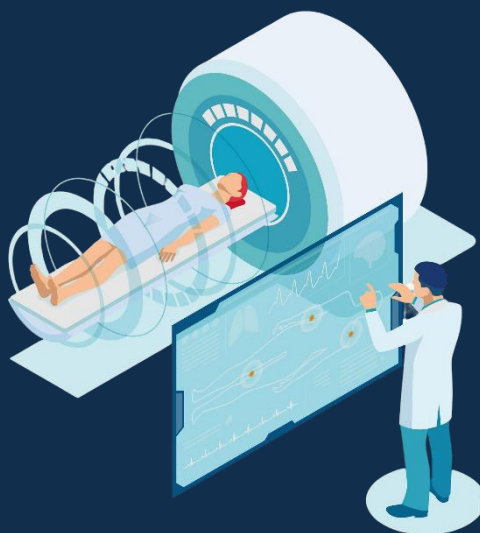




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for assessing digital health technologies in Europe
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Call for Artificial Intelligence-based technology used in radiology



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1 Introduction and purpose of the call

1.1 The ASSESS DHT project

ASSESS DHT is a European project running from January 2024 to December 2026 that aims to boost the adoption of reliable digital health technologies (DHTs) across Europe, contributing towards a unified digital single market for healthcare systems and patients to access DHTs and establishing a strong European market. The project is in the process of developing a novel assessment framework, surpassing existing models, to ensure consistent Health Technology Assessment (HTA) adoption throughout Europe and addressing emerging challenges in areas such as Digital Therapeutics, Artificial Intelligence, and telehealth.

ASSESS DHT is implemented by a consortium comprising 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, Member State, and regional level.

More information about the project can be found at www.assess-dht.eu.

1.2 The ASSESS DHT assessment framework

The project has developed an overarching framework of criteria and guidance for the evaluation of DHTs that could be applied to a variety of technologies, incl. mHealth, AI-based health technologies and telehealth, and covering all stages of their lifecycle. The framework is operationalised in the form of an assessment manual with associated multi-stakeholder toolkits aimed at guiding the generation and evaluation of evidence, including – but not limited to:

- Guidance to demonstrate and evaluate how DHTs adhere to data quality, data protection and safety, and cybersecurity standards
- A tool to support technology developers in early optimisation of their evidence generation plans
- Methods for the economic evaluation of DHTs
- Technical components of DHTs, including their functions, design and technical characteristics, that ought to inform assessments
- Validation of AI-based decision support systems

1.3 Relevance of AI-based technologies in radiology

As a next step, the assessment framework is to be tested using real-life DHTs, by simulating elements of a health technology assessment (HTA) process. For this, the project has several partner organisations which have their own DHT products in the fields of:

- telemedicine
- digital health application platform (connection with medical devices, integration of health data, and analysis using AI for clinical decision support)
- AI-driven algorithm in support of remote management of patients with heart failure

With these three DHT available for testing, a good range of case studies can be carried out to test the assessment framework.

In addition, the **project has identified the radiology domain as an interesting case study to be included**. Radiology is one of the most advanced fields in AI adoption within healthcare. AI-driven tools in radiology are already being used for image analysis, anomaly detection, and decision support, making it a prime example for testing the ASSESS DHT framework against real-world challenges.

Radiology AI systems generate vast amounts of data and require rigorous validation to ensure diagnostic accuracy, reliability, and safety. This aligns well with the project's focus on developing robust assessment methodologies, particularly for lifecycle evidence generation, regulatory compliance (AI Act, MDR), and health economic evaluation. Moreover, radiology AI often interacts with existing clinical workflows, making it an excellent test case for assessing interoperability, usability, and human factors. By studying AI in radiology, the project can refine its framework to better address the complexities of AI-driven healthcare technologies across different domains.

1.4 Profile of expected DHTs under the call

ASSESS DHT aims at including one DHT in the piloting of the assessment framework, which should address as many of the characteristics below as possible:

- The applicant should be in full control of the DHT in terms of its IPR, (further) development, maintenance, application in real-life health settings, licensing and marketing
- The DHT should clearly demonstrate its core function is in the area of AI-driven radiology
- The DHT should have CE marking (preferably under MDR) or be in an advanced stage of regulatory approval.
- The DHT should be at least in pilot use or deployed in clinical settings.
- The system must integrate with existing radiology workflows (e.g., PACS, RIS, EHRs)

1.5 Expected activities and outputs

The main activities expected to be undertaken by the selected DHT developer include:

- **Attendance of online meetings:** Kick-off meeting, several progress meeting, final meeting. Meetings are typically attended by the HTA agency in charge of the use case from the ASSESS DHT side and representatives of further project partner organisations, such as the co-ordinator, the scientific coordinators, the developers of the assessment manual, patient representatives, clinical experts on the indication at hand, etc.
- **Following of the manual and overall planned process:** the DHT developer will be provided with relevant materials being produced by the ASSESS DHT consortium that will need to be studied, such as the ASSESS DHT manual, the overall process and timelines to pilot it, etc. The DHT developer is also expected to provide feedback on **those**, and other support materials as part of progress meetings, and in writing as part of the final meeting and report.
- **Close collaboration with the HTA body:** a mix of offline (email-based) and online (virtual meetings) communication with the HTA bodies leading the pilots in order to clarify open issues, track progress, etc.
- **Preparation of an evidence dossier** – under the guidance of the HTA body leading this case study, this includes evidence (real or synthetic) informing the different domains listed under the ASSESS DHT manual, and feedback on how usable the manual and its accompanying tools are to support manufacturers in the production of the types of evidence requested.
- (possibly) facilitating access to one clinician familiar with the DHT, and one patient or patient representative for a short interview or written answers of a short questionnaire in English

The DHT developer should actively engage in the assessment process, providing necessary data and documentation.

The main outputs / deliverables to document work include:

- **Inception report:** an updated version of the submitted application, providing further details on the DHT and available data
- **Interim report:** a brief summary of main activities (meetings, evidence collection, etc.) the contractor has carried out

- **Final report:** an explanation of the work carried out, the feedback the DHT developer provided to the HTA body and the wider ASSESS DHT consortium, documenting lessons learned and recommendations regarding the process and the manual, summary of the outcomes for publication purposes

It should be noted that the work will focus on testing the overall framework, manual and defined processes in order to improve it in view of offering a comprehensive framework in the EU. The results of these tests will not result in an official HTA approval/endorsement.

1.6 Funding Budget

The total budget that will be awarded to one successful applicant is €86,000.

One contract will be awarded to the selected applicant with the highest ranked application.

The funding for the contract is made available through the ASSESS DHT project. While the budget is provided through the EU via the Horizon Europe programme, the EU is not part of the award process.

1.7 Call timeline

Date	Activity
27.03.2025	Publication of the call on the ASSESS DHT project website
27.04.2025	Deadline for questions by applicants
27.05.2025 17:00 CET	Deadline for submissions by applicants
28.05-04.06.2025	Evaluation period and notification of applicants about the outcome
June 2025	Contracting of the selected applicant
August – September 2025	Expected earliest possible start of activities
August 2026	Latest end of all activities

Note: The ASSESS DHT project is expected to end in December 2026. The successful applicant may be invited to different project-related events and opportunities, depending on their interest and availability.

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

Questions about the call can be submitted in English to assess-dht-applications@empirica.com within the deadlines specified in the timeline. The summary of all questions and answers posed will be presented in an anonymised question and answer (Q&A) document that will be published on the project website.

Unless otherwise instructed, do not use any other contact email address or contact any other persons in connection with this call.

2 Information for applicants

The focus of the call is on organisations which own and operate in real conditions on EU territory a DHT that addresses the profile provided in section 1.4.

Participation in the tendering procedure is open on equal terms to all types of operators from any country, regardless of their geographic location, size or governance structure. As per the profile described in section 1.4, the operators must be owners of a DHT that is being used in real healthcare settings in one or more EU countries.

2.1 Contractual conditions

An application must be submitted by a single entity. If successful, the applicant will be offered a Contract by the ASSESS DHT co-ordinator¹ for the implementation of for other “goods, works and services”, as defined within the Horizon Europe Programme, under which ASSESS DHT receives funding.

Interested parties are required to submit applications electronically no later than the dates specified in the call timeline. They should take full account of the call document and application template which must be downloaded from the project website (<https://assess-dht.eu/call-radiology>).

Only the filled in application template needs to be submitted as part of the application.

An email must be sent to assess-dht-applications@empirica.com by the deadline specified in the time schedule. The email must contain one searchable PDF attachment, clearly named (e.g. ASSESS DHT_RadiologyDHT_NameOfOrganisation.pdf)

Any questions about the call document and call process must be sent to assess-dht-applications@empirica.com before the deadline set in the call timeline.

Offers that do not comply with the formal requirements described in this section will be rejected.

2.2 Other application conditions

Confidentiality

Applicants must keep confidential any information obtained in the context of the application procedure (including EU-classified information²).

Language

Applications, as well as outcomes in the form of deliverables, must be submitted in English.

The working language is English and the Contract must be signed in its English version.

Communication (relating to either the application procedure or the implementation of the Contract) must be carried out in English.

With the submission of their applications, applicants accept these requirements.

¹ The ASSESS DHT co-ordinator is empirica Gesellschaft für Kommunikations- und Technologieforschung mbH

² Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information

Cancellation of the application procedure

The ASSESS DHT co-ordinator may, at any moment, cease to proceed with the application procedure and cancel it. The ASSESS DHT co-ordinator reserves the right not to award any contracts at the end of the application procedure. The ASSESS DHT co-ordinator is not liable for any expense or loss the applicants may have incurred in preparing their application.

2.3 Evaluation and award

Exclusion, selection and compliance criteria

All applicants need to fulfil the criteria described in this section. The mechanism for providing for fulfilment is built into the application template and its section “ADMINISTRATIVE INFORMATION”. An overview is provided in the table below. Detailed information for each criterion is provided in Annex I.

Criteria type	Definition	Evidence
Exclusion	A) Conflict of interest	Application Template Section “ADMINISTRATIVE INFORMATION”
	B) Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014	
Selection	C) Ability to perform the expected activities	
Compliance	D) Compatibility with other public financing	
	E) Compliance with ethics and security requirements	

Award criteria

Award criteria	Maximum points	Threshold
Relevance and fit Includes aspects such as the extent to which the proposed DHT fits with the profile defined in the call, alignment with AI in radiology use cases (e.g., image analysis, decision support, anomaly detection), and potential impact on clinical workflows and radiology practice.	50	25
Maturity and technical performance Includes aspects such as demonstrated accuracy, sensitivity, specificity, and robustness in real-world radiology settings, availability of performance validation studies (e.g., peer-reviewed publications, clinical trials), and well elaborated AI interpretability and transparency of decision-making processes.	30	15
Feasibility of the contract implementation Includes aspects such as appropriateness of the team members to be involved over the duration of the DHT evaluation.	20	10
Total maximum	100	60

The award criteria scoring is based on the information provided by the applicants in the Application Template Section “TECHNICAL INFORMATION”.

A five-point system is defined as:

0. *Insufficient* (fails to address the criterion under examination or the criterion cannot be judged due to missing or incomplete information).

1. *Poor* (the criterion is addressed in an inadequate manner, or there are serious inherent weaknesses or gaps in expected information).
2. *Fair* (while the criterion is broadly addressed, there are some weaknesses to it or gaps in expected information).
3. *Good* (the criterion is addressed well, although improvements or further information would have been highly desirable).
4. *Very good* (the criterion is addressed well, although certain improvements or additional information are still possible).
5. *Excellent* (all relevant aspects of the criterion are successfully addressed; any shortcomings are minor).

Evaluation process

The ASSESS DHT co-ordinator will appoint an Expert Evaluation Committee (EEC) consisting of experts from the ASSESS DHT consortium.

Members of the EEC are appointed in their personal capacity. After application deadline, the ASSESS DHT coordinator will provide the EEC members with access to the submitted applications. In case of a conflict of interest identified by an EEC member, he/she will immediately notify the ASSESS DHT coordinator and will withhold from providing an evaluation for that particular application.

The EEC will first read and check the administrative section. The EEC may request clarifications about the applications or additional evidence if needed, in which case the applicant concerned will be notified by the ASSESS DHT co-ordinator by email. The applicant will have five calendar days (from the day of receipt of the notification) to send the clarifications and / or evidence requested. After this deadline, if no response is received from the applicant, the application will be rejected and will be excluded from the evaluation. The applicant will be informed by the ASSESS DHT co-ordinator by email.

The EEC will carry out the selection of twinning offers, apply the exclusion, compliance and selection criteria. Only offers that satisfy the criteria provided, that are not excluded on the basis of the exclusion criteria, and that meet the selection criteria, are admissible for evaluation under the award (quality) criteria.

The EEC will then score the applications based on the award criteria. Each EEC member provides a score for each award criterion. A final joint decision is reached by a simple majority vote in a dedicated EEC meeting chaired by the ASSESS DHT coordinator. Applications must score above the thresholds given, for each threshold. Applications that do not reach the minimum quality thresholds (individual and totals) will be rejected.

The highest ranked application will be awarded and offered a contract.

The applicants will receive a written report via email on the result of the evaluation, including the scoring and their rank.

Annex I: Details pertaining to the exclusion, selection and compliance criteria

- A) Conflict of interest: An applicant who is subject to a conflict of interest may be excluded. If there is a potential conflict of interest, an applicant must immediately notify the ASSESS DHT co-ordinator in writing. A conflict of interest is any situation where the impartial and objective implementation of the evaluation of applications and/or implementation of the subsequent Contract is compromised for reasons relating to economic interests, political or national affinity, family, personal life (e.g. family of emotional ties) or any other shared interest. If an actual or potential conflict of interest arises at a later stage (i.e. during the implementation of the Contract), the contractor must contact the ASSESS DHT co-ordinator, who will notify the EC and take steps to rectify the situation. The EC may verify the measures taken and require additional information to be provided and/or further measures to be taken.
- B) Exclusion grounds as defined in Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014: An applicant will be excluded if it has been the subject of a conviction by final judgement for one of the following reasons:
 - Grounds relating to criminal convictions
 - Participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;
 - Corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union and Article 2 of Council Framework Decision 2003/568/JHA (34), as well as corruption as defined in the national law of the ASSESS DHT co-ordinator or the economic operator;
 - Fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests;
 - Terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of the aforesaid Framework Decision;
 - Money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
 - Child labour and other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council.

The obligation to exclude an applicant shall also apply where the person convicted by final judgement is a member of the administrative, management or supervisory body of that application or has powers of representation, decision or control therein.

- Grounds relating to the payment of taxes or social security contributions
 - An applicant shall be excluded from participation in where the ASSESS DHT co-ordinator is aware that the applicant is in breach of its obligations relating to the payment of taxes or social security contributions, and where this has been established by a judicial or administrative decision having final and binding effect in accordance with the legal provisions of the country in which it is established or with those of the country of the ASSESS DHT co-ordinator.
 - Furthermore, the ASSESS DHT co-ordinator may exclude from participation an applicant where the ASSESS DHT co-ordinator can demonstrate by any appropriate means that the applicant is in breach of its obligations relating to the payment of taxes or social security contributions.

- This paragraph shall no longer apply when the applicant has fulfilled its obligations by paying or entering into a binding arrangement with a view to paying the taxes or social security contributions due, including, where applicable, any interest accrued or fines.
- Grounds of insolvency or professional misconduct
 - The ASSESS DHT co-ordinator may exclude an applicant in any of the following situations:
 - Where the applicant is bankrupt or is the subject of insolvency or winding-up proceedings, where its assets are being administered by a liquidator or by the court, where it is in an arrangement with creditors, where its business activities are suspended or it is in any analogous situation arising from a similar procedure under national laws and regulations;
 - Where the ASSESS DHT co-ordinator can demonstrate by appropriate means that the applicant is guilty of grave professional misconduct, which renders its integrity questionable;
 - Where the ASSESS DHT co-ordinator has sufficiently plausible indications to conclude that the applicant has entered into agreements with other economic operators with the intention of distorting competition;
 - Where a conflict of interest cannot be effectively remedied by other less intrusive measures;
 - Where a distortion of competition from the prior involvement of the applicant in the preparation of this twinning procedure cannot be remedied by other, less intrusive measures;
 - Where the applicant has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity or a prior concession contract which led to early termination of that prior contract, damages or other comparable sanctions;
 - Where the applicant has been guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the selection criteria.
 - Where the applicant has undertaken to unduly influence the decision-making process of the ASSESS DHT co-ordinator, to obtain confidential information that may confer upon it undue advantages in the procurement procedure, or to negligently provide misleading information that may have a material influence on decisions concerning exclusion, selection or award.
- C) Ability to perform the expected activities
 - This criterion is evaluated on a pass/fail basis. “Fail” means that the evidence given does not provide sufficient indication of the applicant’s expertise, ability and/or equipment to fulfil the expected activities and outputs. Any application that cannot meet the selection criteria requirements will not be selected.
 - To measure this criterion, applicants are asked to provide the following information (as part of the application template):
 - Brief description of relevant references and / or previous projects demonstrating that the applicant can work in similar conditions
 - Demonstrate the expertise and working experience required to carry out the activities by providing short curriculum vitae (CVs) of key personnel and competences necessary to complete the activities
- D) Applicants that receive public funding from other sources will be excluded if this leads to double public financing of the same activities at the time of the contract implementation, or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules.
- E) Compliance with ethics and security requirements
 - Applications will be excluded if they:

- Do not comply with ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity , and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
- Include plans to carry out activities that are prohibited in all EU Member States.
- If the application involves activities that raise ethical concerns, the applicant must submit an ethics self-assessment that:
 - Describes how the application meets the legal and ethical requirements of the Member State(s) where the tasks raising ethical issues are to be carried out
 - Explains in detail how the applicant intends to address the ethical issues identified, in particular as regards:
 - Objectives (e.g. dealing with vulnerable populations and dual-use goods)
 - Methodology (e.g. involvement of children and related consent procedure and protection of data collected)
 - The potential impact (e.g. issues relating to the dual use of goods, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing and malevolent use of results).
- For information on ethics issues, see the guidance for EU grant beneficiaries [How to complete your ethics self-assessment](#).
- For information on ethics issues, see the guidance for EU grant beneficiaries [How to complete your ethics self-assessment](#).