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

EDiHTA EU-project

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EDiHTA

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EDiHTA project: The first European Digital HTA framework

Consortium (19 partners from 10 European Countries)

- 1 Ministry of Health
- 3 **HTA agencies**
- 7 **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

The EDiHTA values

EDiHTA solution

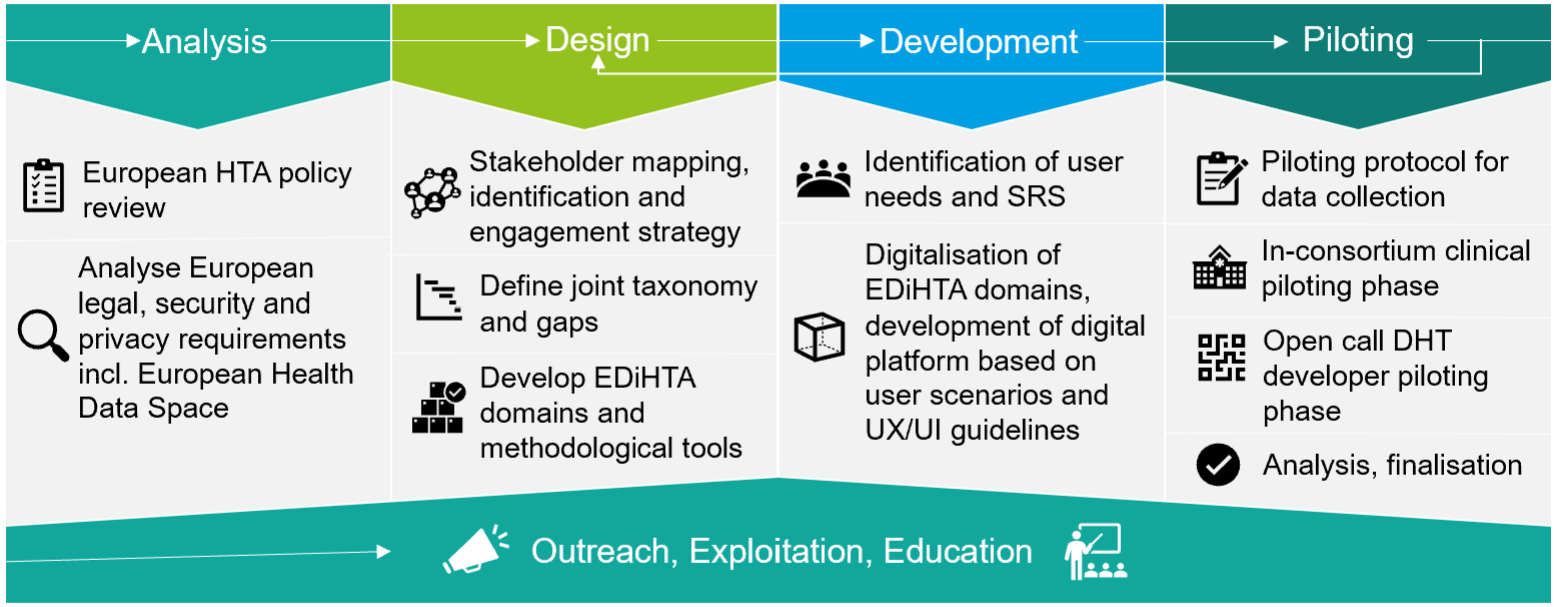
- ✓ We are set to deliver the first innovative and first of its kind **digital HTA framework** that will be developed to assess digital health technologies
- ✓ **Flexible and customized** according to the type of technology, the maturity level and the decision-making level
- ✓ Integrates existing methodologies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

How will EDiHTA contribute to the future of HTA development?

- ✓ **HTA methods** for digital health technologies (taxonomy, classification, full lifecycle assessment, new domains/topics/issues)
- ✓ **Capacity building** through training and dedicated toolkits for all stakeholder groups
- ✓ **Impact:** establish HTA as a catalyst that supports decision-making and drives the digital transition in the health sector

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.



✓ 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

Key facts

Action: HORIZON-RIA

Budget: 7.9M Euro

Duration: 48 Months

Consortium: 19 partners

DHTs Definition

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

Digital Health Technology (DHT) is a broad, umbrella term that encompasses eHealth (which includes mobile Health (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

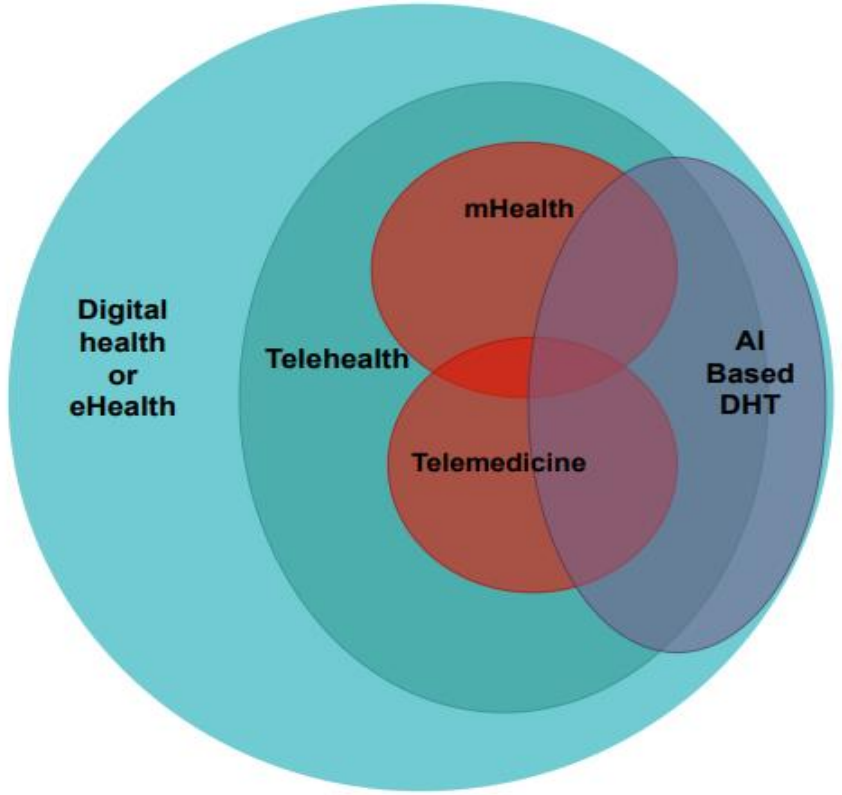


Fig 1: Conceptual map of digital health terms

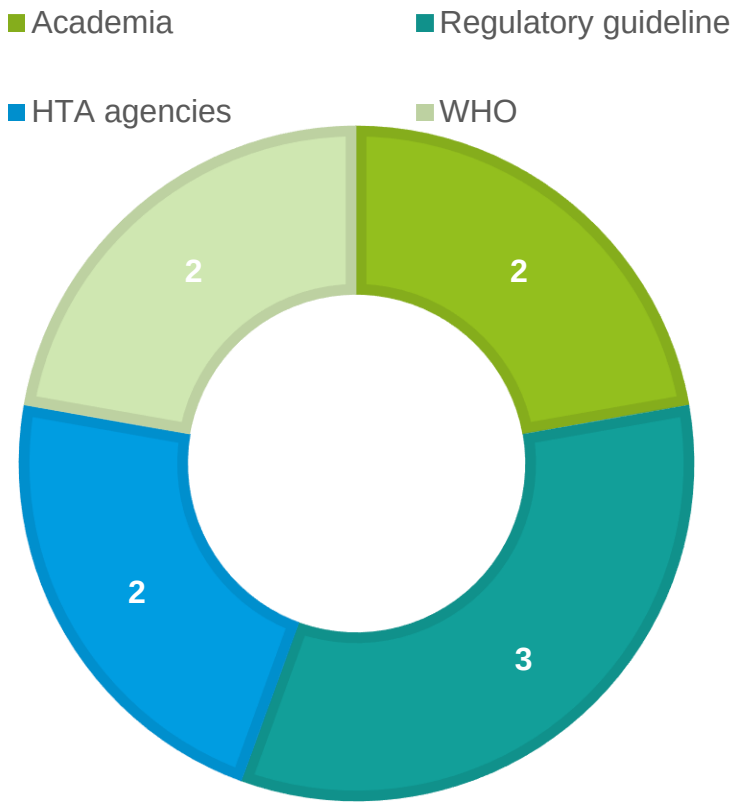
*Consensus threshold: P45 ≥0.7

P45 is proportion of "important" and "very important" rating.

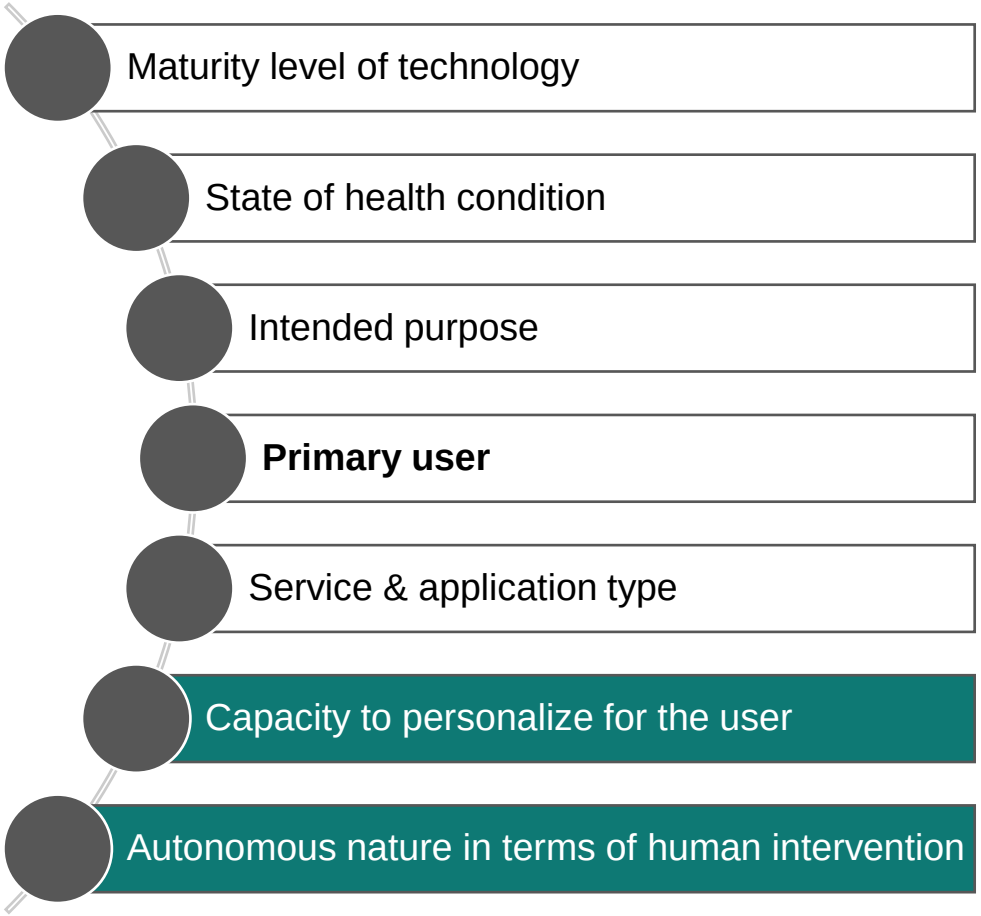
Classification criteria for DHTs

LITERATURE REVIEW

- Nine taxonomies identified from various sources



- Seven classification criteria identified



For AI-based DHTs

TAXONOMY

Results

DELPHI STUDY 1 & 2

TAXONOMY

1. Gain consensus on stages of maturity of technology

- Technology Readiness Levels
- Technology Readiness Level for Machine Learning Systems
- Maturity stages proposed by WHO
- ✓ Healthcare Innovation Cycle

Results

DELPHI STUDY 1 & 2

2. Gain consensus on classification criteria

Intended purpose

- No direct patient, health or care outcome intended to save cost or release staff time.
- Help citizens and patients to manage their own health and wellness.
- Provide general information and provide health professional training material or tools.
- Direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices

Users

- Public
- Patient and care givers
- Healthcare professionals
- Health system managers

Services and application type

- Point of service
- Health system/provider administration
- Registries and directories
- Data management services
- Surveillance and responses

Capacity to personalize for the user

- Capable of providing personalized responses to the user
- Do not support personalization

Autonomous nature in terms of human intervention

- Non-autonomous
- Partially autonomous
- Completely autonomous

TAXONOMY

Stakeholders needs and requirements

EDiHTA

Overview of stakeholder participation and methods of engagement

Policymakers
Number of participants: **16**
Type of involvement: **desktop analysis, survey, interviews, focus groups**

HTA Agencies
Number of participants: **15**
Type of involvement: **review of HTA reports, survey, interviews**
Non-EU countries included: **England, Wales**

Industry and Developers
Number of participants: **29**
Type of involvement: **scoping review, survey, interviews, focus groups**
Non-EU countries included: **UK, USA, Ukraine**

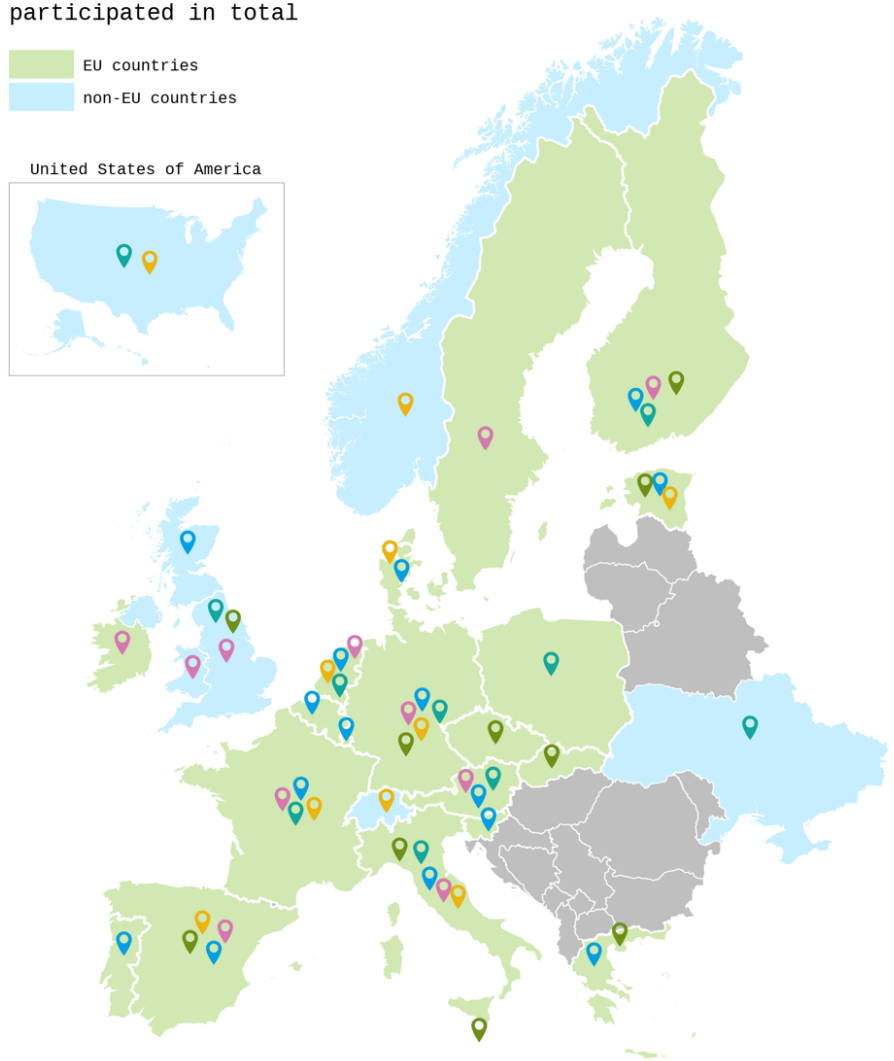
Healthcare Providers
Number of participants: **22**
Type of involvement: **literature review, interviews**
Non-EU countries included: **Brazil, Canada, USA, Kazakhstan**

Patient Representatives
Number of participants: **15**
Type of involvement: **scoping review, focus groups**
Non-EU countries included: **UK**

97 organisations participated in total

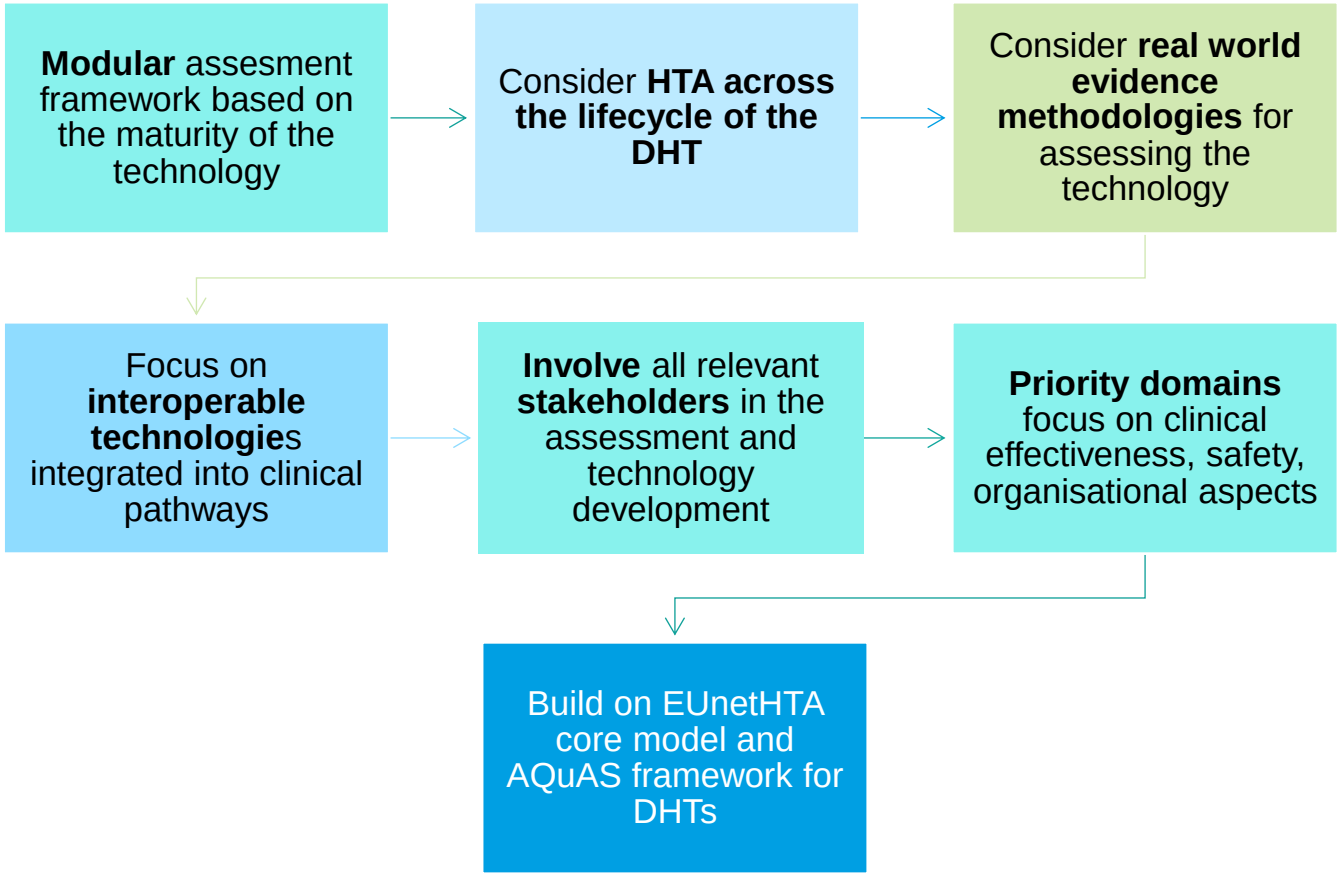
EU countries
non-EU countries

United States of America



Implications on EDiHTA concept design

Harmonised needs and requirements



Next steps

Get in touch

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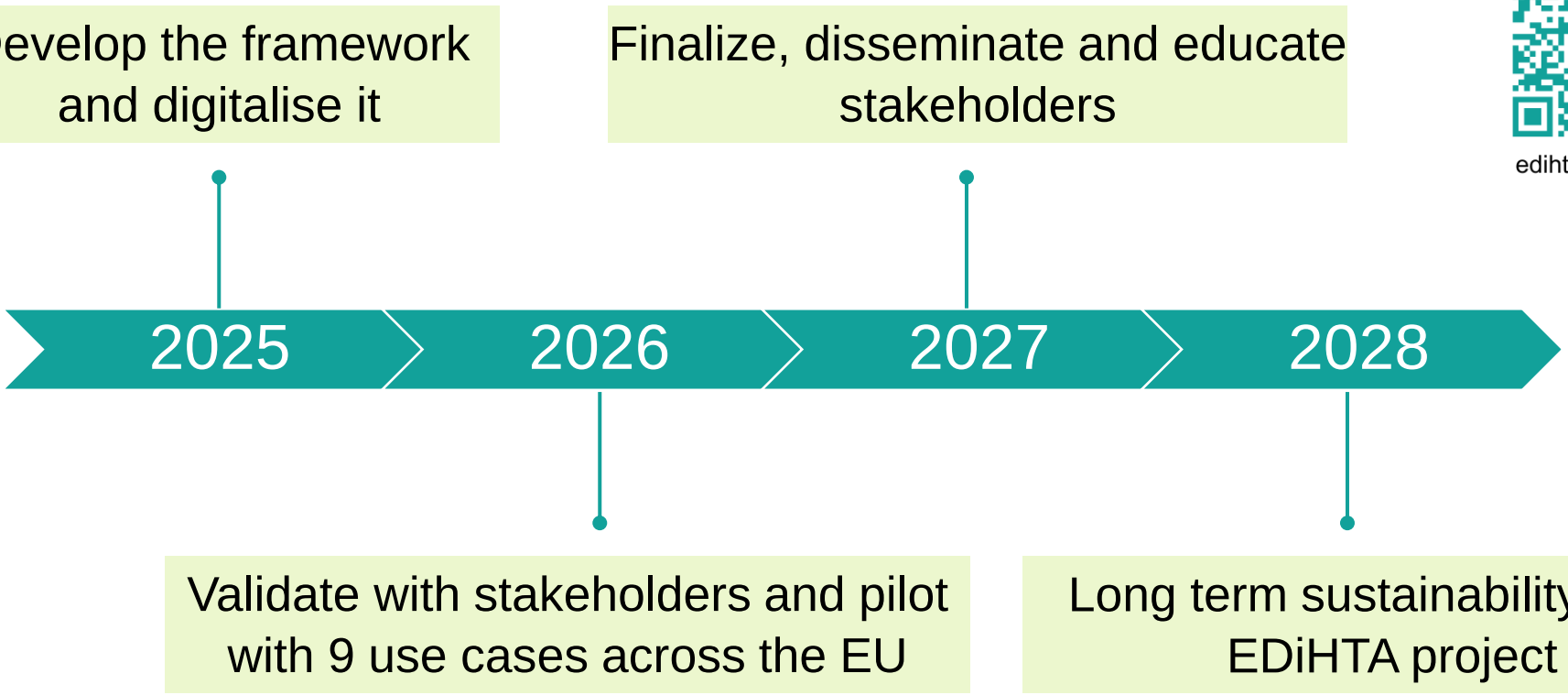

Long term sustainability

Further EU action and research

- Support projects like EDiHTA on the implementation and long-term sustainability and connect it with other projects/initiatives that could have a central impact on HTA

- Support continuous research on this matter with cross-country collaboration involving all key stakeholders to increase capacity and cover the gaps caused by the assymetry of information around DHTs

Contact

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