



Digital Transformation in Action: Health Technology Assessment (HTA) and Digital Health Tools in the EU

Friday, 2 October 2026 – 11:00-12:00 CET

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📢 Save the Date - THCS Learning Week 2026: “Transforming Health and Social Care: Meaning, Models and Measurement”



THCS
TRANSFORMING HEALTH
AND CARE SYSTEMS

THCS Learning Week

 **From 28 September to 2 October**

 **10 sessions** |  **1 hour each** |  **Engaging & collaborative**

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Learning Week 2026

- Thank you for joining this session.
- The session recordings will be hosted on the Knowledge Hub:

<https://knowledgehub.thcspartnership.eu/>



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THCS Learning Week 2026
Digital Transformation in Action: Health Technology

ASSESS-DHT
Development and harmonisation of
methodologies for assessing digital health
technologies in Europe



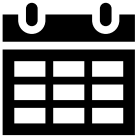
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Development and harmonisation of methodologies for assessing digital health technologies in Europe



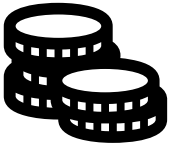
January 2024 – December 2026 (36 months)



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the European Union



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and Innovation



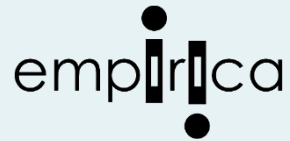
6,422,635 € (plus UK funding)

ASSESS DHT receives funding from the European Union's Horizon Europe Programme under Grant Agreement Number 101137347. UK participants in Horizon Europe Project ASSESS DHT are supported by UKRI grant number 10106825 (National Institute for Health and Care Excellence) and 10108522 (University of Oxford).



14 partners from 7 countries representing HTA, research organisations, DHT companies, professional and patient organisations as well as intergovernmental and multi-stakeholder associations at EU, MS and regional level

PROJECT PARTNERS



Landscape analysis
of existing assessment frameworks and tools

State-of-the-art findings
from initiatives and projects, e.g. IDEAL, CORE-MD

Relevant standards
e.g. ISO EN TS 82304-2

Regulatory conformance requirements
e.g. GDPR, MDR, EHDS, EEHRxF

Data protection & cybersecurity
related requirements

Data quality, bias, interoperability
Requirements including AI



LEADING TO:

- A novel **taxonomy** of DHT and mapping to assessment pathways
- Gap analysis of existing frameworks
- Specific recommendations for **assessing data protection, cyber-security, data quality, interoperability**

A new overarching assessment framework

Including:

- regulatory compliance, data protection and cybersecurity
- data assessments: data quality, bias, metadata, interoperability
- system level impact and human factors

Specialised pathways for:

- phased adoption including iterative assessment
- approaches for AI and other innovative technologies
- assessing DHT services that are embedded within healthcare services

Assessment manual and toolkit

for assessment bodies with checklists and criteria

Compliance toolkit

for developers (and decision makers) with guidance on compliance with the framework and evidence generation planning

A formal assessment of four products

each undertaken by paired HTA body experts with companies who are not involved in developing the new framework

Digital Therapeutics
mHealth app

An AI-based digital
health technology

an AI-based
radiology image
interpretation
solution for hospitals

An intervention
based on telehealth

Undertaken by:

- an **industry partner**, who generated the evidence, and present a value dossier, using our framework.
- an **HTA body**, who developed the assessment report, applying our methods guidance, on the appraisal of the evidence presented by the industry partner
- a **clinical expert**, to provide expert advice, particularly in areas where evidence is scarce
- a **patient representative**, to provide the patient perspective, which is always very valuable in HTA

Expert advisory groups with key stakeholders

especially HTA, policy-makers, developers, payers and end users

Wider public consultations

Sustainability round tables with EU27, EC, WHO...

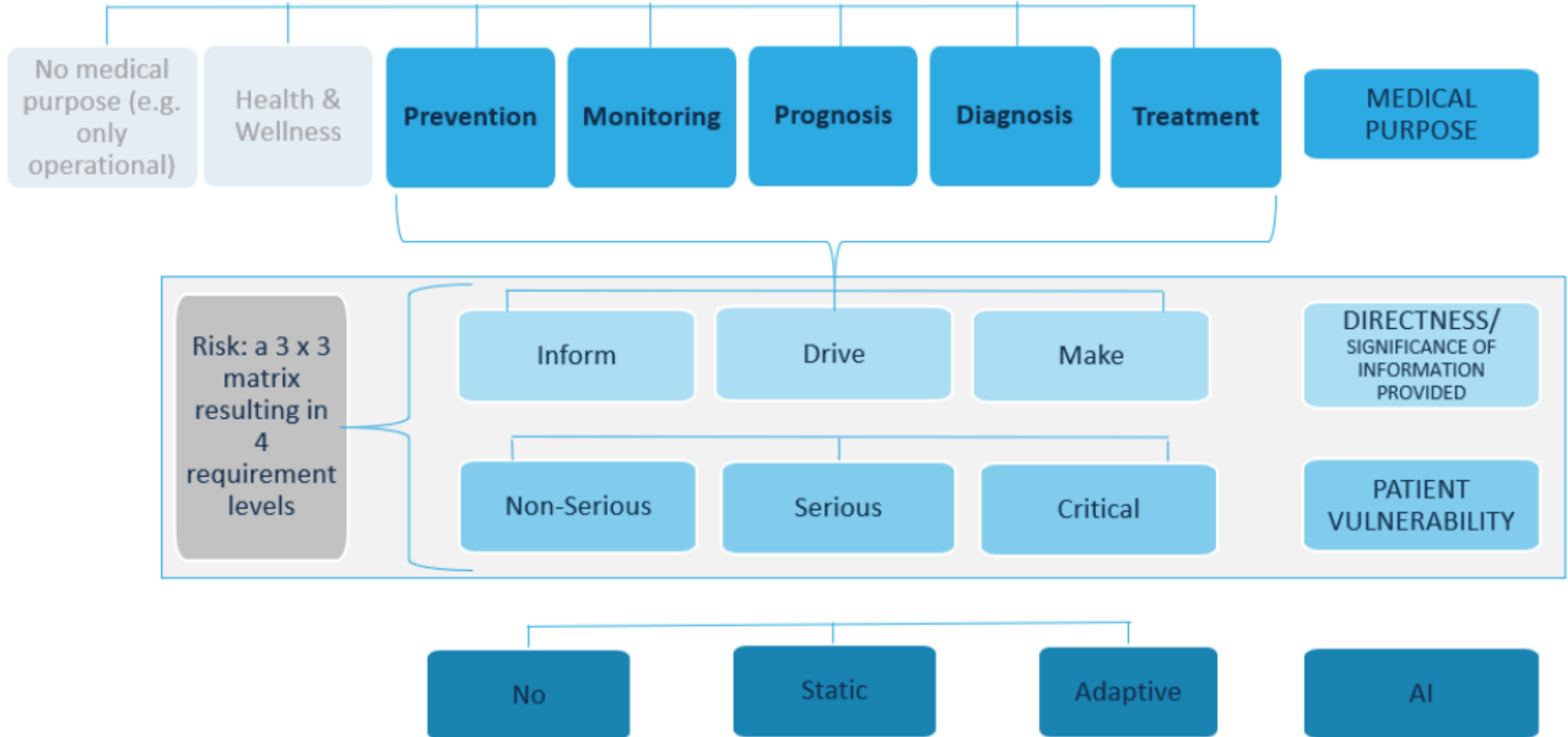
Knowledge Hub

To support developers and HTA bodies to discover which evidence requirements are most relevant to a particular DHT, at its current lifecycle stage

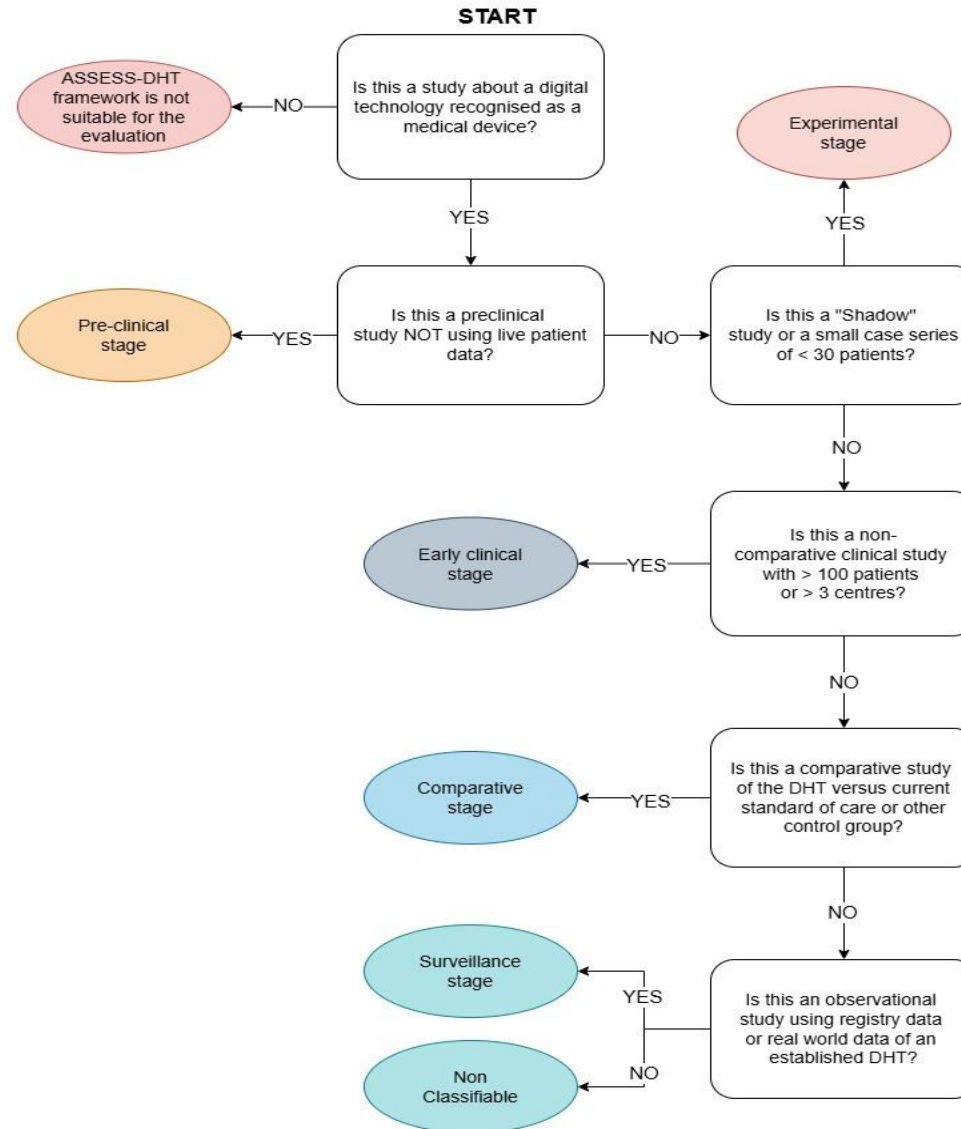
To be sustained and enriched after the project

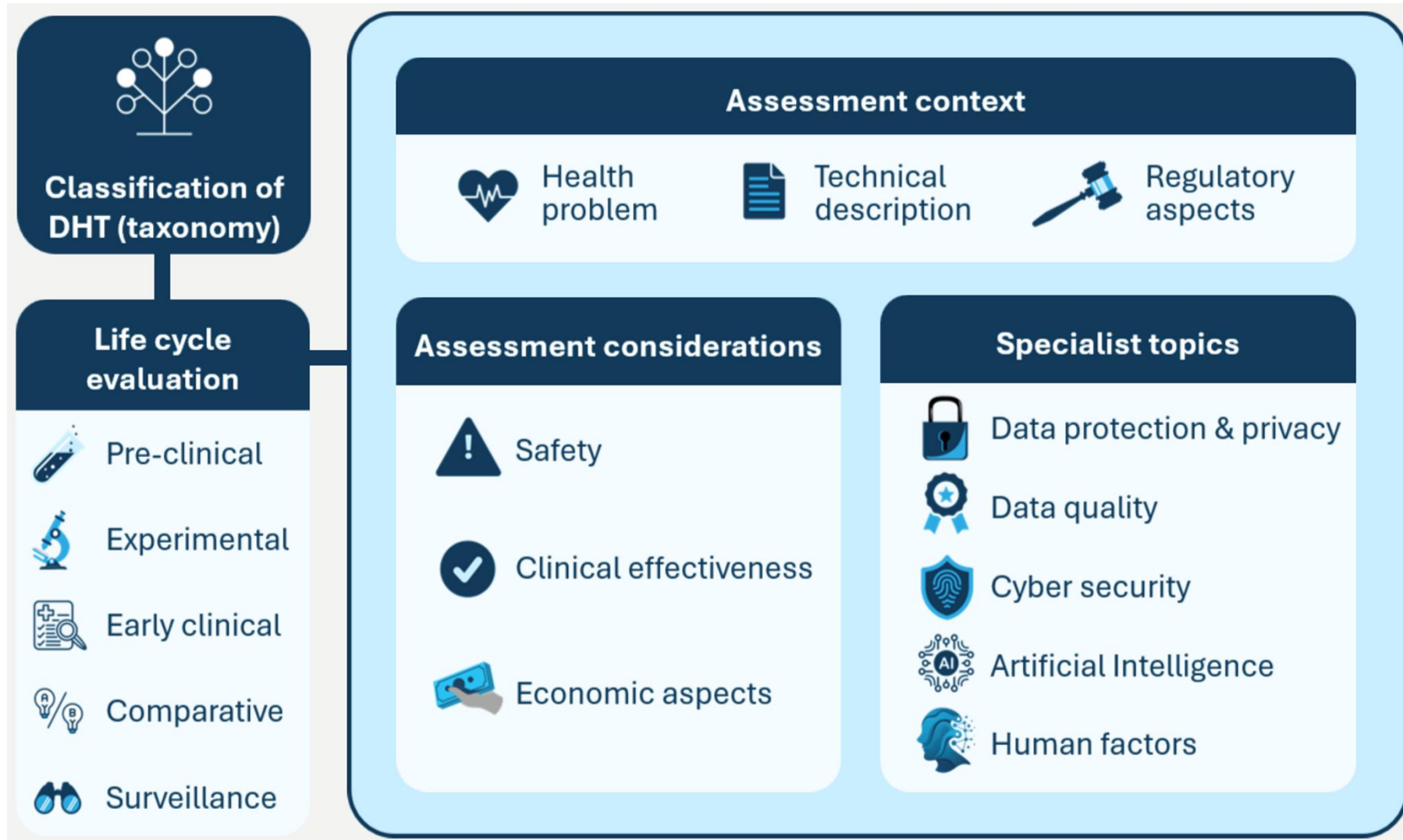


The ASSESS-DHT Taxonomy framework



Tailoring assessment to the DHT lifecycle

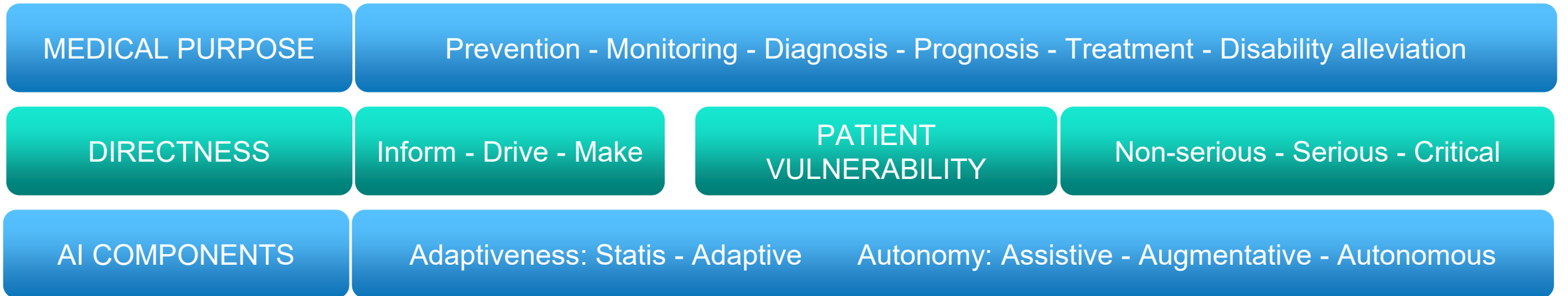




The ASSESS-DHT Assessment Framework



The ASSESS-DHT Taxonomy





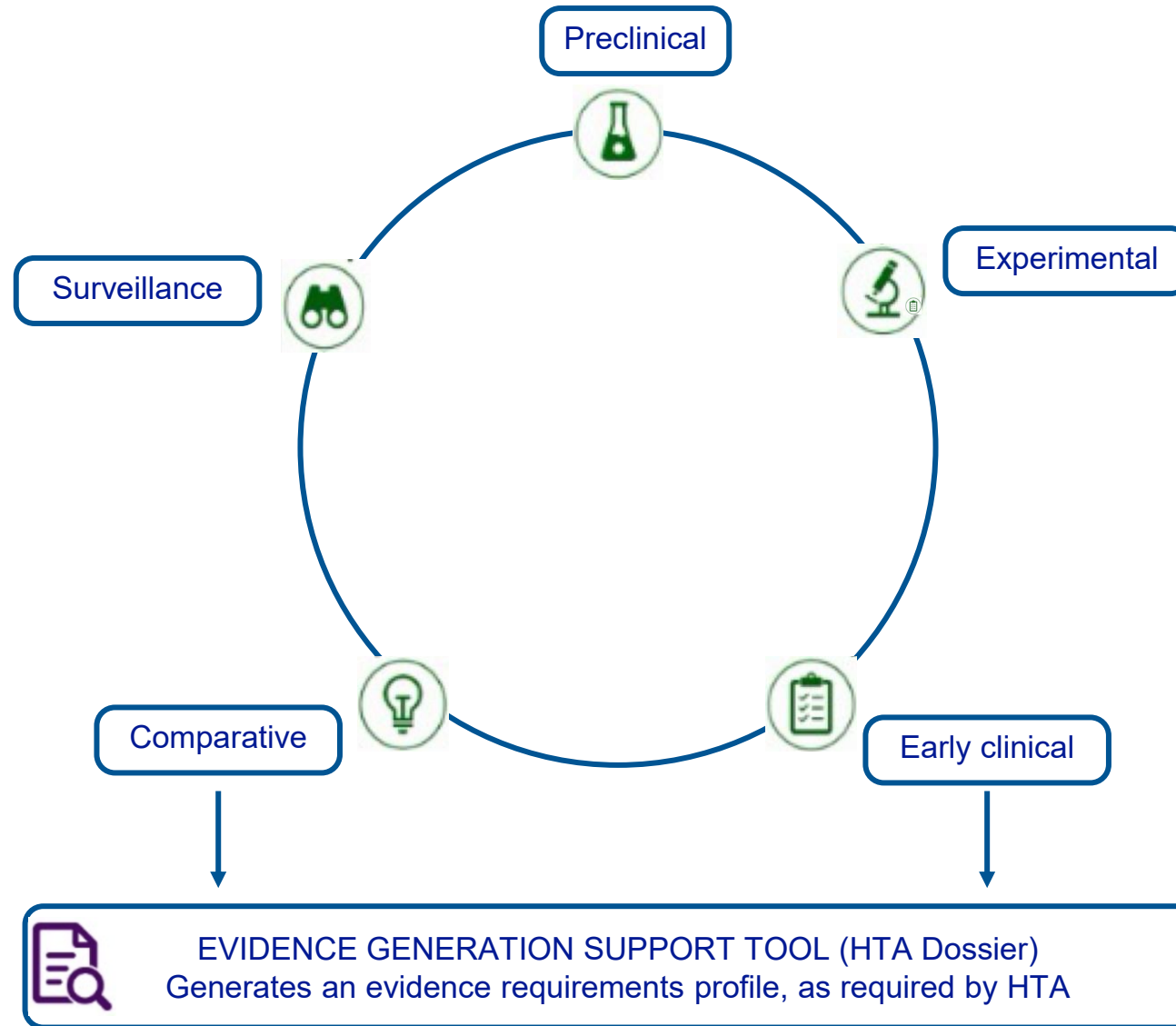
PRISM platform

Lifecycle-specific
evidence based
guidance

Connects to specialist
topics

Maps to HTA
Evidence Generation
Support Tool

Supports innovation
and patient safety



Two specialist tools



Six specialist checklists

Data protection and
privacy

Cybersecurity

Data quality including AI

Interoperability

Human factors (AI and
non- AI)

Clinical impact evidence



THANK YOU



EDiHTA

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

The EDiHTA project

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Università Cattolica del Sacro Cuore



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

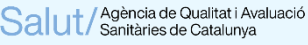
The Swiss participant is supported by the Swiss State Secretariat for Education, Research and Innovation (SERI).

EDiHTA project: The first European Digital HTA framework

Consortium (18 partners from 10 European Countries)

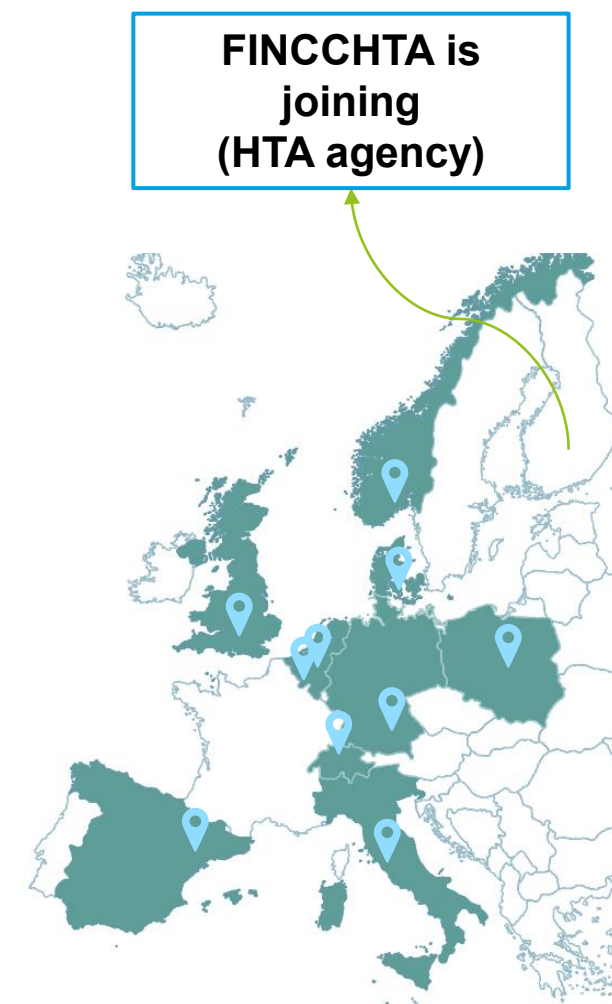
- 1 Ministry of Health
- 3 **HTA agencies**
- 6 **hospitals** as end-users of DHTs
- 1 **NGO** specialised in HTA
- 1 global quality assurance and risk management company and **notified body** for MDR certification
- **European Institute of Technology (EITHealth)**
- **European Patients' Forum**
- European 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	
 Patient engagement, communication, dissemination	 Health economics, clinical and cost-effectiveness, education	 EU project administration, communication, dissemination	 HTA, guidelines, evidence-based practice, real-world evidence	

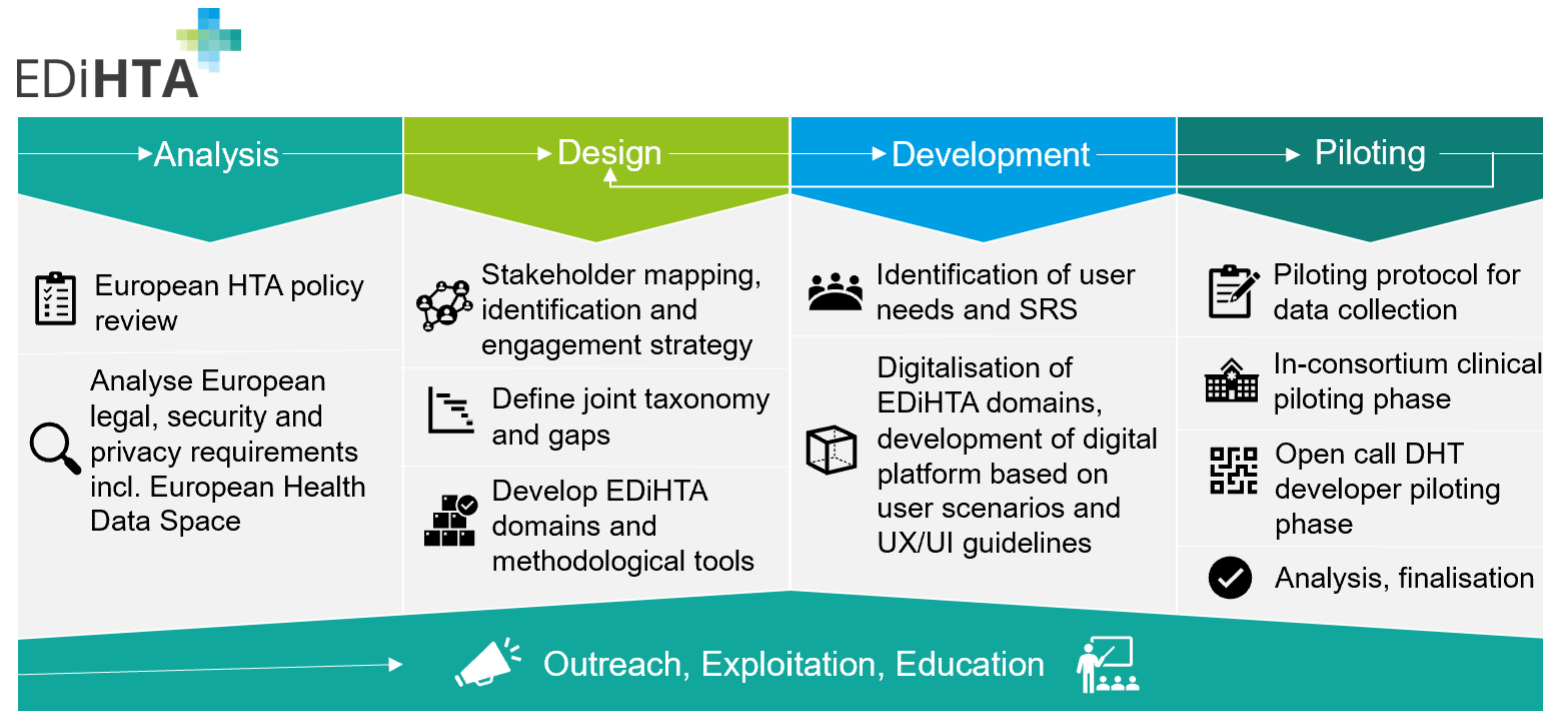
Key:

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



Key facts

Action: HORIZON-RIA

Budget: 7.9M Euro

Duration: 48 Months

Consortium: 19 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

DHTs DEFINITION

- 118 complete responses received (Delphi study)
- Consensus* reached on all the building blocks of the definition

Digital Health Technology is a broad, umbrella term that encompasses **eHealth (which includes mHealth)**, **telehealth**, as well as **emerging areas, such as artificial intelligence**. It is used by diverse groups, including the **public, patients and care givers, healthcare professionals, and health system managers**, to improve or support health system functioning and to improve health outcomes.

 Underlying technology of DHT
  Users of DHT
  Purpose of DHT

* Consensus threshold: $P45 \geq 0.7$
P45 is proportion of "important" and "very important" rating.

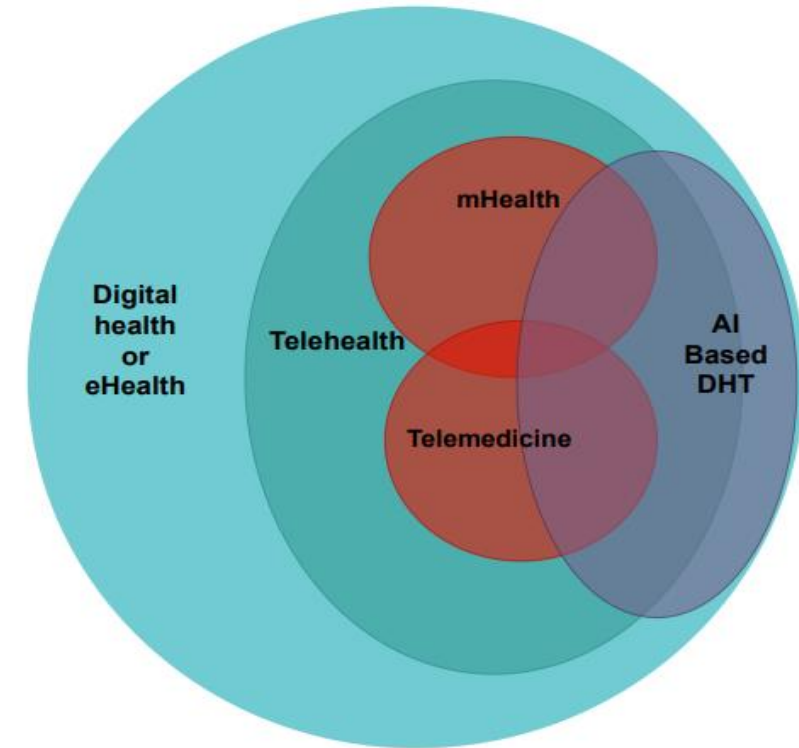


Figure 1: Conceptual map of digital health terms

How the EDiHTA taxonomy works?

Maturity Level of Technology	Classification criteria			
Healthcare Innovation Cycle Stages	Class of DHT based on intended purpose	Class of AI capability of DHT	Users of DHT	Services and application type
☐ Stage 1: Need ☐ Stage 2: Idea ☐ Stage 3: Proof of Concept ☐ Stage 4: Proof of Feasibility ☐ Stage 5: Proof of Value ☐ Stage 6: Initial Clinical Trial ☐ Stage 7: Validation of Solution ☐ Stage 8: Approval & Launch ☐ Stage 9: Clinical Use ☐ Stage 10: Standard of Care	☐ 1. DHT <u>with no direct patient, health or care outcome</u> intended to save cost or release staff time. ☐ 2. DHTs intended to help citizens and patients to <u>manage their own health and wellness</u> . ☐ 3. DHTs intended to provide <u>general information and provide health professional</u> training material or tools. ☐ 4. DHTs with direct health outcomes intended to treat or <u>diagnose a specific condition or guide treatment, diagnosis and care choices.*</u>	☐ (a) No AI capability ☐ (A) Class A ☐ (B) Class B ☐ (C) Class C	☐ Public ☐ Patient and care givers ☐ Healthcare professionals ☐ Health system managers	☐ Point of service ☐ Health system/provider administration ☐ Registries and directories ☐ Data management services ☐ Surveillance and responses

A harmonised EU framework for the evaluation of DHTs



The EDiHTA framework introduces a **comprehensive** and **methodologically robust** approach to assessing digital health technologies (DHTs) across Europe based on how these are currently assessed by agencies. (EUnetHTA core model and AQuAS framework). 12 domains identified.



Building on the architecture and standardised terminology of the EUnetHTA Core Model, the framework is organised into three structural layers (**domains, topics and subtopics**).



A DHT specific and guided by the EDiHTA taxonomy literature review was performed across 12 domains in a bottom-up approach to develop the content of the domains.

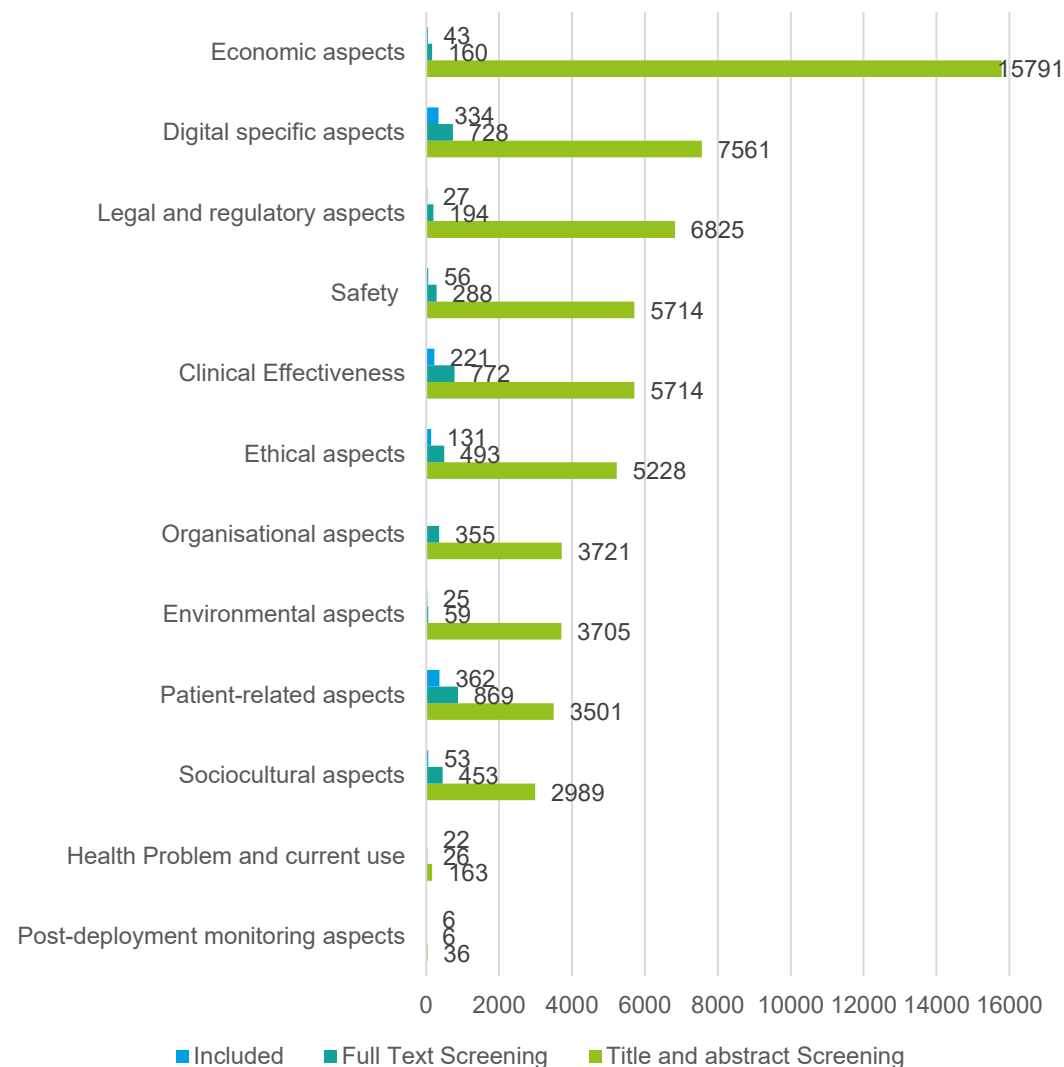


Each domain provides information relevant to the **lifecycle evaluation** of the technology, supported by **evidence requirements, measures** and **methods** needed for the assessment.



By embracing a common methodology, EDiHTA aims to **streamline evaluation pathways**, enhance cross-border collaboration, and build readiness for the evolving European HTA landscape.

Review in numbers



➡ Title&abstract **60948** references screened

➡ Full Text **4403** references screened

➡ Included **1280** references

➡ 45 different people from 11 institutions

A harmonised EU framework for the evaluation of DHTs

Health problem and current management •Population targeted by the technology •Health problem targeted by the technology •Management of the health problem in current practice	Description of the technology •Technology Utilisation and Positioning •Regulatory and Reimbursement Status	DHT specific aspects •Technology acceptance •Accessibility and Inclusivity design •System adaptability through interoperability and integration •Compliance with recognised standards •Data Quality and Integrity	•Explainability and Transparency of AI systems •Functionality and Features •Interoperability and Integration •Interpretability •Quality •Reliability and Robustness •Safety and Risk Management of the DHT	•Scalability, Maintainability and Flexibility •Security and Privacy •Technical Infrastructure and Support •Technical Performance •Trust, Ethics and Bias •Usability •Validation and Evidence
Safety •Clinical Safety •Technical Safety	Clinical effectiveness •Clinical Safety Outcomes •Physical •Psychological •Psychosocial	•Well-being/ QoL •Behaviour •Knowledge •Healthcare Utilization •Process •Diagnostic	Economic aspects •Costs and Resource Use •Economic Evaluation •Budget Impact Analysis	Organisational aspects •Organisational prerequisites •Implementation Process •Organisational effects of implementation of DHT
Ethical aspects •Control, user autonomy and contestability •Equity and Fairness •Ethical transparency, explainability and interpretability •Responsibility, accountability and governance	Patient related aspects •Patient as active participant •Responsiveness of services— an individualized approach •Lived experience •Continuity of care and relationships •Communication •Information •Support •Caregiver burden •Satisfaction	Sociocultural aspects •Determinants influencing technology acceptance •Behavioural Change and technology acceptance •Equitable access and use •Determinants of technology adoption •Implementation and scale-up determinants •Social determinants of Health	Environmental aspects •Material Extraction •Material Production/ Manufacturing •Material Transportation •Computational Model Development and Maintenance •Facility and Device Resource Use •Patient and Provider Transport Emissions •Material Disposal •Circularity Potential	Legal and regulatory aspects •Accountability •Legal transparency of data and AI use •Legal and regulatory compliance •Data protection



On 16–17 February, the **EDiHTA Co-Creation and Evaluation Workshop** brought together 50 key stakeholders in Brussels for two days of structured dialogue and validation. Organised by Odense University Hospital with the support of Università Cattolica del Sacro Cuore, the meeting gathered representatives from **18 EU Member States, plus the UK and Norway**, including national policymakers, payers, HTA agencies, industry leaders, clinicians, hospital managers, patients and patient representatives.

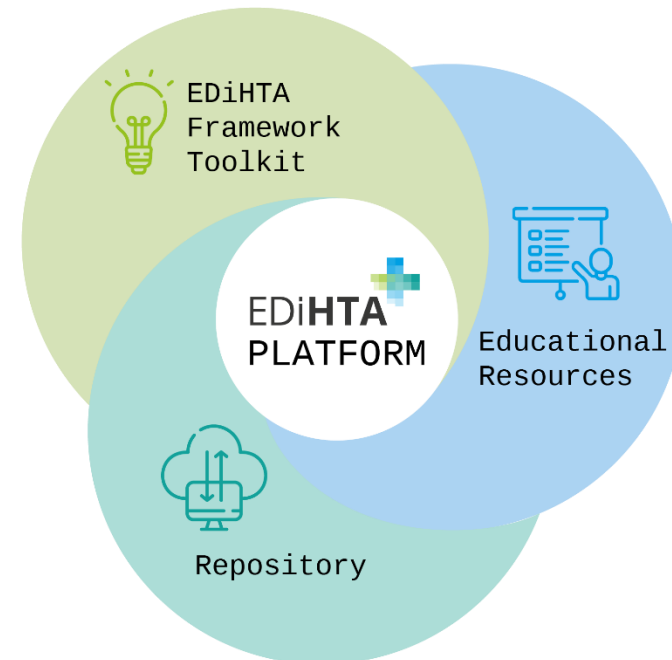
The EDiHTA platform as final product

To ensure practical usability, the EDiHTA framework is complemented by tools to guide stakeholders (HTA practitioners/doers and beneficiaries/users) through the evaluation process, educational materials for using the framework, as well as an open-access repository of studies on the assessment of DHTs.

Pillar 1: EDiHTA framework toolkit and user guidance

Pillar 2: Open-access repository

Pillar 3: Educational resources



The EDiHTA toolkit

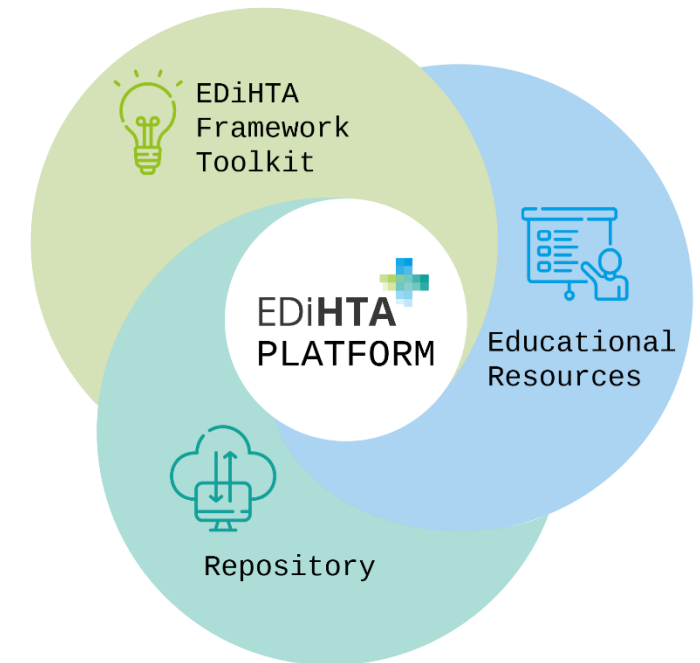
Pilar 1: EDiHTA framework toolkit and user guidance

- **Descriptive tool and stakeholder guidance**

An informative, easy-to-navigate toolkit designed to introduce the EDiHTA framework to all healthcare stakeholders. It offers: Definitions of domains, topics, subtopics, with their related outcomes, methods and evidence requirements, Practical guidance to support consistent interpretation, This toolkit strengthens a shared understanding and fosters alignment across diverse user groups and contexts.

- **Interactive tool for HTA doers/practitioners and industry**

A dedicated tool that supports HTA doers in preparing and conducting assessments. This tool enhances operational efficiency and ensures uniform application of the EDiHTA methodology across HTA agencies, healthcare providers (clinicians, managers) and research teams. It helps users to: Identify the criteria relevant to the specific DHT, Tailor assessments based on lifecycle stage and context, Streamline the scoping and planning process.



Support the HTA process

Using this toolkit will help to prepare your HTA or prepare your DHT for industry assessment and to prioritize next steps such as strengthening submissions or preparing for scientific dialogues between HTA doers and Health Technology Developers.

Create project

+

Toolkit features



Identify framework areas relevant to your use case.

Based on your DHT classification, a set of recommended assessment criteria will be displayed.



Complete evidence readiness questionnaire and view evidence gaps

Your questionnaire responses identify evidence gaps against the previously generated assessment criteria. The result is a structured analysis, demonstrating where your evidence is strong and where gaps remain.



Collaborate and save as you go

Invite colleagues to contribute so different team members can complete relevant sections. Save progress at any time and return later without needing to complete everything in one session.

New project



Project name *

Enter project name

0 / 200

These attributes are core components of the EDiHTA framework. Each selection will be linked to relevant domains, topics, and sub-topics, ensuring that output you receive is tailored to your DHT. You can also explore the EDiHTA framework without a specific DHT or use case.

Intended purpose of technology *

Select one

▼

AI Capability *

Select one

▼

Maturity level *

Select one

▼



You may invite collaborators after the

Show domain list



Safety

Topic 1: Clinical Safety

Show

All questions

▼

Sub-topic 1a. Adverse events: Morbidity

To what extent is there evidence of the frequency and severity of adverse events caused by the DHT, with these adverse events clearly described, measured, and attributable to the intervention?

- ☐ Strong evidence or documentation
- ☐ Minor weaknesses in evidence or documentation
- ☐ Limited evidence or documentation
- ☐ No evidence or documentation
- ☐ Not applicable

Sub-topic 1b. Adverse events: Mortality

To what extent is there evidence of the frequency of deaths caused by the DHT, with the causes of death clearly described, measured, and attributable to the intervention?

- ☐ Strong evidence or documentation
- ☐ Minor weaknesses in evidence or documentation

Rating scale definitions

This scale is not relevant for questions related to 2 of the 12 domains: (1) Health problem and current management, (2) Description of the technology.

Rating = 4, Strong evidence or documentation

No gaps: Evidence or documentation is strong, reliable, consistent, and directly applicable to the question.

Quantitative study characteristics that imply **no gaps**:

- RCTs with adequate allocation concealment, blinding appropriate to the outcome, and low loss to follow-up (<10%)
- Outcomes measured with validated instruments over clinically appropriate timeframes
- Adequate sample size with narrow confidence intervals
- Consistent results across multiple studies or populations (I² <40%)
- Direct evidence: study population, intervention, and outcomes match the assessment question

Qualitative study characteristics that imply **no gaps**:

Hospital piloting (Internal to EDiHTA)

EDiHTA partner	Country	Healthcare Innovation Cycle levels (HIC)		Class of DHTs based on Intended Purpose		AI/not AI	Class of AI capability of DHT	Users
UCSC	Italy	Level 7: Validation of Solution	Pilot stage	4	DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices	AI	B	Patient and care givers Healthcare professionals
HCB 1	Spain	Level 9: Clinical Use	Post-marketing stage	2	DHTs are intended to help citizens and patients to manage their own health and wellness	Not AI	No AI capability	Public
HCB 2	Spain	Level 7: Validation of Solution	Pilot stage	4	DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices	Not AI	No AI capability	Primary care professionals: support decision Patients: customized therapeutic plan (no drug included)
Vestre Viken Hospital (VV)	Norway	Level 9: Clinical Use	Post marketing stage	4	DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices	AI	B	Healthcare professionals
OUH	Denmark	Level 7: Validation of Solution	Pilot stage	4	DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices	AI	B	Patient and care givers Healthcare professionals
RUMC 1	The Netherlands	Level 8: Approval & Launch	Market approval stage	2	DHTs that are intended to help patients manage their own health and wellness (remote monitoring and self-management)	Not AI	No AI capability	Children with severe or difficult-to-treat asthma, parents/caregivers, and hospital asthma team
RUMC 2	The Netherlands	Level HIC 1-2: Idea / Concept stage	Research and concept design stage	1	DHT is intended to record and transcribe pre-hospital trauma calls from the ambulance to the emergency department to minimize information loss	Not yet	Not yet	Staff in the emergency department responding to trauma calls
GUF	Germany	Level 3: Proof of Concept	Research and concept design stage	1	DHT with no direct patient, health, or care outcome, intended to save cost or release staff time.	Not AI (for now)	No AI capability	Healthcare professionals

Open validation - Pilot participants

Part of national
HTA programmes

	Pilot 1	Pilot2	Pilot 3
DHT	██████████	██████████	██████████
Developer	██████████	██████	██████████
HTA agency	AQUAS	AGENAS	FinCCHTA
Intended purpose	IP4: DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices. Remote monitoring of chronic conditions	IP4: DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices. Remote monitoring of pulmonary artery pressure in heart failure	IP4: DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices. Remote monitoring for long-term illness treatment and rehabilitation management
Indication	Cardiovascular Disease	Heart Failure	Multipile Sclerosis
Type / components	Patient smartphone app + web-based clinical dashboard, with data from connected IoT and wearables	Implanted sensor + patient electronics + hospital electronics + platform	Data platform for healthcare professionals + mobile app for patients
Regulatory status	CE-marked medical device, MDR (Class IIa)	CE-marked, implantable medical device under MDR (Class III)	CE-marked medical device under MDD (Class I), MDR Class IIa planned
Setting	Healthcare professionals, patients, including hospitals and decentralised clinical trials across Europe	Healthcare professionals, Hospitals, Heart Failure clinics	Healthcare professionals and patients

The value for HTA practitioners and innovators



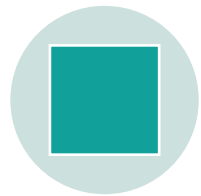
Support the HTA of DHTs with the same assessment criteria provided by the framework and across all contexts (EU, national, regional, hospital)



Identify the comparative value of DHTs in the EU health ecosystem and across health system levels



Supports industry with the development of DHTs with specific considerations on assessment criteria (evidence generation plan and later the market access dossier)



Supports open dialogue between innovators and HTA agencies and decision makers on the evidence requirements



Support cross country collaboration and dialogue amongst all stakeholders, leading to system efficiency through increased HTA capacity



Increase transparency of DHTs assessment and their introduction in the health systems

Sustainability of EDiHTA beyond 2027^{EDiHTA}



Bi-fold strategy (political and market approach)



Implementation of EDiHTA and usage of the platform across Europe



Top down working with EC and HTA agencies (HAg group, HTA coordination group)



Bottom up with pilots created within member states as part of national HTA programmes



Business model path to support the maintenance and further development of the EDiHTA platform

Contact



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