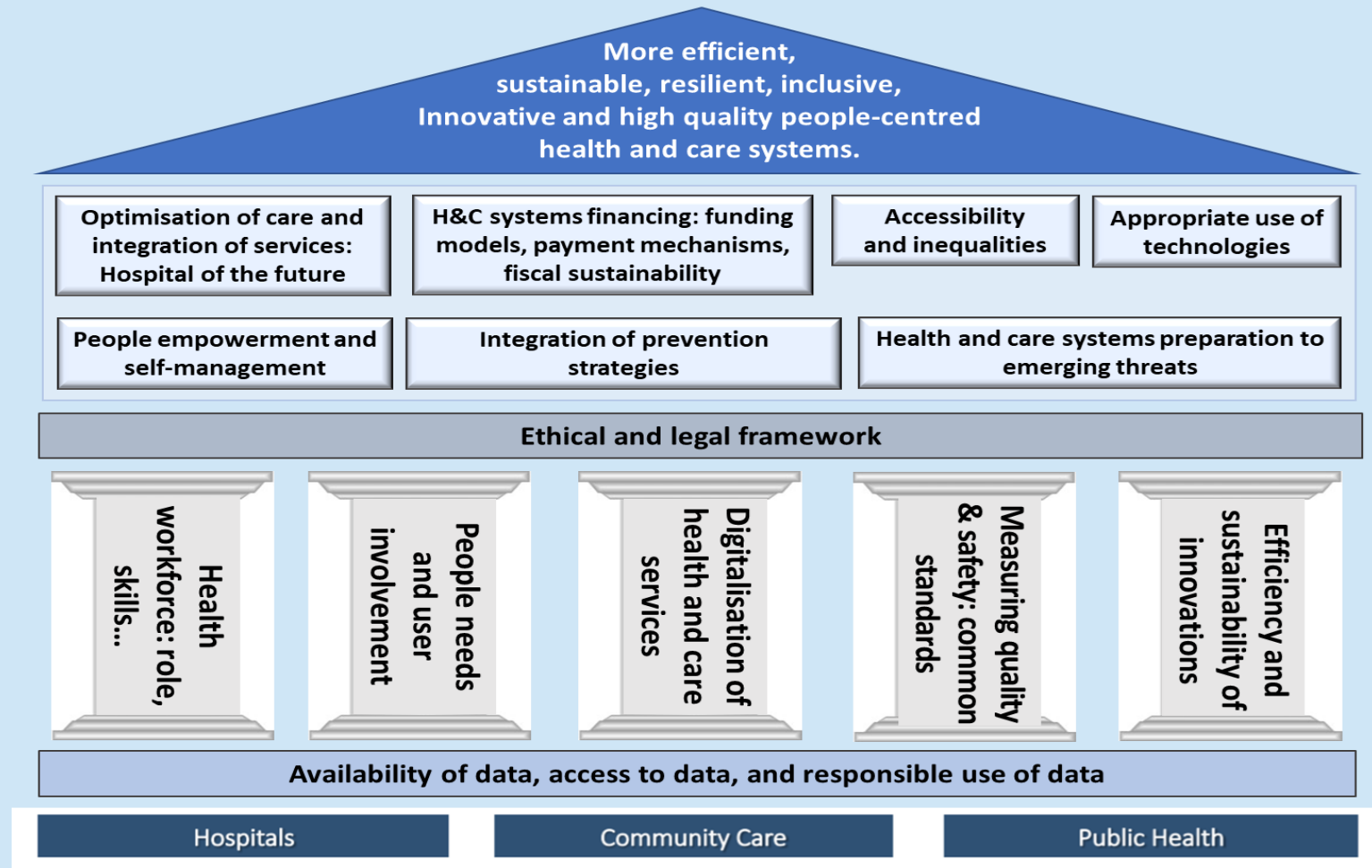
- **Increase funding opportunities and strengthen the research and innovation community**
- **Fill the knowledge gap**
- **Increase the ability to implement innovation**
- **Intensify cooperation among countries and beyond healthcare**
- **Increase stakeholders' involvement**



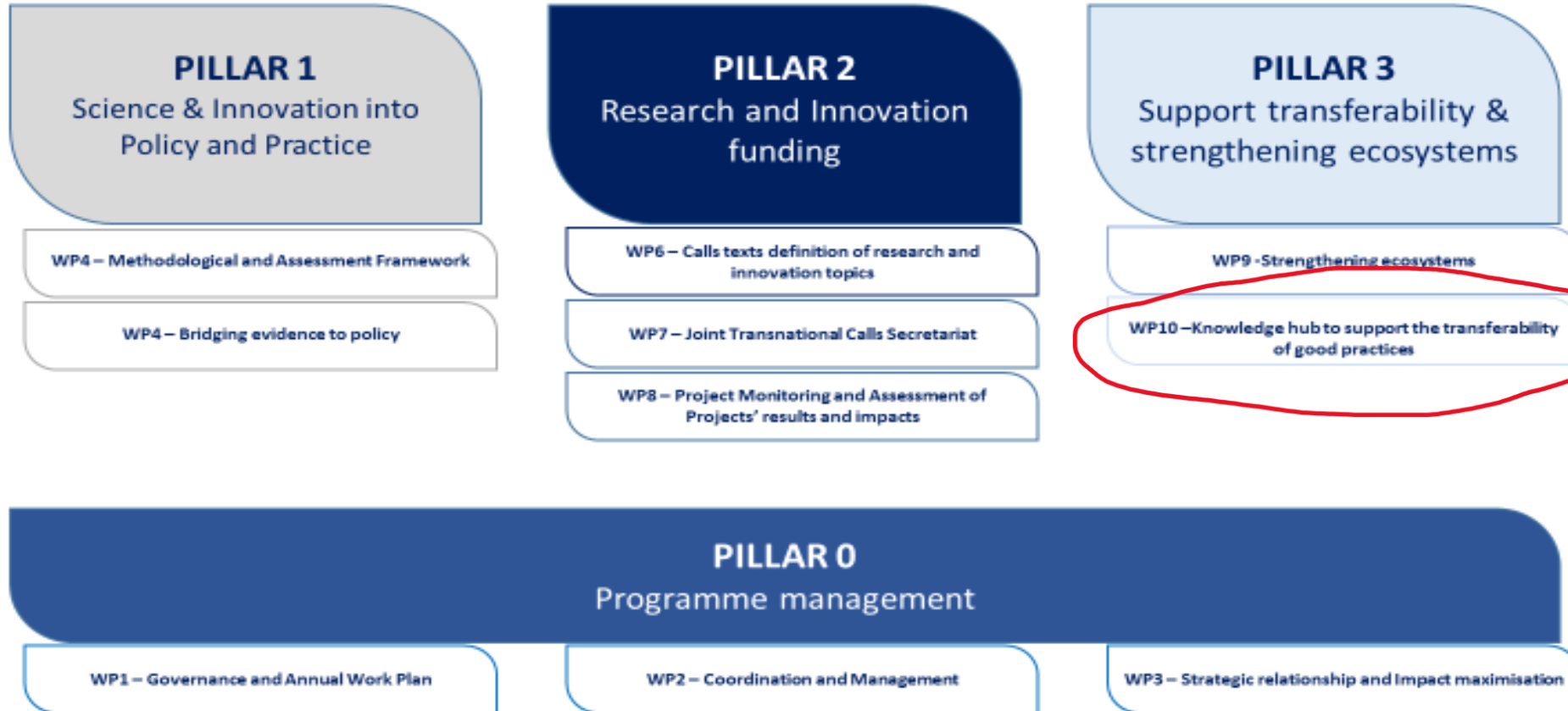
THCS Approach



Thematic Priorities and Building Blocks



Pillars and Work Packages



As a registered member, you'll enjoy:

Ability to share: you will be able to contribute / upload your own resources to the Hub.

Community Access: Connect with like-minded individuals in our vibrant Community section. Share ideas, ask questions, and build lasting connections.

Personalised Experience: Save your preferences and receive tailored recommendations.

Notifications: Stay updated with member-only updates, including early access to capacity-building opportunities.

Don't miss out—join us now and make the most of your experience!

[Get started →](#)

Welcome to the THCS Knowledge Hub

The ambition of the THCS Knowledge Hub (KH) is to maximise the value of the existing evidence and experience in transforming health and social care systems in order to improve the capacity of countries, regions and organisations to adopt and scale up the necessary change by:

[Learn more →](#)



Experience

Capturing, sharing and exchanging experience that help to address the needs and priorities of European regions and countries in transforming their health and social care systems.



Evidence

Generating new evidence and knowledge on the transformation of health and social care systems.



Personalised support

Co-designing personalised support for those seeking support to prepare the ground for transition and/or improve existing system design by facilitating tailored knowledge transfer activities.



Capacity building

Utilising outcomes of capacity-building activities to speed up the transformation of health and social care systems in Europe.



Introduction to digital health and implementation of digital health technologies in the EU

Marc Lange, Secretary General, EHTEL

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Collaborating for Digital Health and Care in Europe

Introduction to digital health and implementation of digital health technologies in the EU

Marc Lange, Secretary General

26/03/2025



HTA & Digital Health Technologies (DHTs)

Evaluating the medical, economic, social, and ethical implications of health technologies

Developed initially for


- *Pharmaceuticals,*
- *Medical devices,*
- *Diagnostics, and*
- *Treatment methods.*



Now extended to

- *mHealth apps,*
- *Telemedicine,*
- *Wearable medical devices, and*
- *Artificial Intelligence-driven solutions.*

Examples of Assessment Frameworks



Region Syddanmark

For further information, please contact:

HTA consultant
Kristian Kidholm, PhD

Phone: +45 3058 6477
Email: Kristian.Kidholm@ouh.regionsyddanmark.dk

PARTNERS

Italy
- Veneto Region

Denmark
- Region of Southern Denmark

Sweden
- County Council of Norrbotten
- Health Innovation Centre, CIC
- Luleå Technical University

Norway
- Northern Norway Regional Health Authority
- Norwegian Centre for Integrated Care and Telemedicine

Spain
- Department of Health - Generalitat de Catalunya
- Catalan Agency for Health Technology Assessment and Research - Fundació TICSalut

Finland
- South Karelia District of Social and Health Services

Greece
- Intermunicipal Development Company Digital Cities of Central Greece S.A.
- Trikala AE
- Municipality of Trikala
- Regional Health Authority of Sirois & Thessaly

Austria
- Carinthia Region
- KABEG


Germany
- Pflanzwerk

In partnership with
- European Patients' Forum (EPF)
- European Health Telematics Association (EHTA)
- Continous Health Alliance (CHA)


www.renewinghealth.eu

MAST


- MODEL FOR ASSESSMENT OF TELEMEDICINE



RENEWING HEALTH
Regions of Europe Working Together for HEALTH

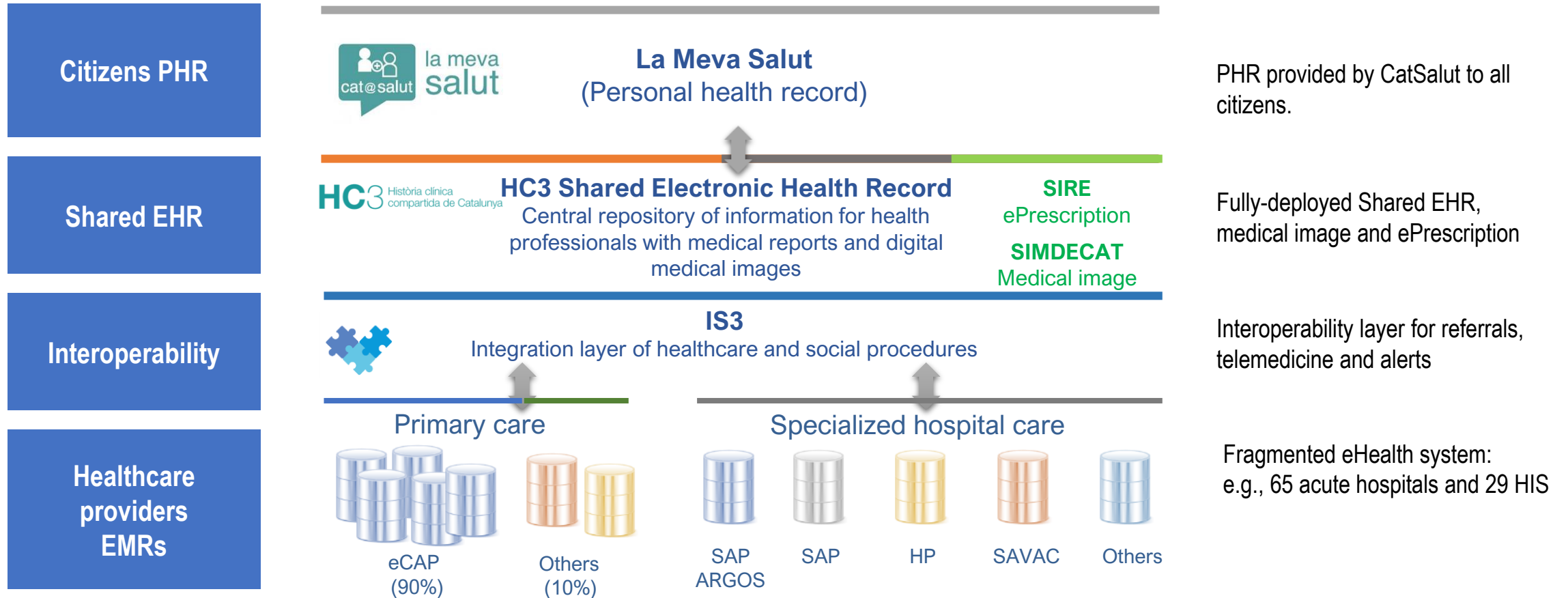


The project is partially funded under the ICT Policy Support Programme (ICT PSP) as part of the European Community's Competitiveness and Innovation Framework Programme (www.ec.europa.eu/ict_psp).

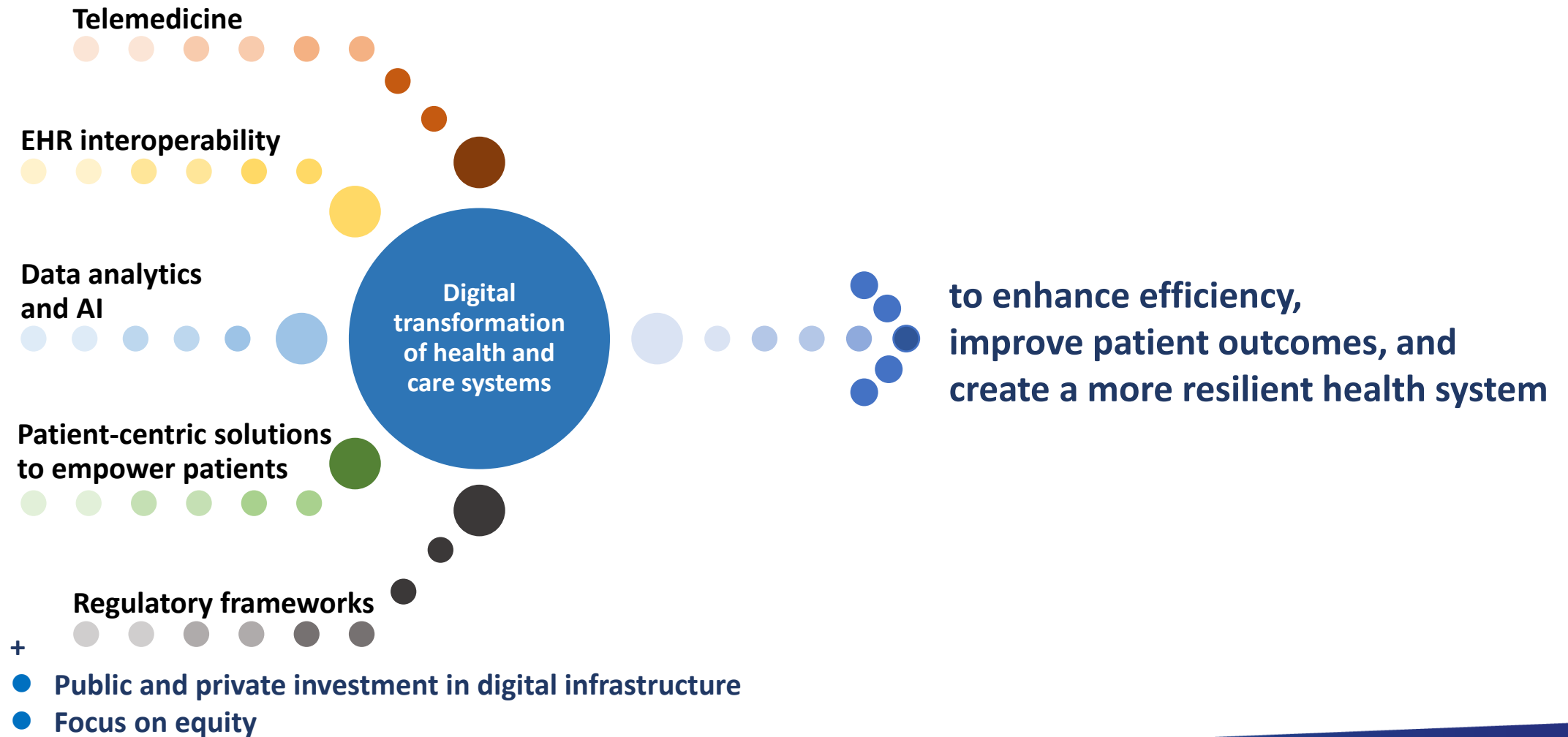




An example: Digital Health Infrastructure of Catalunya

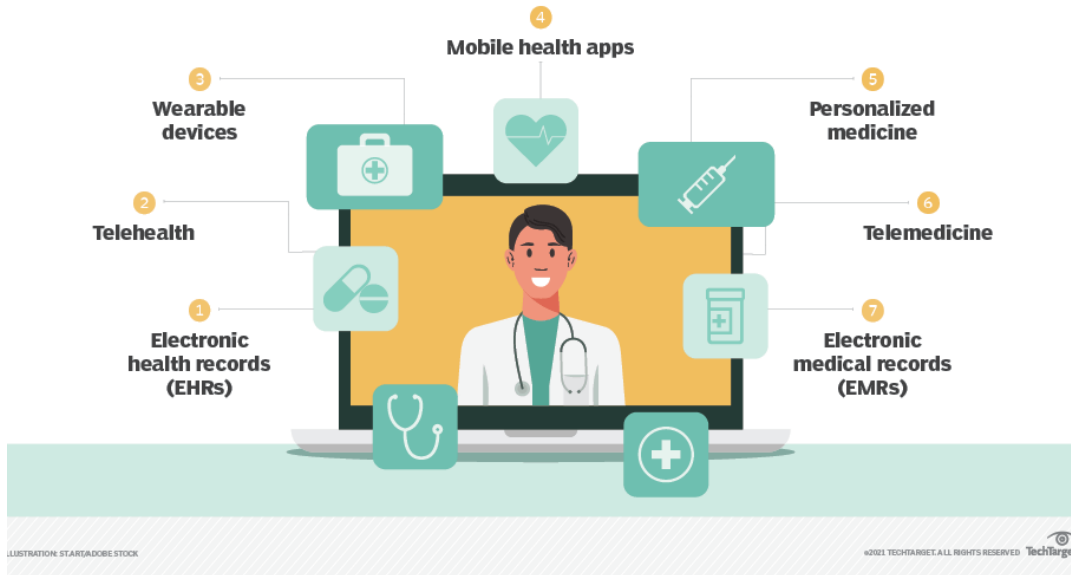


The Ongoing Digital Transformation of Health and Care Systems



Keys for success

Digital Health Technologies: Better and cheaper than existing alternatives



Digital Transformation of Healthcare: 7 Success Factors

01 Designing digital health solutions for better human experiences

Bringing everyone on board through effective change management

02

03 Training staff to help them get the most out of digital technology

Taking an inclusive approach that leaves no patient behind

04

05 Adopting cloud-based platforms for data access anytime, anywhere

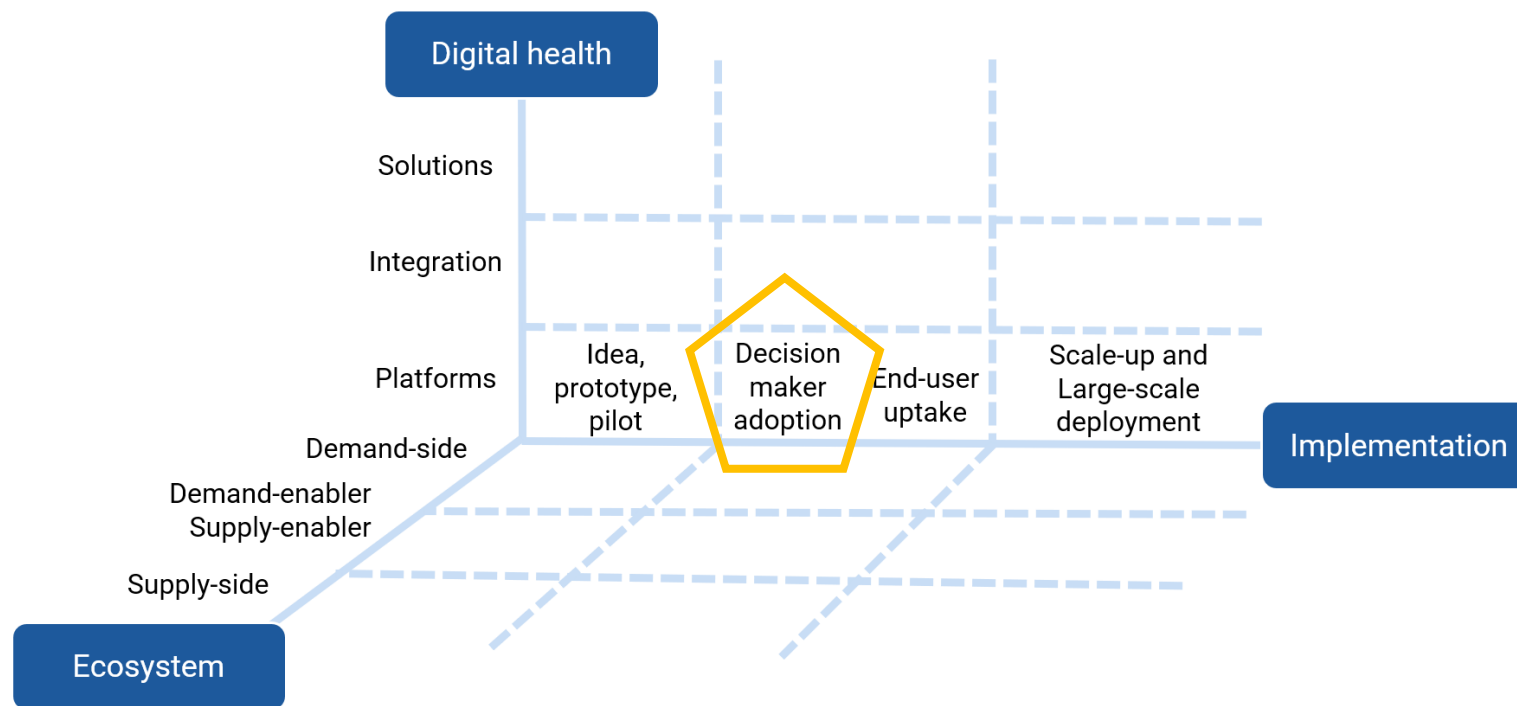
Building digital trust by safeguarding data privacy and security

06

07 Joining forces through strategic partnerships and ecosystem collaboration

CALLIDU

HTA and the Digital Health Uptake dimensions



Design of solutions

Business modelling

Risk stratification tools

Compliance to standards and norms

Maturity and readiness levels

Innovation procurement

Capacity building

Change management

Data governance and privacy

Value assessment tools

Idea

Prototype

Pilot

Decision maker adoption

End-user uptake

Scale-up

Large-scale deployment

Uptake

Scale-up

Ideation process

Implementation process

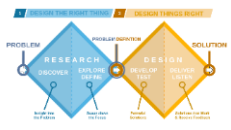
Design of solutions

Business modelling

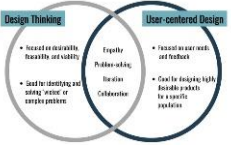
Compliance to standards and norms

Maturity and readiness levels

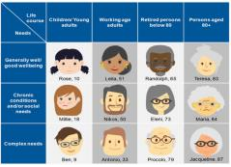
Value assessment tools



Design thinking



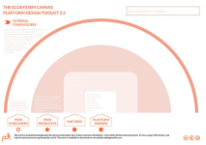
User centred design



Blueprint personas



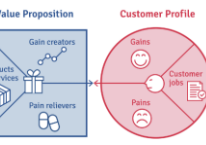
Business Model Canvas



Platform design toolkit



Rulebook for fair data economy



Value proposition canvas

Data governance and privacy



PGHD Trust Canvas

Risk stratification tools



Idea Ideation process

Prototype

Pilot

Innovation procurement



Decision maker adoption

Innovation Readiness Framework

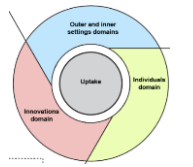


End-user uptake

Change management



4-Wheel Framework Model



Crisis communication

DT uptake factors

Large-scale deployment

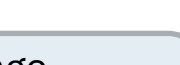
Implementation process



ASSIST



ASSESS DHT



EDIHTA



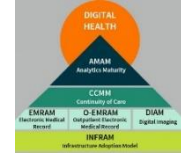
MAFEIP

HIMSS maturity models INFRAM

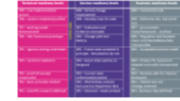
MAST



Momentum



AMAM



Technology, Service, Business readiness levels



Scirocco



Scale-up model



Telemedicine Community Readiness level



mHealth assessment frameworks

ISO 13485



Capacity building



Digital health assessment technology

LABEL2 ENABLE

EU Artificial Intelligence Act

Innovation procurement



Decision maker adoption



End-user uptake



transforming health and care systems

Open DMAT

Scale-up



ASSIST



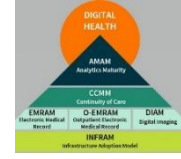
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HIMSS maturity models INFRAM

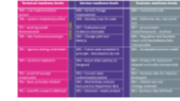
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Scale-up model



Telemedicine Community Readiness level



mHealth assessment frameworks

ISO 13485



Capacity building



Digital health assessment technology

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Innovation procurement



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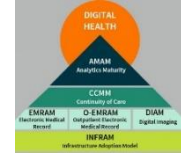
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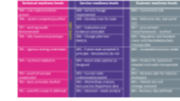
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Scirocco



Scale-up model



Telemedicine Community Readiness level

Děkuji Gracias Ačiū
Merci Tak
Thank you תודה
Danke Kiitos Paldies
Mulțumesc Grazie Takk
Благодарам

More at www.ehtel.eu
and with marc.lange@ehtel.eu

The logo for EHTTEL, featuring the word "EHTTEL" in a bold, dark blue, sans-serif font. The letter "E" is slightly larger and positioned to the left of the other letters. The letters "H", "T", "T", "E", and "L" are of uniform height and are closely spaced. The background of the logo area is white, which is part of a larger graphic element consisting of several overlapping, semi-transparent white bands that create a sense of depth and movement across the bottom of the slide.

EHTTEL

Collaborating for Digital Health and Care in Europe



TRANSFORMING HEALTH
AND CARE SYSTEMS

Introduction to EDiHTA project

Emmanouil Tsiasiotis, Project Manager EDiHTA

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EDiHTA

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

MPH Emmanouil Tsiasiotis

www.edihta-project.eu



 EDiHTA EU-project

 @EDiHTAproject



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The UK participant is supported by UKRI grant No 10106869 (National Institute for Health and Care Excellence).









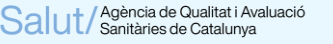











The Swiss participant is supported by the Swiss State Secretariat for Education, Research and Innovation (SERI).

EDiHTA project: The first European Digital HTA framework

Consortium (17 partners from 10 European Countries)

- 1 Ministry of Health
- 3 HTA agencies
- 8 hospitals as end-users of DHTs
- 1 NGO specialised in HTA
- 1 global quality assurance and risk management company and **notified body** for MDR certification
- **European Institute of Technology (EITHealth)**
- **European Patients' Forum**
- European Health Management Association (**EHMA**)



 HTA methods, hospital based HTA, health economics, AI, coordination, pilot site	 Integrated HTA, stakeholder engagement, early HTA, pilot site	 Telemedicine, health economics, organisational studies, pilot site	 Promotion and management R&I, innovation & technology assessment	 Healthcare provider – hospital Trust
 Developer and provider centred HTA, pilot site	 Hospital-based HTA, end-user engagement, pilot site	 Regulatory aspects, health care management, quality assurance	 RWE, evidence standard framework, HTA, professional / patient engagement	 Italian Ministry of Health Policy maker
 Social science perspective on health and digital HTA, pilot site	 Global assurance and digital solutions provider and notified body EU MDR	 Healthcare management, tech dev promotion, communication, harmonisation	  Industry representation / developer, health sector network, education / exploitation	 Hospitals network
 Patient engagement, communication, dissemination	 Health economics, clinical and cost-effectiveness, education	 EU project administration, communication, dissemination	 HTA, guidelines, evidence-based practice, real-world evidence	

Key:

Clinical / patients	HTA research	HTA agencies	Industry network	Health sector network	Management / R&I admin	Policy
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The EDiHTA values

The Need

- ✓ Healthcare systems and workforce under pressure to provide quality services
- ✓ Digital transformation at all levels and real-world evidence
- ✓ Market requirements for access and reimbursement
- ✓ Complex regulatory and HTA environment

EDiHTA solution

- ✓ We are set to deliver the first innovative and first of its kind digital HTA framework that will be developed to assess digital health technologies
- ✓ Flexible and customized according to the type of technology, the maturity level and the decision-making level
- ✓ Integrates existing methodologies into a newly co-created framework where all relevant stakeholders are involved

Objective

Develop a new HTA framework for digital health technologies

Mission

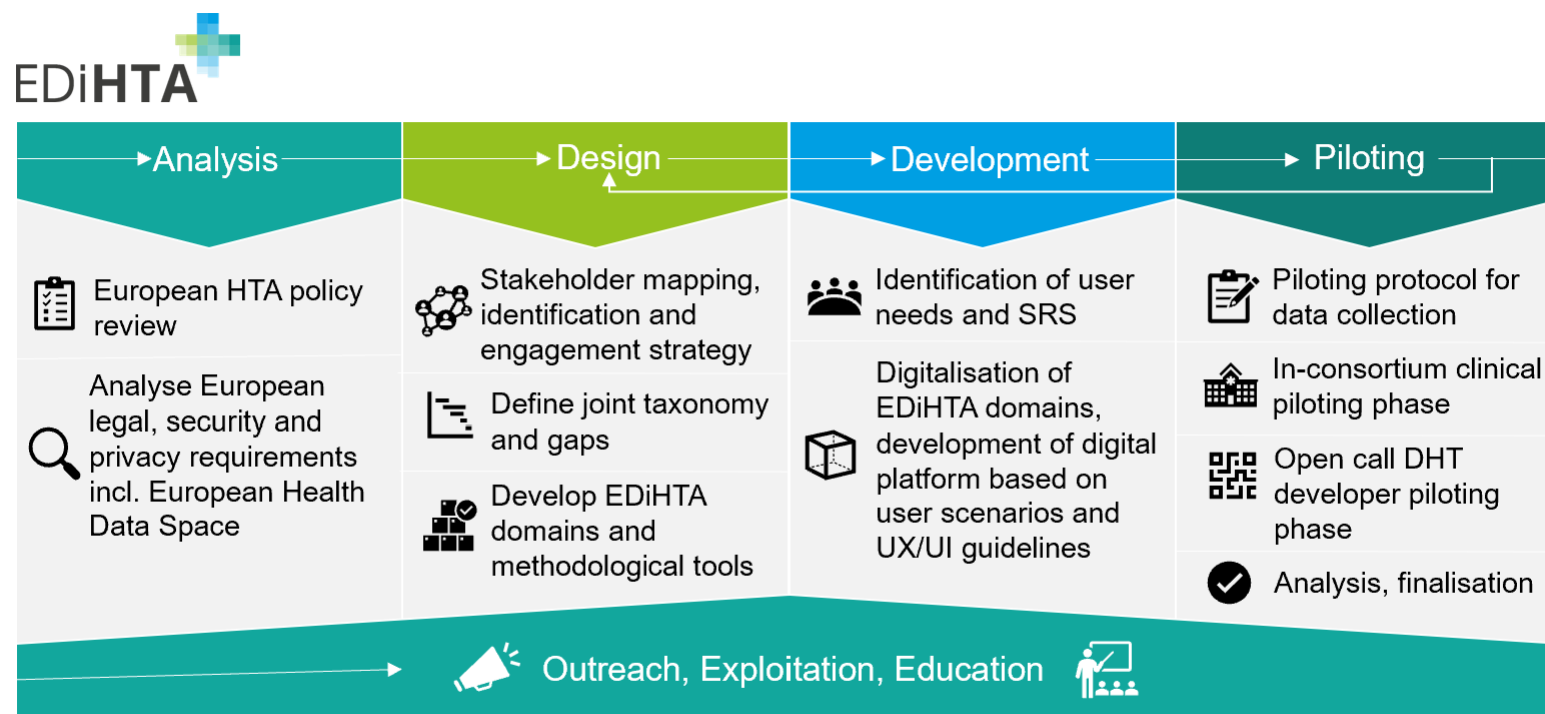
Support the most adequate development and faster integration of digital health solutions in EU health systems

Vision

Create a common EU market for digital health technologies

Work plan

Methodology: Our two-tier approach includes (1) **co-creation** of the EDiHTA design and content through **stakeholder involvement** and (2) **technology-driven solutions** through end-user validation. EDiHTA will be designed and developed based on existing and underdevelopment HTA methodologies while considering the requirements of all relevant stakeholders.



Key facts

Action: HORIZON-RIA

Budget: 7.9M Euro

Duration: 48 Months

Consortium: 17 partners

- ✓ Covers all HTA domains with a focus on AI/legal requirements
- ✓ Includes wide range of DHTs, aligned to their lifecycle
- ✓ Developed for transferability
- ✓ Full multidimensional assessment
- ✓ Adapted to recent technological developments

Stakeholders involved (IHTAM framework)

Stakeholder groups	Policy makers	HTA Agencies	Industry	Healthcare providers	Patients
Numbers	16 policy makers	15 HTA agencies	29 industry developers	22 Healthcare providers	15 Patients
Countries	14 EU countries	9 EU countries and UK (England, Wales)	Present in 10 different EU markets	9 EU countries and USA, Canada, Brazil, Kazakhstan	9 EU countries and UK
Methods	Survey Interviews	Interviews	Literature review, Survey, Focus groups per type of developer and DHT	Literature review, Interview	Literature review, Focus groups per type of technology
Other characteristics	Ministries of Health, Payers, National health organisations	National HTA agencies part of HAg group	24 start ups and 5 big companies also part of MedTech	12 with HTA experience, 10 clinicians and 10 hospital managers	Patient advisors or representatives of patients associations with different experience in DHT use, 10 differente therapeutic areas

Main findings



Despite the diversity in readiness and strategic approaches of countries, there is consensus on the value of harmonizing HTA frameworks across Europe.



Flexibility within a harmonized framework would be essential to allow for the adaptation of processes to meet specific national or regional healthcare needs.



Advanced assessment frameworks and fast access schemes for DHTs are available in some countries. Countries such as Germany, France and Finland have developed centralized evaluation systems prioritizing interoperability and standardized assessments.



Support for developers: Possibility of timely consultations through the HTA process to give clear guidance on appropriate evidence generation methods at different parts of the lifecycle, informed by early and continued discussions with all stakeholders.



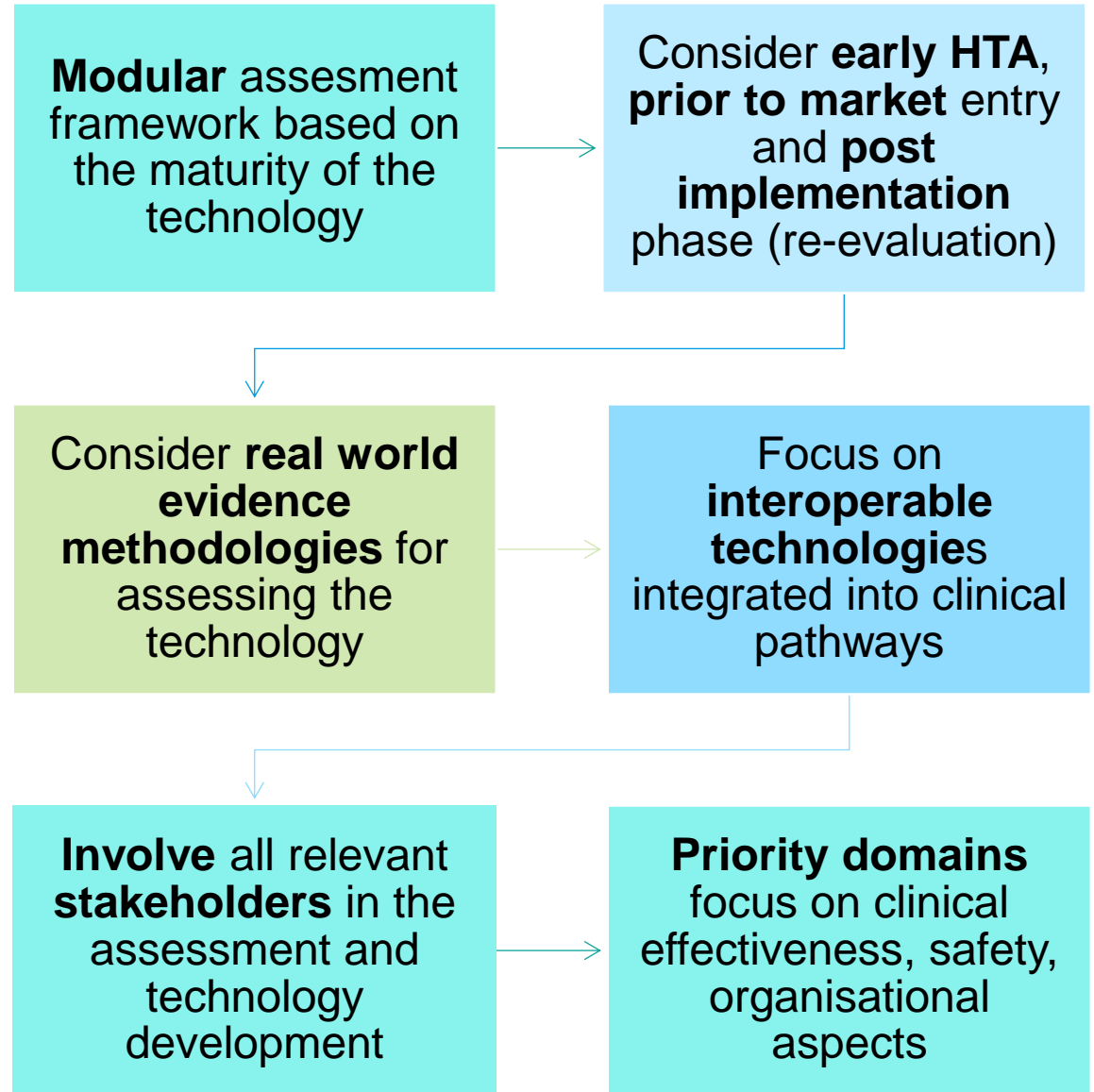
Stakeholders differ in their preferences for reimbursement models. The framework should be flexible and inclusive to link and support national reimbursement models, offering possibility to align with national strategies.



Policy makers and HTA agencies lean towards outcome-based reimbursement, linking payments to demonstrated health benefits. Developers often prefer reimbursement tied to specific technologies to simplify financial planning. Healthcare providers and patients advocate for models that prioritize broader care outcomes and accessibility.

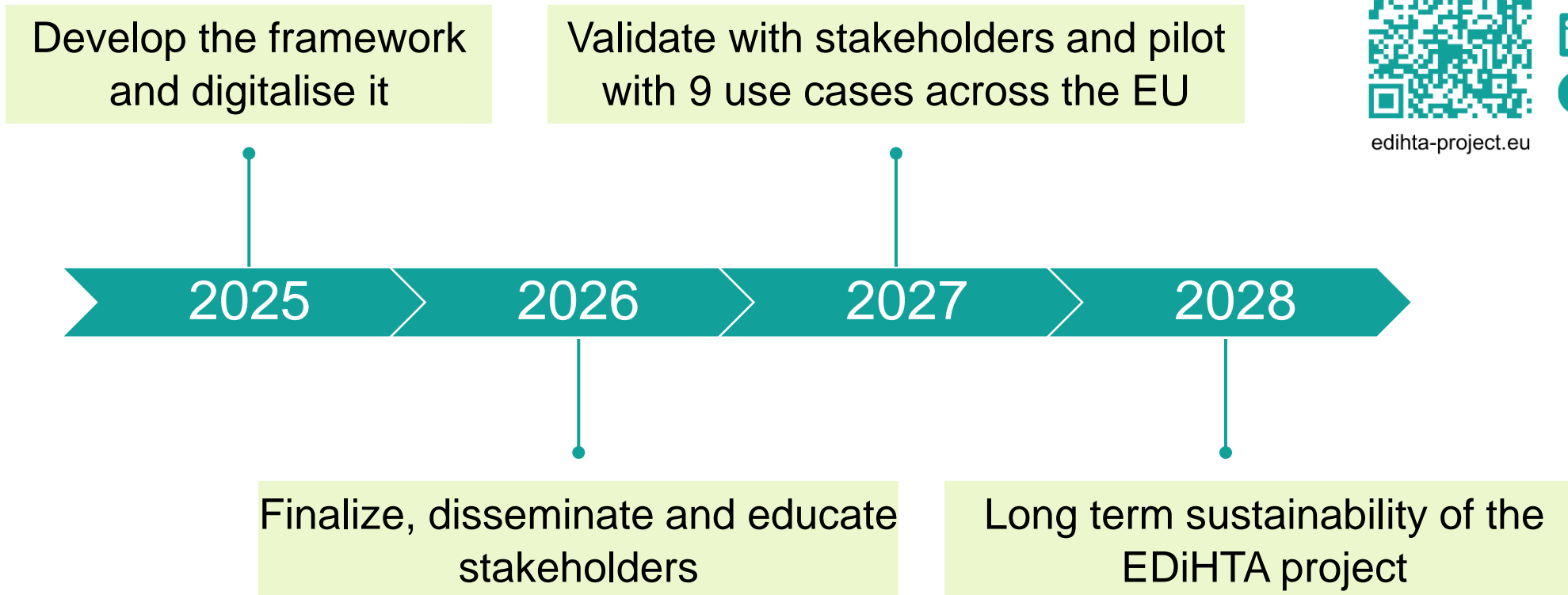
Implications on EDiHTA concept design

Harmonised needs and requirements



Next steps

Get in touch



edihta-project.eu

-  @EDiHTAProject
-  EDiHTA-EU-project
-  info@edihta-project.eu

Contact



Emmanouil (Manos) Tsiasiotis

Research project manager

Università Cattolica del Sacro Cuore



emmanouil.tsiasiotis@unicatt.it

Get in touch



edihta-project.eu



[@EDiHTAProject](https://twitter.com/EDiHTAProject)



[EDiHTA-EU-project](https://www.linkedin.com/company/edihta-eu-project)



info@edihta-project.eu



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Discussion

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Save the Date

THCS WP10 Shared Learning Webinar

Workforce in the Remote Areas

7 May 2025 – 11.00-12.00CET

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