# This form should be completed for technologies that meet ALL inclusion criteria for assessment:

1. The digital programme (online or an app) delivers a substantial portion of the therapy but is designed to be used with therapist assistance.
2. The technology must be designed to treat one of the 13 conditions covered by IAPT:
	* depression
	* generalised anxiety disorder
	* social anxiety disorder
	* panic disorder
	* agoraphobia
	* post-traumatic stress disorder
	* health anxiety (hypochondriasis)
	* specific phobia
	* obsessive-compulsive disorder
	* body dysmorphic disorder
	* irritable bowel syndrome
	* chronic fatigue syndrome
	* medically unexplained symptoms not otherwise specified.
3. The content of the treatment should mirror a NICE recommended psychological therapy for the relevant condition (for example in OCD the programme should not just be a generic CBT intervention. It would need to include exposure and response prevention).
4. The digital programme should be designed to support a model of care where the therapist guides the user through the programme and regularly reviews the user’s work, clinical outcomes and risk. To facilitate this process it is expected that the digital programme will have inbuilt mechanisms that:
	1. Support direct two-way communication between the therapist and the service user to facilitate the effective delivery of the intervention.
	2. Enable the regular collection, monitoring and reporting of outcome and risk data to the service user and the therapist supporting the intervention.
	3. Enable the therapist to view the work that the user is doing with the programme in order to provide personalised feedback on progress, and direct the service user to the most relevant content, features and tools of the programme.
5. The technology should be designed to treat adults.
6. The technology should use (or the technology owner should be prepared to add) the outcome measures required by IAPT.
7. The technology must have at least 1 published randomised controlled trial.
8. The technology must be supplied by an organisation committed to keep ownership and responsibility to maintain and update the technology.

**Return your completed form to** **IAPT@NICE.NHS.UK**

**Please read the FAQs which can be accessed from the** [**NICE IAPT webpage**](https://www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/iapt) **when completing this form**

# Your information

The person detailed here will be contacted by a member of the NICE team.

|  |  |
| --- | --- |
| Name |  |
| Role |  |
| E-mail |  |
| Phone number |  | Date |  |
| Name of organisation that currently holds ownership of the technology |  |
| Organisation website link  |  |
|  |  |

# General information

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| What is the name of the digital technology?What is the current version number? |  |
| Who owns the intellectual property rights to this digital technology? | Please give the name and contact details if these differ from the details given above. |
| Please describe the ownership history of this technology. For example, was this technology developed by an academic group and bought/commercialised/spun-out by a commercial organisation? |  |
| Is an evaluation of this product by a UK national organisation planned or in progress? For example:* National Institute for Health Research
* NICE
* Public Health England

If yes, please give details | *Evaluation by another UK national organisation does not stop NICE from considering the product. This information is used to assess when a NICE evaluation could take place, as it would be unhelpful for two UK national organisations to evaluate the technology at the same time*. |
| When was the digital technology made available to the UK health and social care system? Or when you expect it to be made available?  | Enter the date in DD/MM/YYYY format  |
| The product

|  |  |
| --- | --- |
| Please briefly describe the digital technology. | Keep this brief.  |
| How is this digital technology accessed by the user? | For example, through an app to run on smartphones or tablets, through a website, via an SMS messaging based service. |
| Are any developments to this digital technology planned in the next 2 years? | Please describe any planned major changes to the functionality, presentation or format of the digital technology.  |
| In what form(s) does the digital technology deliver therapy? | Examples could include cognitive behavioural therapy, guided self-help, peer-support, counselling; low intensity or high intensity. |
| What NICE guidance relates to the use of this product?  |  |
| Which recommendation(s) in the guidance relate to the use of this product? | Please specify by recommendation number |

The condition or indication

|  |  |
| --- | --- |
| What condition is the digital technology intended to treat?  | Please select from the list: depressiongeneralised anxiety disordersocial anxiety disorderpanic disorderagoraphobiapost-traumatic stress disorderhealth anxiety (hypochondriasis)specific phobiaobsessive-compulsive disorderbody dysmorphic disorderirritable bowel syndromechronic fatigue syndromemedically unexplained symptoms not otherwise specified. |
| Is the digital technology designed to treat adults or children? | Please delete as appropriate:Adults Children Adults and children  |
| Is the technology designed to be delivered as part of a blended model of care? | Please describe in detail how it is intended to be used as part of a blended model of care. What role does the therapist have in facilitating the user’s progress through the programme? Can the technology be used without therapist input or is this integral to its use? |
| Does the technology have the facility for therapist access?  | Yes / No Please describe this facility.  |
| What modality/modalities of therapy is the technology designed to deliver? |

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| --- |
| Guided self-help (book) |[ ]
| Non-guided self-help (book) |[ ]
| Guided self-help (computer) |[ ]
| Non-guided self-help (computer) |[ ]
| Behavioural activation (low intensity) |[ ]
| Structured physical activity |[ ]
| Ante/post-natal counselling |[ ]
| Psycho-educational peer support |[ ]
| Other low intensity |[ ]
| Employment support |[ ]
| Applied relaxation |[ ]
| Behavioural activation (high intensity) |[ ]
| Couples therapy for depression |[ ]
| Collaborative care |[ ]
| Counselling for depression |[ ]
| Brief psycho-dynamic psychotherapy |[ ]
| Eye movement desensitisation reprocessing |[ ]
| Mindfulness |[ ]
| Other high intensity (not specified above) |[ ]
| Employment support (high intensity) |[ ]
| Cognitive behavioural therapy (CBT) |[ ]
| Interpersonal psychotherapy (IPT) |[ ]

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| What is the current standard of care for most people with this indication, population or subgroup?  | Please describe the care that most people in this indication, population or subgroup currently have. |
| Does this technology cater to the needs of a hard to reach population? | Yes / No Please describe this.  |
| Does this technology meet an unmet need? | Yes / No Please describe this.  |

The evidence Please use the table below describe the clinical evidence that is available now, or is planned to be generated.**To meet the eligibility criteria there must be at least one RCT for the notified indication**. Evidence generated in any country, including real-world data, audit, confidential and unpublished evidence, may be included. The NICE team can provide further advice about the evidence once this form has been completed.

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| **What is the status of the evidence for this benefit?** | **For evidence that has been generated:** |
| **Was the product used to generate this evidence? (give product version number if relevant)**  | **What was the indication or population**  | **What is the study design?** | **Please include a reference to the evidence (use hyperlinks if available)** |
| *Example: Publicly available* | *Yes, this product was used to generate this evidence* | *People with Crohn’s disease* |  | *Author(s), date, title of paper, name of journal, issue and page number* |
| **Options:** Publicly available Commercial /academic in confidence unpublished generation of evidence is planned don’t know | **Options:** Yes – this product was used to generate the evidence No – an earlier version / prototype was used to generate the evidence No – a similar product was used to generate the evidence No – the evidence doesn’t relate to any specific product  |  |  |  |
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Please add additional rows if needed.

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| If further evidence is being generated or is planned to be generated, please add details of it here. Please don’t copy and paste protocols. These can be attached as a separate document if necessary.  | For example:Start dates, anticipated end dates, expected number of participants, key outcomes, trial number/identifier  |

Costs

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| --- | --- |
| Is using the digital technology in a health or social care setting in England likely to be cost incurring, or cost saving overall, compared with the standard of care? | Options (please select one): Not inferior to current care and cost savingBetter than standard care and cost savingBetter than standard care and cost incurring  |
| If the digital technology is likely to be cost saving, please describe where the cost savings are likely to occur.  |  |
| Please describe the costs and pricing structure for this digital technology. | Please describe how the health and social care system or the user would be charged for using this digital technology. Examples include charging for individual licences for healthcare professionals, or for user subscriptions. |
| What is the average cost for each treatment, patient or use associated with the **current standard of care**? Please estimate this as best you can.  |  |
| What is the average cost for each treatment, patient, use or test for **the digital technology**?  | Please break this down to show costs incurred by the user, such as costs of phone calls or SMS messages, and the costs to the health and social care system, such as licences or subscription fees. |
| Please **provide any evidence** on the cost effectiveness of the digital technology, such as cost-utility, cost effectiveness, cost-consequence or cost-benefit analyse and attach any additional information or studies on the cost and resource impact of this technology. |

Safety issues

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| --- | --- |
| Please describe potentially adverse events for people having care with this product, including any reported to a notified body or other regulatory authority, in the published literature, or known to you from other sources (please include references). Please indicate their likely frequency. |  |
| Please describe any particular risks or potentially adverse events that might affect the health and social care system, its staff or its facilities because of using the product. |  |

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# Confidentiality agreement

All information submitted at this stage is confidential between the notifier, NICE, and panel members, all of whom are bound by confidentiality agreements.

All notifiers must read and complete the confidentiality agreement below.

# We, [insert name of organisation] (the ‘Organisation’), acknowledge that information may be disclosed to us in relation to our participation in the work of the Institute which is confidential (‘Confidential Information’). Often this material will be commercially sensitive, or provided to the Institute on an academic-in-confidence basis (for example, research that has not yet been published). Confidential Information may include, but is not limited to:

* 1. the fact that a technology is being considered by the programme
	2. the IAPT assessment briefing (pre publication)
	3. information relating to the existence, content or outcome of confidential discussions.

# Subject to paragraph 8.3 below, we undertake to the Institute that we shall:

1. keep all Confidential Information strictly confidential and, except as expressly permitted under this agreement shall not disclose, use, copy in whole or in part or modify or adapt any Confidential Information in any way without the Institute's prior written consent which may be given or withheld in its absolute discretion
2. not use any Confidential Information for any purpose other than participating in the work of the Institute
3. limit access to any Confidential Information to such individuals within the Organisation as require access for the purpose set out in paragraph 8.2 (b) above
4. procure that any individual within the Organisation with access to any Confidential Information complies with this agreement
5. return all Confidential Information to the Institute on written demand, and
6. in the event that the Institute authorises any disclosure of Confidential Information by the Organisation to a third party we shall procure that such third party complies with this agreement as if he were a party to it.

# The undertakings set out in paragraph 8.2 above (the ‘Undertakings’) shall not apply to information which:

1. is in the public domain otherwise than through a breach of any of the Undertakings or a breach of any other confidentiality obligation owed by any person to the Institute
2. was lawfully within our possession before it was disclosed to us by the Institute, and neither the Organisation nor our alternative source of the information owed any confidentiality obligation to the Institute in respect of it
3. is required to be disclosed by any court of competent jurisdiction or any government agency lawfully requesting the same provided that we use our best endeavours to notify the Institute in advance of such disclosure or
4. is approved for release by prior written authorisation of the Institute.

# The Institute acknowledges that if the Organisation is a public authority as defined by the Freedom of Information Act 2000 ("the Act") then the Organisation will have to deal with any request for the Confidential Information in accordance with the Act.

1. The Institute considers that as it is careful only to undertake to keep information confidential where there is good reason to do so, any request for Confidential Information is likely to be exempt from disclosure under section 41 of the Act.
2. If the Organisation receives a request under the Act for Confidential Information and its initial view is that the Confidential Information should be released then it shall:
* promptly notify the Institute of this fact, providing a copy of the request and of the information requested
* allow the Institute a period of five working days to make representations on how it considers the request should be responded to
* conscientiously consider those representations, and
* if it decides to release any Confidential Information, provide the Institute with a copy of that information and the covering letter sent to the applicant.
1. If the Organisation decides not to release Confidential Information in response to a request, it shall notify the Institute if the requestor challenges that decision by appealing to the Information Commissioner or the Information Tribunal.

# We acknowledge that:

1. breach by the Organisation of any of the Undertakings could cause the Institute harm that is irreparable and that cannot be compensated by damages, and that in the event of any actual or threatened breach by the Organisation of any Undertaking the Institute shall be entitled to apply for and obtain (regardless of any rights the Institute may have to claim damages) an injunction or other equitable relief against the Organisation
2. this agreement constitutes the entire agreement between the Organisation and the Institute relating to the Confidential Information
3. any amendments to or waiver of any of the terms of this agreement must be set out in writing and signed on behalf of the Organisation and the Institute
4. this agreement is governed by English law and subject to the exclusive jurisdiction of the English courts.

Please insert an electronic signature. Alternatively, please print this document and provide a handwritten signature. **A typed signature cannot be accepted.** By providing an electronic or handwritten signature the technology owner/developer\* (If appropriate list separately) agree to the terms and conditions (listed in section 9) of this process, and consent to the proposed process of assessment.

\*Technology owner/developer means the notifier who in their organisation will be responsible for this. It may be one and the same individual or separate individuals who have the authority to disclose the information and take part.

Signature: [insert handwritten or electronic signature]

A duly authorised officer for and on behalf of: [insert organisation’s name]

Print Name: [insert name] Date: [insert date]

# Terms and Conditions

* 1. The technology owner/developer certifies that they have the right and authority to enter into this agreement and hereby agrees to hold NICE and its 3rd parties harmless if they breach this condition.
	2. The technology owner/developer must supply the required information to support the screening, prioritisation and assessment stages.
	3. The technology owner/developer must provide free access to the technology to appropriate members of the NICE IAPT team and expert advisors for the purpose of assessing the technology.
	4. The technology owner/developer must notify NICE of any proposed technology upgrades. All technology upgrades must be notified to NICE and brought to the attention of the NICE expert panel. It is the responsibility of the technology owner / developer to also advise what impact the planned upgrade will have on the technology function. The NICE IAPT team and expert panel and steering group retain the right to remove the technology from assessment or testing in practice, if the upgrade impacts in the function of the technology, which will affect the assessment outcome or testing on practice.
	5. Work with NICE and NHS England project team to establish mechanism to collect and report data from ‘testing in practice’
	6. Technology owner/developers will be expected to participate in the process free of charge. This will include:
		+ Making their product available to a number of testing services
		+ Providing training and technical support to testing services
		+ Making necessary product developments to ensure that the data required for evaluation is collected