EDiHTA

The first **E**uropean **D**igital **Health Technology Assessment** framework co-created by all stakeholders in the European Health Ecosystem

EDiHTA framework validation open pilot

Call for digital health technology developers/manufacturers

Funded by the European Union

UK Research and Innovation

Funded by the European Union (GA no. 101136424). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union the European Health or the Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.
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).

Contents

List of participating partner institutions in the EDiHTA project consortium

UCSC	Università Cattolica del Sacro Cuore
FPG	Fondazione Policlinico Universitario Agostino Gemelli IRCCS
RUMC	Radboud University Medical Center
OUH	Odense Universitetshospital
FCRB	Fundació de Recerca Clínic Barcelona
HCB	Hospital Clinic of Barcelona
GUF	University Hospital Frankfurt
AGENAS	The Italian National Agency for Regional Healthcare Services
AQuAS	Agencia de Calidad y Evaluación Sanitarias de Cataluña
NSE	Norwegian Centre for E- Health Research
DNV	DNV AS
DNV-IT	DNV Business Assurance Italy Srl
EHMA	European Health Management Association
EITH	EIT Health e. V.
EPF	European Patients' Forum
HPI	Health Policy Institute
accelCH	accelopment Schweiz AG
NICE	National Institute for Health and Care Excellence
ITMOH	Italian Ministry of Health
VV	Vestre Viken HT

Abbreviations

DHT	Digital health technology
EDiHTA	EU-funded project; The first European Digital Health Technology Assessment framework co-created by all stakeholders in the value chain
EU	European Union
FinCCHTA	Finnish Coordinating Center for Health Technology Assessment
HTA	Health Technology Assessment
HTAR	HTA Regulation (EU)
IML	Innovation Maturity Level
MDR	Medical Devices Regulation (EU)
MS	Member State (EU)
RWE	Real-World Evidence
SME	Small and medium-sized enterprise

Definitions

Definitions under the EDiHTA project[1]
Digital health technologies (DHTs) 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.
Health technology assessment (HTA) *"HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system."* [2]
Developers/manufacturers Also known as 'technology developers/manufacturers. Micro, small- and medium-sized enterprises (SMEs) or larger technology companies working on digital health solutions and technologies and bringing them to market.

[1] Prakash A, Tummers M, Kievit W, et al. OP55 Defining And Classifying Digital Health Technologies: A Review Of Literature And Delphi Consensus Approach. *International Journal of Technology Assessment in Health Care*. 2025;41(S1):S26-S27. doi:10.1017/S026646232510113X.
[2] O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. *International journal of technology assessment in health care*, *36*(3), 187-190.

1 Introduction to the EDiHTA project

Health systems are under pressure to provide high quality services despite shortage of healthcare professionals, ageing populations and limited financial resources. Digital health technologies (DHTs) can be game-changers in improving the quality of healthcare services, leading to more sustainable healthcare systems in Europe.

DHTs offer a unique opportunity for the collection and application of real-world data and evidence relevant for decision makers relying on health technology assessments (HTA) to evaluate new technologies. However, the implementation of DHTs implies methodological challenges to the standardisation of assessment criteria used for conducting an HTA process. As long as existing HTA methodologies remain fragmented at an EU level, they are unable to capture the real added value of DHTs.

The EDiHTA project, titled “the first European Digital Health Technology Assessment framework co-created by all stakeholders in the value chain”, is a research and innovation initiative funded under the EU’s Horizon Europe programme (Grant Agreement No. 191136424) running from 2024 until 2027.

EDiHTA aims to deliver a fit-for-purpose HTA framework with supporting materials (platform, toolkit, user guidance) to inform decision-making for different types of DHTs (e.g. telemedicine, mobile apps, AI-driven solutions) at different maturity levels.

Developers/manufacturers of DHTs contribute to the design and development of the framework through co-creation and piloting activities. This open pilot process will help to test the EDiHTA framework and related supporting tools with real-world DHT use cases.

Please visit **https://edihta-project.eu/** for further information on the project.

2 Aim and rationale

To test the comprehensiveness of the EDiHTA framework and related supporting tools, the EDiHTA consortium launches an open piloting process engaging developers/manufacturers of DHTs. **The EDiHTA consortium is accordingly inviting DHT developers/manufacturers to propose their technologies as use cases on which to pilot the EDiHTA framework and corresponding toolkit.**

Using selected real-world DHTs that fit the scope of EDiHTA, the pilot will generate insights on whether the framework and related materials can support a consistent, transparent and proportionate HTA evaluation of DHTs, while identifying areas for improvements for future scale-up or policy uptake across EU markets.

Each pilot will see an HTA Agency partner of the EDiHTA consortium (AQuAS, FinCCHTA) applying the EDiHTA framework to perform an assessment of the selected technology. The pilot will also assess the EDiHTA toolkit for its usability in facilitating the assessment process. To carry out this exercise, relevant stakeholders, including decision makers, payers, HTA agencies, patients and the developer/manufacturer will be involved in the pilot phase.

To build a pilot use case portfolio, and considering specific national HTA context as well as defined validation approaches for the EDiHTA framework before wider scaling, the call will select two technologies as use cases:

DHT Use Case 1	DHT Use Case 2
• CE-marked medical device (under the MDR) • On the market • Implemented in minimum two countries (EU Member States (MS) including their outermost regions, the Overseas Countries and Territories linked to the Member States or in countries associated to Horizon Europe)	• **Either** non-medical device **or** CE-marked medical device (under the MDR) • On the market • Implemented in Finland (and possibly other countries)

3 Value proposition for applicants and pilot participants

Selected pilot participants (DHT developers/manufacturers) will be given the opportunity to contribute to the future development of the EDiHTA framework and associated toolkit by providing detailed, open and constructive feedback. DHT developers/manufacturers expressing an interest to participate in the pilot will benefit from:

(I) Early access to the EDiHTA platform and tool dedicated to industry.
(II) Training for the EDiHTA framework and processes at organisation level (company).
(III) Detailed feedback on evidence gaps, methodological expectations, and potential future HTA requirements based on the EDiHTA framework.
(IV) Visibility and exposure to the European digital health ecosystem through interacting with the EDiHTA partners, including opportunities for dissemination about pilot participation through the EDiHTA consortium's communication channels.
(V) Dialogues with a full scope of stakeholders, including decision makers, payers, HTA agencies developing the first pan-European HTA framework for DHTs.
(VI) Chance to contribute to and shape the first pan-European HTA framework for DHTs.

Participation in the pilot and collaboration with HTA agencies **DOES NOT** constitute or lead to formal endorsement, certification, market access or guarantee of reimbursement for the DHT. Participation in the pilot is **NOT FUNDED** and applicant DHT developers/manufacturers partake on a voluntary basis, committing own effort and resource. The selected use cases will benefit from a unique opportunity to receive HTA insights and feedback (no evaluation consequences).

4 Objectives of the open pilot

The piloting process in EDiHTA will consider the following objectives and outcomes.

Objectives

(I) To pilot the EDiHTA framework and its comprehensiveness in a real-world context.
(II) To test the acceptance, usability, clarity and added value of the EDiHTA toolkit.

How will the pilot achieve the above objectives

1. Apply the EDiHTA framework on selected digital health use cases of different intended purposes and different maturity levels.
2. Evaluate the framework with standardised indicators in terms of its comprehensiveness

and capability to evaluate different DHTs by collecting structured feedback from involved stakeholders.

3. Evaluate the usability of the corresponding toolkit available to all stakeholder types and refine it.
4. Identify gaps, ambiguities and improvements needed both for the framework and the toolkit that will drive further refinement before launching the final EDiHTA platform.
5. The pilot will also drive the development of educational material that will be used as a base to train all relevant stakeholders on the EDiHTA platform.

What the pilot is NOT

- Not a regulatory approval process for the pilot participant technologies.
- Not a reimbursement decision.
- Not a fast-track like evaluation or decision of reimbursement readiness.
- Not a binding HTA-related recommendation or decision.
- Not an accelerator programme for technology developers/manufacturers.

5 Pilot open validation timeline

Date	Step
20 Mar 2026	Deadline for applications submissions
March – May 2026	Evaluation period Interviews with shortlist of applicants Notification of applicants about the outcome
May – July 2026	Pilot preparation (including participant agreements, contracting, admission, ethical approvals if necessary)
July 2026	Anticipated kick-off of piloting activities
April 2027	Anticipated end of piloting activities

Should any changes to the time be necessary during the application period, the call document will be updated.

A dedicated pilot protocol and data management plan to accompany the piloting activities will be shared with the selected developers/manufacturers participating in the pilot.

6 Application

The EDiHTA open validation pilot welcomes interested DHT developer/manufacturer teams with diverse backgrounds, including technical/scientific, clinical, product design/development and business.

DHT developers/manufacturers interested to participate in the pilot must submit their applications via the short application form by **20 March 2026 at 16:00 CEST**: **APPLICATION FORM** (Google Forms).

Only applications submitted directly via the Google Forms link will be accepted. A copy of the application form is available on the EDiHTA website for download in an offline version (PDF document) for applicants to be able to review questions and prepare draft responses. Applicants should always transfer the final responses to the Google Form for submission.

7 Eligibility criteria

The pilot invites expressions of interest from DHT developers/manufacturers meeting the following criteria:

- Micro, small- or medium-sized enterprises (SMEs; according to the EU definition[3]) and larger companies developing digital health technologies.
- The companies must be established in one of the EU Member States (MS) including their outermost regions, the Overseas Countries and Territories linked to the Member States or in countries associated to Horizon Europe.[4]
- The technology must be currently implemented in EU Member States (MS) including their outermost regions, the Overseas Countries and Territories linked to the Member States or in countries associated to Horizon Europe.
- For DHTs that are classified as medical devices under the MDR, the technology must be CE marked.
- Technologies in-scope of the pilot include telemedicine, mobile apps, AI-driven tools (as per DHTs definition under the 'Definitions' section of this document).
- The following solution types are excluded from the scope of this pilot:
    - purely hardware solutions without a digital component;
    - robotics solutions.
- Teams must be available and willing to collaborate with HTA agencies and the EDiHTA consortium, and provide documentation, evidence and feedback.
- Applications must be in English.
- Applicant companies must submit their applications via the above short application form before the deadline on **20 March 2026 at 16:00 CEST**. Applications after the deadline will not be considered.

Each application will be reviewed against these eligibility criteria by the EDiHTA Selection Committee.

8 Selection criteria

For eligible applications, the selection criteria for selection into the EDiHTA open validation pilot are:

(I) Company relevance and fit
(II) Technology relevance and fit.
(III) Feasibility of pilot implementation

The table below provides further detail on the selection criteria applied to assess pilot fit.

Selection criteria & description	Maximum score
(I) Company relevance and fit Extent to which the company profile fits with the pilot ambitions detailed in the call, including alignment with the call use cases.	20

[3] European Commission: SME definition. Available from: https://single-market-economy.ec.europa.eu/smes/sme-fundamentals/sme-definition_en

[4] List of Participating Countries in Horizon Europe: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

(II) Technology relevance and fit Extent to which the DHT fits with the objectives of the pilot; extent of complementary and diversity of use cases in the pilot DHT portfolio; availability of data and evidence for HTA.	35
(III) Feasibility of pilot implementation Appropriate profiles within the applicant team to fulfil pilot objectives; motivation, readiness and appropriateness of the team to participate in piloting activities; previous relevant projects; willingness to share data and evidence for HTA purposes with the EDiHTA consortium under controlled, confidential boundaries.	45
Total maximum	**100**

Applications will be assessed independently by 5 evaluators on the EDiHTA Selection Committee. Applications will be ranked based on their final score to inform the final selection.

9 Selection process

Use case selection will follow a stepwise approach. The EDiHTA coordinator will appoint a Selection Committee consisting of experts from the EDiHTA consortium, including HTA agencies, academic partners, pilot coordination partners and members of the EDiHTA Independent Advisory Board. After the application deadline, the submitted applications will be reviewed against the eligibility criteria set by the EDiHTA consortium. Once this phase is completed, applications passing the eligibility checks may be contacted to respond to some additional questions regarding the specifics of the technology and the piloting through a survey or an interview step (depending on the volume of applications received). The Selection Committee will apply the selection criteria to ascertain pilot fit. The highest ranked use cases will be invited for a final interview to discuss in-depth the participation in the EDiHTA pilot. Final shortlisted applications will be confirmed by a consensus of the Selection Committee, and will be invited to partake in the pilot.

The eligibility check and evaluation of pilot fit (including the interview) will follow the criteria outlined in the preceding sections of this document.

10 Pilot admission

The final admission decisions will be made by combining the outcome of the pilot fit assessment and, if applicable, the online interview. Applicants will be notified of their admission status via e-mail following the interview stage. Participants invited to enrol in the pilot will receive detailed information about the next steps in relation to preparing for the pilot. This includes information on pilot admission, including meeting the consortium and securing sign-off on the relevant administrative documentation to support the piloting process (including the necessary participant agreements, non-disclosure and confidentiality agreements, or ethical agreements, where applicable).

11 Commitment anticipated from pilot participants

Selected pilot participants will be expected to:

(I) Provide all required documentation and evidence to the assigned HTA agencies and the EDiHTA consortium within agreed timelines.
(II) Provide structured feedback on undergoing an HTA process using EDiHTA, testing and validating the i) EDiHTA framework and ii) the relevant EDiHTA toolkit.
(III) Join virtual workshops or interviews with EDiHTA consortium partners and HTA agencies during the pilot.
(IV) Review the pilot outcomes report and contribute feedback on the framework and toolkit.
(V) Participate in feedback sessions to support improvement of the framework and toolkit.
(VI) Participants participating in the piloting activities do so on a voluntary basis with own resources and will not receive funding from the EDiHTA consortium.

12 Conflicts of interest (selection process)

The EDiHTA project aims to ensure a high level of methodological fidelity throughout the pilot, allowing for the collection of robust and unbiased insights that can inform and strengthen the new EDiHTA framework and toolkit for evaluating digital health technologies. In parallel, the project seeks to provide participating DHT developers/manufacturers with constructive feedback on HTA expectations and processes. This support will remain strictly advisory and will not influence, pre-empt, or substitute any future regulatory, certification, market access or reimbursement decisions by competent authorities.

The EDiHTA consortium is committed to maintaining the highest standards of confidentiality and managing conflicts of interest throughout the admission process. All application materials and information provided by applicants will be treated as strictly confidential. EDiHTA partners, staff and external evaluators from the EDiHTA Independent Advisory Board participating in the Selection Committee or the piloting activities are required to sign confidentiality agreements, ensuring that sensitive information is not disclosed to unauthorised parties.

To further safeguard the integrity of the selection process, EDiHTA implements rigorous conflict of interest policies. Evaluators and staff involved in the selection process are required to declare any potential conflicts of interest. Any evaluator with a conflict of interest will be recused from assessing the relevant application to ensure an unbiased review. This commitment to confidentiality and conflict of interest management guarantees a fair and transparent selection process, fostering trust and integrity within the pilot.

13 Ethics, Data Protection and Research Integrity

Selected applicants are expected to adhere to applicable ethical standards, data protection requirements, and principles of research integrity as outlined in this Call and relevant EU legislation, including the General Data Protection Regulation (EU) 2016/679 (GDPR) where applicable. Participants shall ensure that all activities are conducted responsibly and in line with good research practice, as well as with the pilot protocol and data management plan that will be made available to the selected pilot participants.

14 Redress procedure

The selection process intends to consider and select applications that fit the closest to the concept and requirements of the pilot. This will help to validate the EDiHTA framework and toolkit through meaningful and synthesised intelligence on the one hand, while on the other

maximising value and benefits for the pilot participants through early access to the framework to build structured HTA insights to strengthen evidence strategy and gain visibility towards European stakeholders.

No redress will be accepted.

15 Further information and contacts

For further information on the EDiHTA project, please visit https://edihta-project.eu/.

For queries on the open pilot, please contact fruzsina.mezei@unicatt.it and adam.lukacs@eithealth.eu.