NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

Draft for feedback pre-consultation April 2022

# Introduction

The NICE evidence standards framework (ESF) for digital health technologies (DHTs) describes standards for the evidence that should be available or developed for DHTs to demonstrate their value in the UK health and social care system. The framework encompasses evidence of performance relevant to the purpose of the technology and evidence of economic impact relative to the financial risk. This ESF update also includes associated design factors and deployment considerations.

The ESF can be used by evaluators and innovation teams in the NHS and care system when they are evaluating a DHT for a commissioning or purchasing decision. This will enable high-quality innovation to be identified and used in the UK. NICE considers the evidence outlined in the ESF when developing medical technologies guidance and diagnostics guidance on DHTs.

The ESF can also be used by DHT companies to understand how the UK health and care system evaluates DHTs, and what kinds of evidence need to be shown to facilitate commissioning or purchasing decisions in the NHS and care system.

The ESF has been designed to complement the expected regulatory and technical standards that apply to DHTs. The framework focuses on evaluating DHTs to ensure they perform as expected and represent good value for money to the health and care system. The evidence for performance standards has been set at levels that are intended to be realistic and achievable for DHT companies, while being of a sufficiently high standard to give the health and social care system confidence in the DHT. This balance is intended to encourage the confident use of innovative, effective DHTs in the health and social care system. The standards about delivering value are based on the guidance evaluation methods used at NICE, and are designed to assess the economic impact of a DHT. We have designed this framework within the context of a health and social care system that is seeking innovative ways to improve care while reducing cost burden on the system.

The development of the medical device regulatory framework and evaluation methods for DHTs, particularly those with adaptive algorithms, is progressing rapidly and we expect that the ESF will be updated to reflect the changes in the health technology assessment landscape for these technologies.

NICE is grateful to the wide range of stakeholders who helped develop the concepts and content, and to all those who have provided feedback on the ESF since it first published in December 2018.

Find out more details about the development and use of the ESF in the [ESF user guide](https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/ESF-user-guide-2022-consultation.docx).

The ESF is presented here in 4 sections:

* [Section A: Technologies suitable for evaluation using the ESF](#_Section_A:_Technologies)
* [Section B: Classification of technologies](#_Section_B:_Classification)
* [Section C: Evidence standards tables](#_Section_C:_Evidence)
* [Section D: Early deployment standards for evidence- generation programmes](#_Section_D:_Early)

# Section A: Technologies suitable for evaluation using the ESF

The NICE evidence standards framework (ESF) has been designed to be suitable for the evaluation of most digital health technologies (DHTs) that are likely to be commissioned in the UK health and social care system. This includes a wide range of products used in the health and social care system, including apps, software and online platforms that are intended to benefit people or the wider health and social care system. DHTs may be standalone apps or programmes, wearables, or be designed as optional accessories to other products such as medical devices or diagnostic tests.

The ESF can be used to evaluate all DHTs commissioned in the health and care system for medical, health or wellness, or system efficiency purposes. It is applicable to medical therapeutic and diagnostic technologies including in vitro diagnostics (IVDs) and screening technologies. The ESF can be used for technologies where the intended benefit is at the population level as well as those that benefit the individual service user or the health and care system.

The ESF is intended to be used alongside requirements for regulation and does not constitute or replace any regulatory process. It can be used to evaluate DHTs that are regulated as medical devices under the [Medicines and Healthcare products Regulatory Agency](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) (MHRA), those that constitute health and care services within remit for regulation by the [Care Quality Commission](https://www.cqc.org.uk/) (CQC), and those DHTs that do not fall within remit for any specific UK regulation. The MHRA has issued [guidance on medical devices: software applications (apps)](https://www.gov.uk/government/publications/medical-devices-software-applications-apps) to help identify whether software technologies are medical devices.

The ESF has been updated in 2022 to include standards relevant to DHTs whose performance is expected to change over time (such as those with machine-learning algorithms that are expected to re-train over time).

The ESF is not intended to be used for evaluating the following types of DHT:

* software that is integral to, or embedded in, a medical device, also called software in a medical device (SiMD)
* surgical robots
* DHTs designed for providing training to health or care professionals (such as virtual reality [VR] or augmented reality [AR] surgical training)
* DHTs that facilitate data collection in research studies.

# Section B: Classification of DHTs

Classifying digital health technologies (DHTs) by intended use (see figure 1) allows them to be stratified into tiers based on the potential risk to service users and to the system. The evidence level needed for each tier is proportionate to the potential risk to service users from the DHTs in that tier. The classification used in the evidence standards framework (ESF) has been designed so that most regulated medical devices will be in tier C. Table 1 describes each classification group in more detail and gives some specific examples. We plan to publish some examples of DHTs classified using the ESF classification system in June 2022.

For tier C, the classification groups have been aligned to the [software as a medical device (SaMD) classification framework proposed by the International Medical Device Regulators Forum (IMDRF)](https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf). Table 2 is adapted from the IMDRF classification document showing the relationship between the ESF classification groups and the medical device classes. Please note the MHRA’s [consultation on the future regulation of medical devices in the United Kingdom](https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom) contained a section on software as a medical device. Table 2 will be updated as necessary.

For more information about how the classification was developed, please see the [ESF user guide.](https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/ESF-user-guide-2022-consultation.docx)

Figure DHTs classified by intended use and stratified into risk tiers

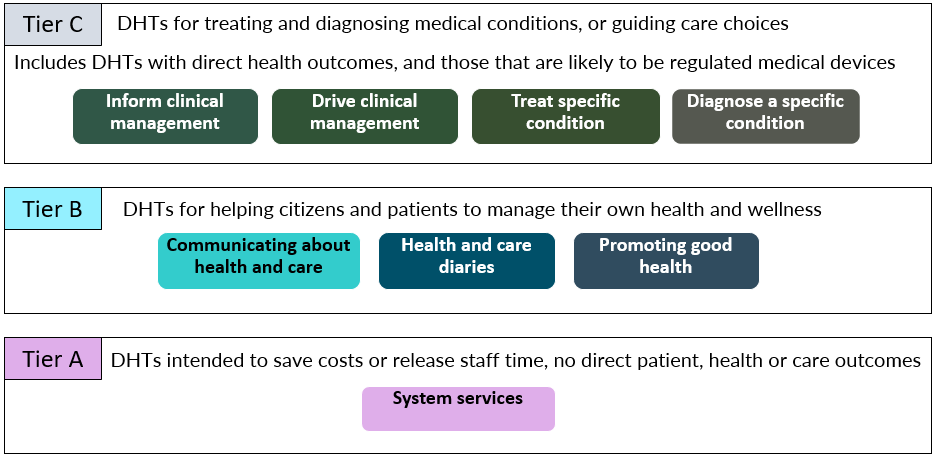


Table 1 ESF evidence tiers and classification groups

| Tier | Intended use | Description | This tier includes (for example) | This tier excludes (for example) |
| --- | --- | --- | --- | --- |
| **Tier A: system service** | Digital health technologies (DHTs) intended to release costs or staff time, or to improve efficiency. | Unlikely to have direct health outcomes measurable for individual service users. | Electronic prescribing systems that do not provide patient-level advice on prescribing.  Electronic health record platforms.  Ward management systems including those that use resourcing data (such as waiting times or bed capacity) to help manage clinical or care workloads by guiding people’s access routes to care.  **Examples:** eScription One (Deliver Health Solutions) | DHTs that influence treatment or diagnoses, such as early warning systems that monitor vital signs.  Triaging systems that use individual patient health data (such as vital signs, symptoms or self-reported health measures) to guide treatment, diagnosis or care decisions. |
| **Tier B: managing own health and wellness** | Communicating with health professionals or others, to help service users to manage their own health and wellness. | Allows 2-way communication between service users and professionals, carers, third-party organisations or peers. | Instant messaging apps for health and social care.  DHTs that provide platforms for communication with carers or professionals or other service users.  **Examples:** Celo (Celo Ltd), | DHTs that provide clinical content themselves (such as cognitive behavioural programmes for depression). |
| **Tier B: managing own health and wellness** | Health and care diaries to help service users to manage their own health and wellness. | Allows service users to record information to create health diaries. Information and data stay with the service user and are not automatically shared with others for review. | Health tracking information, such as from fitness wearables.  Symptom or mood diaries.  **Examples:** Well.Me (Wellpoint Group Ltd), MoleCare (2AY Ltd), OWise breast cancer (Px HealthCare Ltd). | DHTs that share information with professionals, carers or other service users.  DHTs that provide treatment for or diagnosis of a condition. |
| **Tier B: managing own health and wellness** | Promoting good health.  Population-level information to help people and service users to maintain healthy lifestyles and manage conditions. | Provides information and resources to service users. May encourage behaviours that promote good health and address issues such as smoking, eating and exercise. May also provide information about specific conditions. | DHTs used as part of general weight-loss programmes.  DHTs that aid good sleep habits.  **Examples:** Headspace (Headspace Health), LymEx (US Department of Health & Human Services). | DHTs that describe themselves as a treatment for a diagnosed condition. |
| **Tier C: treating and diagnosing** | Inform clinical management. | DHTs that record and calculate data and transmit the data to a professional, carer or third-party organisation, to inform clinical management decisions in the future. Information provided by the DHT will not trigger an immediate or near-term action. | DHT that stores historical blood pressure information for a healthcare provider's later review.  Symptom monitors where data is automatically shared with care teams for later review.  **Examples:** Fibricheck (Corda Campus), Livongo (Teladoc Health). | DHTs whose intended purpose is a treatment for a diagnosed condition.  DHTs that monitor a condition to trigger immediate or near-term action. |
| Tier C: treating and diagnosing | Drive clinical management. | Information provided by the DHT will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions. | DHT that analyses heart rate data intended for a clinician as an aid in diagnosing arrhythmia.  Triaging systems that use individual patient health data (such as vital signs, symptoms or self-reported health measures) to guide health and care decisions.  **Examples:** HeartFlow FFRCT (HeartFlow), Zio XT (Irhythm). | DHTs that describe themselves as a treatment for a diagnosed condition.  DTHs that provide information that triggers immediate or near-term action.  Triaging systems that only use resourcing data (such as waiting times or bed capacity) to help manage workloads and guide people’s access routes to care. |
| Tier C: treating and diagnosing | Diagnose a condition. | Information provided by the DHT will be used to take an immediate or near-term action to diagnose, screen or detect a disease or condition. | DHT that performs diagnostic image analysis for making treatment decisions in service users with acute stroke.  **Examples:** Brainomix (Brainomix), Behold AI (Behold.AI technologies Ltd). | DHT offering general (non-personalised) health or wellness advice. |
| Tier C: treating and diagnosing | Treat a condition. | Information provided by the DHT will be used to take an immediate or near-term action to treat, prevent or mitigate by means of providing therapy to a human body. | DHT that uses the microphone of a smart device to detect interrupted breathing during sleep and sounds a tone to rouse the sleeper.  **Examples:** MyCOPD (My Mhealth), Sleepio (Big Health), Space from Depression (SilverCloud). | DHT offering general (non-personalised) health or wellness advice. |

Table 2 Potential mapping between the ESF classification groups in tier C and the medical devices classes

|  |  |  |
| --- | --- | --- |
| Evidence standards framework (ESF) classification group in tier C | Description | Healthcare situation or condition with the medical device class as per IMDRF categories mapped to the current UK medical device regulations |
| Inform clinical management | Digital health technologies (DHTs) that record, calculate and transmit data to a professional, carer or third-party organisation to inform clinical management in the future. | * Non-serious: Class 1 * Serious: Class 1 * Critical: Class 2a |
|
|
| Drive clinical management | Information provided by the DHT will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions. | * Non-serious: Class 1 * Serious: Class 2a * Critical: Class 2b |
|
|
| Diagnose a condition | Information provided by the DHT will be used to take an immediate or near-term action to diagnose, screen or detect a disease or condition. | * Non-serious: Class 2a * Serious: Class 2b * Critical: Class 3 |
|
|
| Treat a condition | Information provided by the DHT will be used to take an immediate or near-term action to treat, prevent or mitigate by means of providing therapy to a human body. | * Non-serious: Class 2a * Serious: Class 2b * Critical: Class 3 |
|
|

This table has been adapted from the [table in section 7.2 of the IMDRF classification framework](https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf). The medical device class names included here align with the classes currently used by the MHRA (low impact: Class 1; high impact: Class 3). The medical device class may also be influenced by other factors including the user type (patient or professional) and level of professional oversight. This table will be reviewed and updated in line with changes to MHRA regulations.

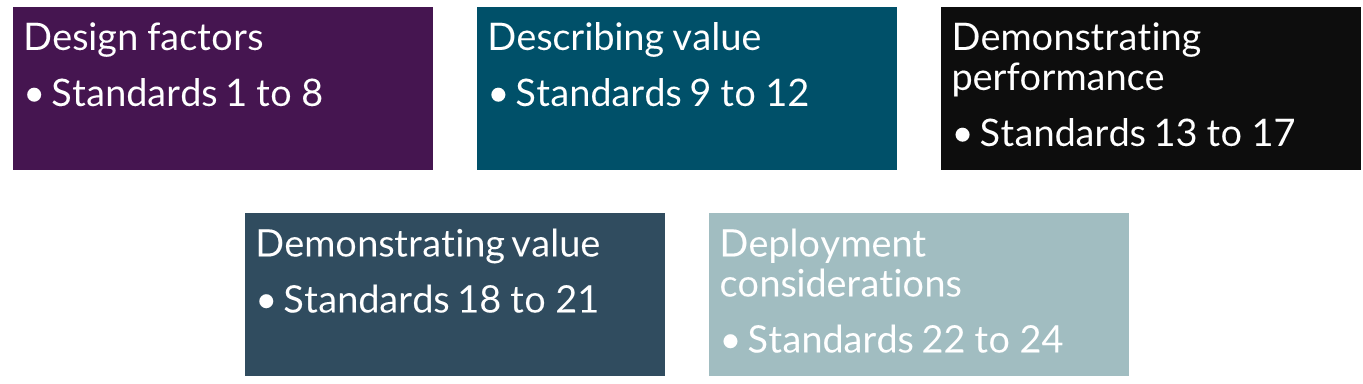
# Section C: Evidence standards tables

The NICE evidence standards framework (ESF) has been designed to inform the health technology assessment of digital health technologies (DHTs) for use in the NHS and social care system. The standards are presented in groups related to phases of the DHT product life cycle. There are 24 standards arranged in 5 groups:

* **Design factors:** The 8 standards identify key aspects of the design process that impact the DHT’s value to the health and care system.
* **Describing value:** The 4 standards apply across all tiers and present the value proposition of the technology.
* **Demonstrating performance:** Standards 15 to 17 ensure the technology has the appropriate technical standards for safety and reliability, and meets the performance expectations. There are 2 additional standards for tier C technologies to demonstrate clinical effectiveness.
* **Delivering value:** The 4 standards apply across all tiers and show how DHTs should demonstrate their value for money.
* **Deployment considerations:** The 3 standards apply across all tiers.

We plan to publish some case studies of different DHTs to show how they have met their evidence standards, in June 2022.

Figure The 5 groups of evidence standards relating to different aspects of the product life cycle



## Summary of NICE ESF standards

Tables 3 to 7 summarise the 24 standards and specify the classification tiers to which each standard applies. Additional information is provided in the [section on how to meet the standards](#_Design_factors), to explain the kind of information that a company needs to show in order for a DHT to meet each standard.

Table 3 Design factors

|  |  |
| --- | --- |
| Standard | Tiers to which the evidence standard applies |
| [1: incorporate service user acceptability in the design of the DHT](#_Information_that_can) | A, B and C |
| [2: consider environmental sustainability](#_Information_that_can_1) | A, B and C |
| [3: consider health and care inequalities and bias mitigation](#_Standard_3:_consider) | A, B and C |
| [4: embed good data practices in the design of the DHT](#_Standard_34:_embed) | A, B and C |
| [5: define the level of professional oversight](#_Standard_45:_define) | A, B and C |
| [6: show processes for creating reliable health information](#_Standard_56:_show) | B and C |
| [7: show that the DHT is credible with UK professionals](#_Standard_67:_show) | B and C |
| [8: provide safeguarding assurances for DHTs where service users are considered to be in vulnerable groups, or where peer-peer interaction is enabled](#_Standard_78:_provide) | B and C |

Table 4 Describing value

|  |  |
| --- | --- |
| Standard | Digital health technologies (DHTs) it applies in |
| [9: describe the intended purpose and target population](#_Standard_89:_describe) | A, B and C |
| [10: describe the current pathway or system process](#_Standard_910:_describe) | A, B and C |
| [11: describe the proposed pathway or system process using the DHT](#_Standard_1011:_describe) | A, B and C |
| [12: describe the health and system impacts and associated cost and resource impacts compared with standard or current care](#_Standard_1112:_describe) | A, B and C |

Table 5 Demonstrating performance

|  |  |
| --- | --- |
| Standard | Digital health technologies (DHTs) it applies in |
| [13: provide evidence of the DHT’s performance to support its claimed benefits](#_Standard_1213:_provide) | C |
| [14: additional evidence for critical conditions or functions](#_Standard_1314:_additional) | C |
| [15: show real-world data of performance in practice](#_Standard_1415:_show) | A, B and C |
| [16: the company and evaluator should agree a plan for measuring changes in the DHT’s performance over time](#_Standard_1516:_the) | A, B and C |
| [17: the DHT should comply with relevant safety and quality standards](#_Information_that_can_16) | A, B and C |

Table 6 Delivering value

|  |  |
| --- | --- |
| Standard | Digital health technologies (DHTs) it applies in |
| [18: provide a budget impact analysis](#_Information_that_can_17) | A, B and C |
| [19: show sensitivity analysis to explore uncertainties](#_Information_that_can_18) | A, B and C |
| [20: for DHTs with higher financial risk: provide a cost-comparison or cost–utility analysis](#_Information_that_can_19) | A, B and C |
| [21: agree a data collection plan to show value](#_Information_that_can_20) | A, B and C |

Table 7 Deployment considerations

|  |  |
| --- | --- |
| Standard | Digital health technologies (DHTs) it applies in |
| [22: ensure transparency about requirements for deployment](#_Information_that_can_21) | A, B and C |
| [23: describe plans for communication, consent and training processes in place to allow the DHT to be understood by end service users](#_Information_that_can_22) | A, B and C |
| [24: ensure appropriate scalability](#_Information_that_can_23) | A, B and C |

## How to meet the standards

## Design factors

### Standard 1: incorporate service user acceptability in the design of the DHT

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 1

Describe how representatives from intended user groups were involved in the design, development or testing of the DHT. Depending on who is intended to operate the DHT, the intended users may include patient groups and service users, or health and care professionals. Describe how user satisfaction was appraised and provide any available data to show user satisfaction with the DHT. DHTs that have passed section D1 of the [NHS digital technology assessment criteria](https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/) may be considered to have already demonstrated compliance with the ESF design factor standard 1. [ISO’s standard IEC 62366-1](https://www.iso.org/standard/63179.html) also covers usability engineering for medical devices.

### Standard 2: consider environmental sustainability

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 2

The [NHS has set ambitions to have a net zero carbon footprint by 2040](https://www.england.nhs.uk/greenernhs/a-net-zero-nhs/). Environmental sustainability should be factored into the design of the DHT. The company should provide a narrative description of any expected environmental sustainability benefits and negative impacts from using the DHT. This should focus on impacts on greenhouse gas emissions, in line with the [NHS carbon footprint and carbon footprint plus](https://www.england.nhs.uk/greenernhs/a-net-zero-nhs/).

### Standard 3: consider health and care inequalities and bias mitigation

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 3

Health inequalities considerations should be factored into the design of the DHT. Describe how this has been approached and how this has been included in the design of the DHT. Describe any specific positive impacts and of any efforts to reduce negative impacts on health inequalities.

If the DHT has a claim of addressing a health or care inequality, it should also show evidence that the DHT contributes to:

* challenging health inequalities in the UK health and social care system, or improving access to care among hard-to-reach populations
* promoting equality, eliminating unlawful discrimination, and fostering good relations between people with protected characteristics (as described in the [Equalities Act 2010](https://www.legislation.gov.uk/ukpga/2010/15/contents)) and others.

For early deployment (ED) DHTs being used in evidence-generation programmes, plans for collecting evidence to support the health inequalities claims should be provided.

[NHS Digital’s guide on digital inclusion for health and social care](https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion) provides information for companies and providers to understand digital inclusion and steps that can be taken to evaluate and support digital inclusion.

For data-driven DHTs (including those with artificial intelligence), the company should describe any actions taken in the design of the DHT to mitigate against algorithmic bias that could lead to unequal impacts between different groups of service users or people.

### Standard 4: embed good data practices in the design of the DHT

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 4

When developing data-driven DHTs, companies should follow the [Medicines and Healthcare products Regulatory Agency (MHRA) guiding principles on good machine learning practice for medical device development](https://www.gov.uk/government/publications/good-machine-learning-practice-for-medical-device-development-guiding-principles/good-machine-learning-practice-for-medical-device-development-guiding-principles).

Any datasets used to train, validate or develop the DHT should be of a high quality. One indicator of quality is that the following information can be provided by the company:

* which datasets (title, source, version) were used for training and validating the DHT
* the size of the training and validation datasets
* why these datasets were collected, and by what means (manual input, through monitors or other devices)
* diversity (demographics, age, clinically relevant subgroups) in these datasets used and how this reflects the intended target population for the DHT
* any synthetic training or validation data should be highlighted; synthetic data should be supported by real data
* how any decision thresholds have been set and how these align to current best practice.

### Standard 5: define the level of professional oversight

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 5

The company must clearly describe the level of professional oversight when the DHT is used in practice.

Professional oversight may include (among others):

* expert review of each decision or output on a case-by-case basis
* periodic overarching review of the trends in the decision outputs of the DHT, to ensure that the decisions are aligned to, or calibrated against, best practice
* monitoring for occasions where the DHT’s decision output has been overridden by professionals.

The level of professional oversight should be proportionate to the level of risk associated with failure of the DHT to perform as expected. Higher levels of professional oversight may be needed when the consequences of the DHT’s failure are serious or critical.

### Standard 6: show processes for creating reliable health information

Applies to DHTs in B and C.

#### Information that can be used to meet standard 6

Be able to show that processes are in place to maintain any health information provided by the DHT:

* valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or recognised UK patient organisations, and appropriate for the target population)
* accurate
* reviewed and updated by relevant experts at defined intervals, such as every year
* sufficiently comprehensive.

### Standard 7: show that the DHT is credible with UK professionals

Applies to DHTs in B and C.

#### Information that can be used to meet standard 7

Be able to show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field. This could include providing evidence to support key factors such as the choice of behaviour change techniques used in the DHT.

Show that relevant clinical or social care professionals working in the UK health and social care system have either been involved in designing, developing or testing the DHT, or given their support to the UK deployment of the DHT.

### Standard 8: provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-to-peer interaction is enabled

Applies to DHTs in B and C.

#### Information that can be used to meet standard 8

Show that appropriate safeguarding measures are in place around peer support and other communication functions within the platform:

* Describe who has access to the platform and their roles within the platform.
* Describe why these people or groups are suitable and qualified to have access.

Describe any measures in place to ensure safety in peer-to-peer communication, for example, through user agreements or moderation.

## Describing value

### Standard 9: describe the intended purpose and target population

Applies to DHTs in A, B and C.

Describe the intended use, target population or user group, and claimed benefits for the DHT. Include any inclusion and exclusion criteria that apply.

Describe the expected uptake profile of the DHT.

#### Information that can be used to meet standard 9

The target population can be defined by a particular health condition or position in the care pathway. Any important subgroups should also be identified.

The size of the intended target population should be calculated using appropriate and current national or local sources (for example, accurate epidemiological data of prevalence and incidence of the relevant health problem), or expert estimates if this is not available. Note that [NICE’s resource impact assessment manual](https://www.nice.org.uk/about/what-we-do/into-practice/resource-impact-assessment) describes an approach to calculating population size.

The expected uptake profile describes the proportion of people within the target population who are expected to use the DHT, and their usage rates. This may be impacted by digital literacy within the intended user population, availability of necessary connectivity, and access to necessary hardware or devices.

Demonstrate that the expected uptake profile is:

* calculated using uptake rates from pilot data or other usage data from the company
* validated as an accurate representation of what is expected (including any variations by subgroup and over time) by showing agreement and support from relevant professionals in the UK health and social care system
* mindful of subgroups with different expected uptake rates and how these may change over time.

### Standard 10: describe the current pathway or system process

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 10

Use national clinical guidelines, national guidance or academic literature and consultation with healthcare professionals and service users to map out the existing care pathway or system processes.

Use a comprehensive, detailed and stepwise approach (for example, using a flow chart).

The representation of current care or system processes should be comprehensive and should be checked and validated by relevant professionals in the UK health and social care system.

If there is no existing care pathway or system process, the impact of adopting the technology should be clearly specified using an approach that can be used as a basis for an economic evaluation.

If there is more than 1 existing care pathway or system process, describe each of them.

### Standard 11: describe the proposed pathway or system process using the DHT

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 11

Provide details of how the proposed care pathway or system process using the DHT will be different to the current pathway or system process, including:

* whether using the DHT would replace an existing technology or step in current care, or whether it would be in addition to current care
* any changes that would need to be made to infrastructure, service provision and workforce, compared with current care or process
* whether the proposed pathway crosses between existing care boundaries, such as between primary and secondary care
* changes needed to implement, operate and maintain the proposed pathway or process using the DHT
* any costs associated with training and education for health and care professionals or end users, in order to effectively implement and use the DHT
* any influential contextual issues that may act as barriers for enablers to implementation.

### Standard 12: describe health and system impacts and associated cost and resource impacts compared with standard or current care

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 12

To assess impact of the DHT, we need to understand and compare the health and system benefits from the current pathway or process and the proposed pathway or process using the DHT:

* Describe the health benefits and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with current practice. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).
* Describe the health benefits and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with using the DHT. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).

Structural and procedural effects could include access to care, health literacy, adherence to care plans, or coordination of care.

Also, it is important to understand whether there are any expected additional costs or cost savings as well as resource impact from the DHT compared with current practice:

* Describe the costs and resource use associated with current practice. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).
* Describe the expected costs and resource use associated with using the DHT. If possible, quantify the uncertainty associated with these figures (for example, with confidence intervals or probability distribution).

The sources for this information should:

* be from the most robust evidence available, for example from clinical studies on the DHT and on current care options (if available), real-world evidence, observational studies or from expert opinion.
* be the same as referred to in the performance and effectiveness standards (if these apply).

Evidence synthesis can be used if there are several studies, in which case a sensitivity analysis should be shown.

Estimates should have minimal bias and all uncertainties should be accurately characterised.

## Demonstrating performance

### Standard 13: provide evidence of the DHT’s performance to support its claimed benefits

Applies to DHTs in C.

#### Information that can be used to meet standard 13

For tier C DHTs, evidence for effectiveness must be shown.

The evidence should show that using the DHT impacts on clinical management of the relevant condition, in a setting relevant to the UK health and social care system. Outcomes relevant to the intended purpose should be captured.

Choice of study design should be guided by the intended purpose of the DHT, and comparative studies are generally more informative than non-comparative studies. Some general guidance on assessing the quality of evidence includes:

* + The results of studies done in a setting that is similar to the UK health and care system (such as where the care pathway is similar, patients have similar care options, and/or similar kinds of staff are involved in care) are easier generalisable to the UK system than those of studies done in settings that are very different to the UK system.
  + Prospective studies are often considered to be more valuable than retrospective studies because they can be designed to capture the most relevant outcomes.
  + Studies that are published in peer-reviewed journals have usually had some independent assessment of their quality before publication.
  + There are different ways to appraise the quality of research studies. [Appendix H of NICE’s developing NICE guidelines: the manual](https://www.nice.org.uk/process/pmg20/chapter/appendices) provides a comprehensive list of checklists that can be used to assess risk of bias or quality of different study types.

NICE is developing a framework on best practice in developing real-world evidence, which is expected to publish in June 2022.

**Effectiveness of DHTs that inform clinical management**

Evidence to support the claimed benefits of the DHT can include published or unpublished studies on the DHT and can include real-world evaluations of its clinical utility. This could include a single-arm study done to support regulatory requirements.

**Effectiveness of DHTs that drive clinical management**

The evidence should include 1 or more high-quality studies to support the claimed benefits, done in a setting relevant to the UK health and social care system.

This could include:

* interventional studies
* prospective observational studies (including real-world evidence)
  + test accuracy studies, using an appropriate reference standard
* a concordance study (to show agreement with currently used tests).

Retrospective studies can be useful in addition to evidence from prospective studies.

**Effectiveness of DHTs that treat a specific condition**

One or more high-quality interventional studies (experimental or quasi-experimental design) to support the claimed benefits of the DHT, done in a setting relevant to the UK health and social care system and showing improvements in relevant outcomes, such as:

* clinically relevant outcomes
* patient-relevant outcomes.

The choice of study design should be appropriate for the intended purpose of the DHT. Randomised controlled trials would be preferrable where this study design is appropriate.

The comparator should be a care option that reflects the current NHS care pathway, such as a commonly used active intervention.

User satisfaction and engagement measures may also be useful.

**Performance of DHTs that diagnose a specific condition**

One or more high-quality test accuracy studies, using an appropriate reference standard, or a concordance study to show agreement with current practice.

If the test provided by the diagnostic DHT is new to the clinical pathway and no other similar tests exist for comparison, show a high-quality clinical study showing clinical consequences of the diagnosis.

### Standard 14: additional evidence for critical conditions or functions

Applies to DHTs in C.

#### Information that can be used to meet standard 14

If the DHT is intended to be used for situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health, more evidence or better-quality evidence is required. For DHTs intended to drive clinical management, this would mean an interventional study would be needed.

Additional evidence could include any well-designed studies or data in addition to those required for the 4 different functional groups in tier C.

This could be real-world data, prospective or retrospective studies that can serve to reduce uncertainty about the performance of the DHT.

### Standard 15: show real-world evidence that the claimed benefits can be realised in practice

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 15

Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to:

* current service provision in the UK (for tier A DHTs) or
* current best practice in the UK (for tier B and tier C DHTs).

This may include a statement from pilot site(s) to confirm that during pilot testing, the DHT:

* was acceptable to users
* performed its intended purpose to the expected level
* successfully integrated into current service provision or current best practice
* caused no negative impacts on service users or services
* showed improvements in outcomes (costs saved, efficiencies achieved, health and care improvements)
* was used in line with expectation (who, how, for how long).

For DHTs that are expected to have high costs or service impact (such as requiring significant service redesign), then higher levels of evidence may help to reduce uncertainty. This could include larger-scale studies or longer-term outcomes.

For DHTs whose performance may be affected by local deployment factors (such as DHTs using artificial intelligence), this may include deploying the DHT to run offline or evaluating it ‘in silent mode’.

Silent mode evaluations allow the DHT’s performance on local data inputs to be observed (but not used in care decisions), before the DHT is integrated into clinical or care pathways. This can show whether the DHT’s performance reaches the expected levels using input data generated in the local environment.

### Standard 16: the company and evaluator should agree a plan for measuring changes in the DHT’s performance over time

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 16

For DHTs whose performance is expected to change over time (such as DHTs that use artificial intelligence or machine-learning algorithms, DHTs whose algorithm is updated in subsequent versions), the company and evaluator should agree on post-deployment reporting of changes in performance.

This may include:

* future plans for updating the DHT, including how regularly the algorithms are expected to retrain
* the sources of retraining data, and how the quality of this data will be assessed
* processes in place for measuring performance over time, to detect any impacts of planned changes or environmental factors that may impact performance
* processes in place to detect decreasing performance in certain groups of people over time
* whether there is an independent overview process for reviewing changes in performance
* an agreement on how and when changes in performance should be reported to commissioners and users (patients, carers, health and care professionals).

### Standard 17: the DHT should comply with relevant safety and quality standards

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 17

Companies should demonstrate that all safety and quality standards relevant to their DHT have been met.

Examples of standards that may apply to different DHTs include:

* UKCA marking under the UK medical device regulations ([MHRA provides guidance on medical devices: software applications [apps]](https://www.gov.uk/government/publications/medical-devices-software-applications-apps)).
* Regulation by the [Care Quality Commission](https://www.cqc.org.uk/files/regulation-digital-healthcare-providers-primary-care) for digital health services.
* Following regulations outlined in the [UK General Data Protection Regulation (GDPR)](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/).
* Registration with the [Information Commissioner’s Office](https://ico.org.uk/for-organisations/data-protection-fee/faqs-data-protection-fee-payment-and-online-registration/) as a data processor.
* For use in the NHS, DHTs may need to show compliance with [the Digital Technology Assessment Criteria](https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/) (DTAC), which includes [DCB0129](https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems) and [DCB0160](https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems), [NHS Digital’s data security and protection toolkit](https://www.dsptoolkit.nhs.uk/) and [interoperability toolkit](https://digital.nhs.uk/services/interoperability-toolkit), and [NHS service standard](https://service-manual.nhs.uk/service-standard).
* Local information governance requirements including data protection impact assessments.
* ISO 13485 for quality management systems, ISO 11073 for personal health data.
* [IEC 82304-1](https://www.iso.org/standard/59543.html) – a non-mandated standard. Compliance with this standard demonstrates safety and security for health software.

## Delivering value

### Standard 18: provide a budget impact analysis

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 18

Provide a budget impact analysis relevant to the setting the DHT is used, which should include:

* size of target population
* all direct costs associated with the technology and implementing the technology, including cost of the technology (purchasing, updating, maintenance), costs of staffing and training, costs of supportive IT infrastructure needed to implement the technology
* all direct costs associated with the comparator
* relevant indirect costs associated with the technology and the comparator, reference test or current practice
  + uptake estimates.

Estimates of resource use should include:

* length of hospital or care home stay
* number of hospitalisations
* outpatient or primary care consultations
  + changes in infrastructure, use and maintenance

Show that the costs used are relevant to the UK health and care system and they should relate to NHS and personal social services resources. Suitable sources include:

* NHS reference costs
* national tariff.

Show that the estimates for resource use are based on clinical practice, which can be based on data from:

* a clinical study
* real-world data including from pilot studies
* information obtained from relevant clinical or social care professionals
* other appropriate sources.

State the source of the data for the cost and resource estimates. State whether the estimates are recognised as accurate and comprehensive by a relevant health and social care professional. Include any expected variations for different groups of service users.

### Standard 19: show sensitivity analysis to explore uncertainties

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 19

Explore the uncertainty of the estimate obtained from the budget impact analysis by varying the assumptions used (for example, using best- and worst-case values for target population size, resource use).

### Standard 20: for DHTs with higher financial risk, provide a cost–comparison or cost–utility analysis

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 20

We define a DHT with higher financial risk as: where the costs of commissioning, purchasing or implementing the DHT are deemed to be substantial within the context of local budgets and system priorities. This will vary between different commissioning organisations, and contributing factors may include:

* coverage of commissioning of the technology, for example whether it’s commissioned at 1 site, multiple sites or nationwide
* the extent of changes needed within an organisation to use the DHT; this could include changes to IT systems, staffing or care pathways
  + the extent of implementation costs needed to use the DHT

Cost‑comparison analysis is preferred if the DHT provides similar or greater health and care benefits at similar or lower costs.

Cost–utility analysis is preferred if the DHT:

* provides similar or greater health or care benefits at higher costs
  + provides marginally lower health benefits for significantly lower costs.

For all analyses, explore the uncertainty of the obtained estimate by using sensitivity and scenario analyses.

If a cost–utility analysis is being done, an appropriate standard measure should be used for utility data (such as EQ-5D). Describe why this measure was chosen. The [NICE health technology evaluations: the manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation) gives further guidance on how these analyses can be done.

### Standard 21: agree a data collection plan to show value

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 21

The company and the evaluator should reach an agreement for ongoing data collection to report:

* ongoing usage of the DHT in the target population in line with the expected usage profile (to be agreed at commissioning)
* anonymised, aggregate data to show service user outcomes, if this is collected by the DHT
* include analysis to show cost per use or per service user of the DHT, based on the data collected
* whether any changes (such as algorithmic changes, upgrades or operational environment or updates) have occurred.

## Deployment considerations

### Standard 22: ensure transparency about requirements for deployment

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 22

The company should provide clear descriptions of the data used in deployment. This should include:

* a full description of the input data for the DHT
* quantifying the level of tolerance that the DHT has for incomplete data (such as inputs that are missing or of insufficient quality), and how outlier data is handled
* a data flow map for deployment of the DHT to allow efficient deployment
* data requirements for the DHT, such as specific data formats, completeness or quality
* the minimum infrastructure requirements for deploying the DHT.

### Standard 23: describe plans for communication, consent and training processes in place to allow the DHT to be understood by end users

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 23

The company must ensure that appropriate communication strategies are in place for service users and health and care professionals, to describe the outputs, key features, benefits and limitations of the DHT. This may include providing a [model card](https://modelcards.withgoogle.com/about) for end users (such as health and care professionals or patients) to allow them to understand when and whether to use the DHT in a person’s care.

If service user consent is needed, the company should describe this process.

The company should describe the outputs for the DHT. Examples could include:

* risk scores
* probabilities of different diagnoses
* recommendations for other tests.

The company should describe their planned approach for training end users of the DHT to allow the benefits of the DHT to be realised in practice.

### Standard 24: ensure appropriate scalability

Applies to DHTs in A, B and C.

#### Information that can be used to meet standard 24

The company should ensure that load testing has been done, to show that the DHT can perform to the scale needed (for example, having servers that can scale to manage the expected number of service users).

Describe the process for load testing and how this relates to the expected uptake for the DHT.

# Section D: Early deployment standards for evidence-generation programmes

It can be challenging for companies whose digital health technologies (DHTs) are at an early development stage, to generate the evidence needed to meet the requirements of the evidence standards framework (ESF). To address this challenge, evidence-generation programmes exist to support companies to develop the evidence base for their DHT.

To be included in such evidence-generation programmes, it is assumed that the DHT has been through its design, development and validation phases, and has obtained the necessary regulatory approval or appropriate technical standards to ensure its safety and reliability. These programmes support the piloting or early deployment of the technology to facilitate evidence generation to demonstrate its effectiveness, place in the care pathway, and economic impact.

The early deployment (ED) subset of the ESF standards can be used to assess DHTs considered for use in an evidence-generation programme. The ED subset includes 15 standards:

* **Design factors:** 8 standards that identify key aspects of the design process that impact on the DHT’s value to the health and care system.
* **Describing value:** 4 standards that present the value proposition of the technology.
* **Demonstrating performance:** 1 standard that shows the DHT has appropriate regulatory approval, and has met the appropriate technical standards.
* **Delivering value:** 1 standard that shows thecompany and the evaluator should reach an agreement for ongoing data collection.
* **Deployment considerations:** 1 standard that describes the communication strategies that are in place for service users and health and care professionals.

### Summary of early deployment standards

Tables 8 to 12 summarise the 15 ED standards that are suggested for early deployment technologies being considered for an evidence-generation programme.

Table 8 Design factors standards included in ED standards

|  |  |
| --- | --- |
| Standard | Tiers to which the evidence standard applies |
| [1: incorporate service user acceptability in the design of the DHT](#_Information_that_can) | A, B and C |
| [2: consider environmental sustainability](#_Information_that_can_1) | A, B and C |
| [3: consider health and care inequalities and bias mitigation](#_Standard_3:_consider) | A, B and C |
| [4: embed good data practices in the design of the DHT](#_Standard_34:_embed) | A, B and C |
| [5: define the level of professional oversight](#_Standard_45:_define) | A, B and C |
| [6: show processes for creating reliable health information](#_Standard_56:_show) | B and C |
| [7: show that the DHT is credible with UK professionals](#_Standard_67:_show) | B and C |
| [8: provide safeguarding assurances for DHTs where service users are considered to be in vulnerable groups, or where peer-peer interaction is enabled](#_Standard_78:_provide) | B and C |

Table 9 Describing value standards included in ED standards

|  |  |
| --- | --- |
| Standard | Tiers to which the evidence standard applies |
| [9: describe the intended purpose and target population](#_Standard_8:_describe) | A, B and C |
| [10: describe the current pathway or system process](#_Standard_9:_describe) | A, B and C |
| [11: describe the proposed pathway or system process using the DHT](#_Standard_10:_describe) | A, B and C |
| [12: describe the health and system impacts and associated cost and resource impacts compared with standard or current care](#_Standard_11:_describe) | A, B and C |

Table 10 Demonstrating performance standard included in ED standards

|  |  |
| --- | --- |
| Standard | Tiers to which the evidence standard applies |
| [17: the DHT should comply with relevant safety and quality standards](#_Standard_17:_the) | A, B and C |

Table 11 Delivering value standard included in ED standards

|  |  |
| --- | --- |
| Standard | Digital health technologies (DHTs) it applies in |
| [21: agree a data collection plan to show value](#_Information_that_can_20) | A, B and C |

Table 12 Deployment considerations standard included in ED standards

|  |  |
| --- | --- |
| Standard | Digital health technologies (DHTs) it applies in |
| [23: describe plans for communication, consent and training processes in place to allow the DHT to be understood by end service users](#_Information_that_can_22) | A, B and C |