EDiHTA

Project No. 101136424

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

Open Pilot Validation

Application Form

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1 Introduction

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 digital health technologies (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 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.

This application form is used to capture information for the EDiHTA Selection Committee to select the use cases that will enter the EDiHTA pilot. By completing this application form, you express your interest to participate in the EDiHTA pilot as a DHT developer/manufacturer (micro, small- and medium size enterprises and larger companies).

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).

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). Final shortlisted applications will be confirmed by a consensus of the EDiHTA Selection Committee, and will be invited to partake in the pilot.

Further information on the pilot, the application process and details of participation are available in the corresponding pilot call documentation on the EDiHTA website.

2 Informed Consent

2.1 By participating in this application, you consent to the following:

- I agree to take part in this application.
- I understand that participation is voluntary and that I may withdraw my application.
- I agree that my name and email address is collected to manage coordination of the pilot application, selection and pilot implementation activities, and to enable the EDiHTA project to communicate with me.
- I acknowledge that the application form collects information related to my company and technology, and I consent to the processing of this information by the project consortium for the purposes of selection, participation, and analysis within the EDiHTA pilot under confidential conditions.

☐ I do not consent
☐ I consent

2.2 Please provide your first name *(free text)*

Text

2.3 Please provide your last name *(free text)*

Text

2.4 Please provide your e-mail address (free text)

Text

3 Company relevance and fit

3.1 Company name

Text

3.2 Year founded

Text

3.3 Registration country

Text

3.4 Please indicate the type of developer you represent:

- ☐ Start-up*
- ☐ SME
- ☐ Large enterprise

** A start-up is defined as a for-profit SME according to the EU definition – an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro.*

3.5 Number of employees *(single choice)*

[] 1-9

[] 10-49

[] 50-249

[] 250 and above

3.6 Website of the company

Text

3.7 Does your company have an HTA unit or an in-house HTA expert?

[] In-house HTA unit

[] In-house HTA expert

[] None

3.8 If you responded yes (you have an HTA unit or in-house HTA expertise), how many people in your company are competent in HTA or have prepared HTA and market access dossiers?

Text

4 Technology relevance

4.1 Name of the digital health technology

Text

4.2 Please provide a short description of the technology (outline the concept of the digital health technology, including indicating its typology – e.g. telemedicine, mobile app, AI-driven tool) *(max 150 words)*

Text

4.3 Is your technology categorised as a medical device under the MDR? *(single selection)*

- ☐ Yes
- ☐ No
- ☐ Unclear

4.4 If yes, what risk is the risk classification under the MDR? *(single selection)*

- ☐ Class I (Low Risk)
- ☐ Class IIa (Medium Risk)
- ☐ Class IIb (Medium-High Risk)
- ☐ Class III (High Risk)
- ☐ Not applicable

4.5 CE marking status *(single selection)*

- ☐ CE-marked
- ☐ Not yet CE-marked

4.6 In which countries(s) in Europe is your technology available on the market and implemented? Please list all applicable countries where your technology is already implemented.

Text

4.7 How long has your technology been on the market (e.g. number of months or years)?

Text

4.8 Please indicate the therapeutic area of interest. (Please write 'not applicable' if non-applicable for your technology). (*max. 150 words*)

Text

4.9 Please briefly describe the real-world use of your technology in terms of use in real settings (in which setting, and for how long), and end users (who, and how many). *(max. 250 words)*

Text

4.10 Has your technology already undergone an HTA assessment? If so, in which countrie(s)? What was the comparator? Has market access dossier been developed based on the HTA assessment? (*max 250 words*)

Text

5 Technology fit for EDiHTA pilot

To complete this section, please kindly visit and consult information on the EDiHTA framework, available on the Media Corner page in the form of the poster on the EDiHTA website.

5.1 Which option below best describes the intended purpose of the DHT? *(multiple selection)*

☐1. DHT with no direct patient, health or care outcome intended to save cost or release staff time.

☐2. DHTs intended to help citizens and patients to manage their own health and wellness.

☐3. DHTs intended to provide general information and provide health professional training material or tools.

☐4. DHTs with direct health outcomes intended to treat or diagnose a specific condition or guide treatment, diagnosis and care choices.

5.2 If applicable: If you feel your technology addresses multiple intended purposes as described above, please outline here.

Text

5.3 What is the AI capability of your DHT based on the descriptions below? *(single selection)*

Supplementary note: AI capabilities are determined by (i) human intervention, and (ii) personalisation. Levels of human intervention, decision making and execution of action are described as guiding points to help select the relevant AI capability for your DHT.

☐ No AI capability

☐ Non-autonomous – Requires human involvement in decision-making and execution. (Human intervention: Full human control | Decision making: No AI decision | Execution of action: Manual execution by human) (*Example: An AI-powered medical transcription tool that converts speech to text*).

☐ Partially autonomous – Assists in decision-making but requires final human validation. (Human intervention: Human validation required | Decision making: AI suggests actions | Execution of action: Human must approve actions) (*Example: Clinical decision support system suggests but does not act*)

☐ Completely autonomous – Operates without human intervention, executing therapeutic, screening on diagnostic functions independently.
(Human intervention: No human intervention needed | Decision making: AI makes decisions |

Execution of action: AI executes actions independently) (*Example: AI-driven insulin pump adjusts dosage automatically*)

5.4 What are the possible end users of your DHT? *(multiple selection)*

☐Public (citizens, non-patients)

☐Patient and care givers

☐Healthcare professionals (clinicians, nurses)

☐Health system managers

☐ Other (specify)

5.5 In which of the following domains do you have evidence available for HTA? What kind of study does this evidence derive from? (*multiple selection*)

	Randomised controlled trial (RCT)	Clinical trial (non-randomised but with control group)	Observational studies – retrospective cohort	Observational studies – prospective cohort	Observational studies – case-control	Observational studies – transversal study	Observational studies – clinical series	Observational studies – surveys	Meta-analysis	Other	No evidence available
Health problem and current management	O	O	O	O	O	O	O	O	O	O	O
Description of the technology	O	O	O	O	O	O	O	O	O	O	O
Digital aspects	O	O	O	O	O	O	O	O	O	O	O
Safety	O	O	O	O	O	O	O	O	O	O	O
Clinical efficacy and effectiveness	O	O	O	O	O	O	O	O	O	O	O
Economic aspects	O	O	O	O	O	O	O	O	O	O	O
Organisational aspects	O	O	O	O	O	O	O	O	O	O	O
Ethical aspects	O	O	O	O	O	O	O	O	O	O	O
Patient-related aspects	O	O	O	O	O	O	O	O	O	O	O
Sociocultural aspects	O	O	O	O	O	O	O	O	O	O	O
Environmental aspects	O	O	O	O	O	O	O	O	O	O	O
Legal and regulat	O	O	O	O	O	O	O	O	O	O	O

ory aspects											
Post deployment monitoring aspects	o	o	o	o	o	o	o	o	o	o	o

5.6 Has any evidence supporting the use of your technology as outlined above been published in peer reviewed scientific publications? If so, please provide the most relevant references (DOI, first author). (max. 500 words)

Text

6 Feasibility of pilot implementation

6.1 Have you participated in or executed any similar relevant project(s) in the last 5 years demonstrating that your company can work in a similar pilot condition? Please provide the name of the project(s) and the purpose of those pilots, as well as any related publications. *(max. 250 words)*

Text

6.2 Please briefly describe the commitment you foresee in participating in the pilot, including how the staff involved will ensure the expected activities and outputs are produced. Please explain the resources (number of staff, expected effort in total days per staff member) you can commit to ensure the expected activities and outputs can be produced, considering the collaborative nature of the work expected with the matched EDiHTA HTA agency, EDiHTA academic partners, the EDiHTA pilot coordination team and other relevant stakeholders. *(max. 500 words)*

Text

6.3 What profiles in your team would be available and ready to participate in piloting activities? (*multiple selection*)

- ☐ Executive, management team
- ☐ Engineer
- ☐ Technical, developers
- ☐ Regulatory affairs
- ☐ Market access
- ☐ Health care professional, medical practitioner
- ☐ Others

6.4 (Optional) Please include any additional comments to support your interest in participating in the pilot. *(max 250 words)*

Text

7 Declarations

7.1 The applicant declares that it is in compliance with the scope of the pilot and the profile of the technologies outlined in the EDiHTA open pilot Call.

[] Yes

[] No

7.2 The applicant as a legal person discloses that a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers company directors, members of management or supervisory bodies, and cases where one natural person holds a majority of shares) is involved in any current or potential conflict of interest, as indicated in the Call, due to its participation in the Call procedure or for other reasons.

☐ I disclose no conflict of interest

☐ I disclose a conflict of interest

7.3 I understand and confirm that all IP relating to my technology will be retained by my company; the EDiHTA consortium makes no claim to my IP.

☐ I understand and confirm

7.4 In case of selection, the applicant agrees to comply with the rules regarding ethics, data protection and research integrity set out in the Call.

[] Yes

[] No

7.5 I declare that my company is available to undergo the relevant process for the selection of the pilot use cases, including where needed follow-up questions or interviews with the EDiHTA Evaluation Committee composed of the EDiHTA consortium and independent experts.

☐ Yes

☐ No

7.6 I declare that my company and all relevant team members will be available to participate actively in piloting activities (e.g. evidence dossier preparation, interviews, workshops, online meetings, data gathering) in the anticipated piloting period between Jul 2026 and Apr 2027.

☐ Yes
☐ No

7.7 I confirm that I have read and understood the information about the EDiHTA project open validation pilot as described in this application form and in the corresponding open pilot call document.

☐ Yes
☐ No