



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

Open Call for DHT developers piloting the EDiHTA framework

Application deadline: 20th March 2026



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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.

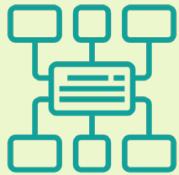
The UK participant is supported by UKRI grant No 10106869 (National Institute for Health and Care Excellence).

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

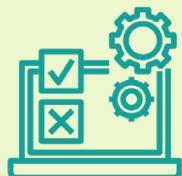
What is EDiHTA and the pilot?



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.**



To test the comprehensiveness of the EDiHTA framework and related supporting tools, the EDiHTA consortium launches an open piloting process engaging developers/manufacturers of digital health technologies (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.

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

Expected timeline for selection of participants



Eligibility critieria for applicants

The EDiHTA open validation pilot welcomes interested Digital Health Technology developers/manufacturers with diverse backgrounds, including technical/scientific, clinical, product design/development and business.

-  **Micro, small- or medium-sized enterprises (SMEs) 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.
-  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 Open Call 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**.

Eligibility criteria for applicants – DHT Use Case 1



Assigned HTA Agency

AQUAS

AQuAS (Agency for Health Quality and Assessment of Catalonia) is renowned for its expertise in healthcare evaluation and its strategic role in the Catalan health system. The **AQuAS framework**, introduced in 2023 addresses the limitations of traditional HTA when applied to DHTs. AQuAS offers expertise and knowledge to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

AQuAS is a key driver behind the EDiHTA project. Their leadership in this pilot ensures established expertise in digital-specific evaluation and alignment with EU-wise harmonisation.

Specific Eligibility Criteria: DHT Use Case 1

CE-marked medical device (under the MDR)

On the market

Implemented in minimum two countries (EU Member States including their outermost regions, the Overseas Countries and Territories linked to the Member States or in countries associated to Horizon Europe)



Assigned HTA Agency

FinCCHTA

FinCCHTA (Finnish Coordinating Center for Health Technology Assessment) is the national body responsible for coordinating health technology assessments across Finland's university hospitals and wellbeing counties.

Through its pioneering **Digi-HTA framework**, FinCCHTA leads the evaluation of digital health technologies (DHTs), including AI, robotics and mobile apps. The Digi-HTA framework provides value by expanding traditional HTA to include digital-specific domains such as cybersecurity, technical stability, and usability, ensuring that tools are safe and functional in a real-world digital ecosystem.

Specific Eligibility Criteria: DHT Use Case 2

Either non-medical device or CE-marked medical device (under the MDR)

On the market

Implemented in Finland (and possibly other countries)

Commitment anticipated from pilot participants

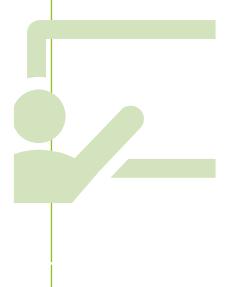
Selected pilot participants will be expected to:

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

Value proposition for applicants & pilot participants



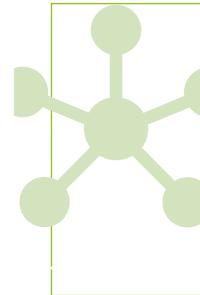
Early access to the EDiHTA platform and tool dedicated to industry



Training for the EDiHTA framework and processes at organisation level (company)



Detailed feedback on evidence gaps, methodological expectations, and potential future HTA requirements based on the EDiHTA framework



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



Dialogues with a full scope of stakeholders, including decision makers, payers, HTA agencies developing the first pan-European HTA framework for DHTs



Chance to contribute to and shape the first pan-European HTA framework for DHTs