Project acronym: ASSESS DHT

Grant Agreement Number: 101137347

Project full title: Development and harmonisation of methodologies

for assessing digital health technologies in Europe

Website: www.assess-dht.eu

**Application Form**

**[Short name of applicant]**

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# ADMINISTRATIVE INFORMATION

*There is no page limit for the information presented in section 1.*

*Do not delete or change the level 1 and level 2 headings.*

*Delete all instructions (given in cursive blue throughout this document and in the boxes).*

## Call participant

* Name of the organisation[[1]](#footnote-2): *provide text here*
* Acronym: *provide text here*
* Country (headquarters): *provide text here*

## Confirmation of legal status for the participants

*Paste a screenshot of a filled in and signed legal entity form of the applicant organisation, such as* [*https://ec.europa.eu/info/publications/legal-entities\_en*](https://ec.europa.eu/info/publications/legal-entities_en)

*Do not include hyperlinks to external documents, use a screenshot to be added directly in the application.*

## Declarations

### Declaration of Honour on Exclusion Criteria

*Fill in the following declaration*

The undersigned *[insert name of the signatory of this form]*, representing:

|  |  |  |
| --- | --- | --- |
| **(only for natural persons) himself or herself:** | **(only for legal persons)  the following legal person:** | |
| ID or passport number:  *[insert ID/passport number]*  (‘the person’) | Full official name: | *[insert text]* |
| Official legal form: | *[insert text]* |
| Statutory registration number: | *[insert text]* |
| Full official address: | *[insert text]* |
| VAT registration number: | *[insert text]* |
| (‘the person’) | |

#### Exclusion grounds relating to the conflict of interest

|  |  |  |  |
| --- | --- | --- | --- |
| (1) | declares 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): | Yes | No |
|  | is involved in any current or potential conflict of interest, as indicated in the Call for Twinnings, due to its participation in the procurement procedure or for other reasons. |  |  |

#### Situation of exclusion concerning the person

|  |  |  |  |
| --- | --- | --- | --- |
| (2) | declares that the above-mentioned person is in one of the following situations: | Yes | No |
| (a) | it is bankrupt, subject to insolvency or winding up proceedings, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations; |  |  |
| (b) | it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract; |  |  |
| (c) | it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following: |  |  |
|  | (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract; |  |  |
|  | (ii) entering into agreement with other persons with the aim of distorting competition; |  |  |
|  | (iii) violating intellectual property rights; |  |  |
|  | (iv) attempting to influence the decision-making process of the contracting authority during the award procedure; |  |  |
|  | (v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure; |  |  |
| (d) | it has been established by a final judgement that the person is guilty of the following: |  |  |
|  | (i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995; |  |  |
|  | (ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract; |  |  |
|  | (iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA; |  |  |
|  | (iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council; |  |  |
|  | (v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision; |  |  |
|  | (vi) child labour or 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; |  |  |
| (e) | the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union’s budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors; |  |  |
| (f) | it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95; |  |  |
| (g) | for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to:  i. facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;  ii. non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;  iii. decisions of the ECB, the EIB, the European Investment Fund or international organisations;  iv. decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or  v. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body. |  |  |

#### Situations of exclusion concerning natural persons with power of representation, decision-making or control over the legal person

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (3) | declares 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 in one of the following situations: | Yes | No | N/A |
| Situation (c) above (grave professional misconduct) |  |  |  |
| Situation (d) above (fraud, corruption or other criminal offence) |  |  |  |
| Situation (e) above (significant deficiencies in performance of a contract ) |  |  |  |
| Situation (f) above (irregularity) |  |  |  |

#### Situations of exclusion concerning natural or legal persons assuming unlimited liability for the debts of the legal person

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (4) | declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations: | Yes | No | N/A |
| Situation (a) above (bankruptcy) |  |  |  |
| Situation (b) above (breach in payment of taxes or social security contributions) |  |  |  |

#### Grounds for rejection from this procedure

|  |  |  |  |
| --- | --- | --- | --- |
| (5) | declares that the above-mentioned person: | Yes | No |
| (h) | has distorted competition by being previously involved in the preparation of procurement documents for this procurement procedure. |  |  |

#### Remedial measures

If the person declares one of the situations of exclusion listed above, it must indicate measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

If not needed, write “N/A”.

### Declaration of Honour on Compliance Criteria

*Fill in the following declaration (if you decide to do it in a separate document, including a screenshot of that document here (each page) will be sufficient).*

I, the undersigned

*[insert name and surname of the signatory of this form]*

As an individual (or position within the legal entity)

Of the following legal entity (hereafter the 'Applicant') (name of legal entity)

With registered office in

*[insert Street name]*

*[insert post code]*

*[insert city]*

Telephone: *[insert]*

Fax: *[insert or write N/A]*

E-mail: *[insert]*

VAT reg. no. CIF nº : *[insert]*

HEREBY STATE AND DECLARE

under my own personal responsibility, fully aware of the infringements and penalties provided for in law in case of fraudulent statements,

THAT

#### Compliance with the scope of the twinning call

|  |  |  |  |
| --- | --- | --- | --- |
| (1) | The applicant is in compliance with the scope and profile of the DHT requested via the Call. | Yes | No |
|  |  |  |  |

#### Compatibility with other public financing

|  |  |  |  |
| --- | --- | --- | --- |
| (2) | If the applicant receives any other public funding in areas related to the scope of the proposed DHT assessment activities, the funding is all permitted by EU state aid rules. | Yes | No |
|  |  |  |  |

#### Compliance with ethics and security requirements

|  |  |  |  |
| --- | --- | --- | --- |
| (3) | In case of selection, the applicant vouches that they will comply with the rules regarding ethics, data protection and research integrity set out in the Call. | Yes | No |
|  |  |  |  |

In witness whereof I sign this affidavit.

*[insert date and place]*

[DATE AND PLACE]

......................................... [*[insert organisation name]*

Signature(s)

Name(s)

Title(s)

## Compliance with the selection criterion

*Provide the required evidence of your compliance with selection criterion “Ability to perform the expected activities”. This may include:*

* *description of relevant reference and /or previous projects (executed during the last 5 years) demonstrating that the applicant can work in similar conditions;*
* *demonstration of the expertise and working experience required to carry out the activities by providing short CVs for key personnel and competences the applicant considers necessary to complete the activities;*

*Applicants may be requested to provide additional information.*

# TECHNICAL INFORMATION

*Please note that section 2 may not exceed* ***5 pages*** *(counting only the pages covering section 2 (from this page up to the page of the last paragraph in section 2.3.2)), using the pre-defined style of this template (i.e., font Calibri Light 11pt (incl. in the boxes), same page margins, header and footer styles, etc.). It is not suggested to use all 5 pages if the applicant is able to convey the requested information in a more concise manner.*

*Do not delete or change the level 1 and level 2 headings.*

*Delete all instructions (given in cursive blue throughout this document section and in the boxes) and use only the blue boxes to provide text.*

*Do not add captions to figures or tables using the Word-native caption functions.*

*The word count per box is only a suggestion to give the applicant a rough estimate of the expected input. It is based on around 3 pages of text, with enough room for graphics, if needed.*

## Relevance and fit of the DHT

|  |
| --- |
| *Describe in detail the digital health technology you have and which you are proposing to put forward for the ‘pilot’ assessment foreseen in ASSESS DHT.*  *Discuss the DHT’s application area(s)/function of your DHT*  *Make sure to explain/substantiate characteristics of your DHT as requested under the Call, section “Profile of expected DHTs under the call”.*  Your text here (estimated word count for this box: 600) |

## Maturity and technical performance of the DHT

|  |
| --- |
| *Detail the DHT maturity, available and planned functionality improvements, evidence of effectiveness, costs and benefits, etc.*  *Discuss the real-world use of your DHT in terms of use in real settings (which, how long), end users (who, how many).*  *Discuss the DHT’s demonstrated accuracy, sensitivity, specificity, and robustness – how are they measured, what evidence exists to date, how was the evidence produced, has any evidence supporting the use of your technology been published in peer reviewed scientific publications (if so, provide the most relevant references please).*  *Discuss the AI component’s interpretability and transparency of decision-making processes.*  Your text here (estimated word count for this box: 600) |

## Feasibility of the contract implementation

|  |
| --- |
| *Describe the commitment you foresee for answering the call.*  *Discuss how the staff put forth (see section 1.4 in this document) will ensure the expected activities and outputs are produced (see the Call section “Expected activities and outputs”).*  *Explain the resources (number of staff, expected effort in total days per staff member) you can commit to ensure the expected activities and outputs (incl. the three deliverables foreseen) can be produced, considering the collaborative nature of the work expected with the HTA body provided by ASSESS DHT.*  *(Optional): Discuss the possibility to 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.*  Your text here (estimated word count for this box: 800) |

1. Legal name, possibly in local language, followed by the English way the organisation is referred to in parentheses [↑](#footnote-ref-2)