How To Demonstrate **Clinical Evidence** For **Digital Health Technologies**

Evidence based guidance from:

NICE National Institute for Health and Care Excellence

The **National institute for Health and Care Excellence** (NICE) in the UK produced an Evidence Standards Framework in 2019 (Updated in 2022) to provide a better way for **Digital Health Technologies (DHT)** to demonstrate their value in the UK health and social care system.

This guidance was made for evaluators and innovation teams in the NHS to have a better understanding of **what good looks like** when they are evaluating a DHT for a commissioning or purchasing decision.

To note,

The Evidence Standard Framework is **not a mandatory requirement** for developers of DHTs to follow.

However, it does set out very practical and actionable guidance for developers to understand what **healthcare systems are looking for** and would ultimately want to purchase.

It provides industry members, clinicians and commissioning bodies **a common language** to discuss what is expected and required of DHTs.

Section A:

Technologies **suitable for evaluation** using the evidence standards framework

DHTs are **digital products** intended to benefit people or the wider health and social care system. This may include:

- **Smartphone apps**
- **Standalone software**
- **Online tools** for treating or diagnosing conditions, preventing ill health, or for improving system efficiencies
- Programmes that can be used to **analyse data** from medical devices such as scanners, sensors or monitors.

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** or in vitro diagnostic (IVD), also called software in a medical device (SiMD)

. 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 digital health technologies

Classifying digital health technologies (DHTs) by **intended purpose** 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.

There are **three tiers (A, B, C)** depending on the clinical utility. The **higher the clinical utility**, the **more evidence required**.

Figure 1: DHTs classified by intended purpose and stratified into risk tiers

Tier A

DHTs intended to **save costs** or **release staff time**. No direct patient, health or care outcomes.

- SYSTEM SERVICES

Tier B

DHTs for helping citizens and patients to **manage their own health** and wellness

- COMMUNICATING ABOUT HEALTH AND CARE
- HEALTH AND CARE DIARIES
- PROMOTING GOOD HEALTH

Tier C

DHTs for **treating and diagnosing medical conditions**, or guiding care choices. Includes DHTS with direct health outcomes, and those that are likely to be regulated as **medical devices**.

- INFORM CLINICAL MANAGEMENT
- DRIVE CLINICAL MANAGEMENT
- TREAT SPECIFIC CONDITION
- DIAGNOSE A SPECIFIC CONDITION

Section C:

Evidence standards tables

The standards are presented in groups related to phases of the DHT product life cycle. **There are 21 standards** arranged in **5 groups**:

Design factors: Standard 1 to 9	Key aspects of the **design process** that impact the DHT's value to the health and care system, including ensuring the technology has the **appropriate technical standards** for safety and reliability.
Describing value: Standard 10 to 13	The 4 standards apply across all tiers and provide information to build the **value proposition of the DHT.**
Demonstrating performance: Standard 14 to 16	Standards 14 to 16 are designed to help ensure that the DHT meets its **performance expectations**.
Delivering value: Standard 17 to 18	The 2 standards apply to DHTs in all tiers and show how DHTs should demonstrate their **value for money**.
Deployment Considerations: Standard 19 to 21	The 3 standards help to ensure that the **claimed benefits** of the DHT can be **realised in practice**, and apply to all 3 tiers.

Design Factors

Standard 1:
The DHT should comply with relevant safety and quality standards

Companies should demonstrate that all **safety and quality standards** relevant to their DHT **have been met**. (UKCA, CQC, GDPR, DTAC, Local information governance).

Standard 2:
Incorporate intended user group acceptability in the design of the DHT

Describe how representatives from **intended user groups** were **involved in the design, development or testing** of the DHT

Standard 3:
Consider environmental sustainability

The company should provide a narrative description of any **expected environmental sustainability benefits** and negative impacts from using the DHT.

Standard 4:
Consider health and care inequalities and bias mitigation

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**.

Standard 5:
Embed good data practices in the design of the DHT

Good data practices are essential to creating high-quality data-driven DHTs. Any **datasets used to train, validate or develop** the DHT should be of a **high quality**.

Standard 6:
Define the level of professional oversight

During the design of the DHT, the company should define the anticipated **level of professional oversight needed** when the DHT is used in practice.

Standard 7:
Show processes for creating reliable health information

The developer should be able to show that processes are in place to maintain any health information provided by the DHT, which are **valid, accurate, updated and comprehensive**.

Standard 8:
Show that the DHT is credible with UK professionals

Show that **relevant health or 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 9:
Provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-to-peer interaction is enabled

Show that **appropriate safeguarding measures** are in place around **peer support** and other communication functions enabled through the DHT.

Describing Value

Standard 10:
Describe the intended purpose and target population

Describe the **target population** and **intended purpose** for the DHT. Include any **inclusion and exclusion criteria** that apply.

Standard 11:
Describe the current pathway or system process

Map out the **existing care pathways or system processes** for the intended purpose and target population using **national clinical guidelines**, **national guidance** or **academic literature** and **consultation with healthcare professionals** and **service users.**

Standard 12:
Describe the proposed pathway or system process using the DHT

Provide details of how the proposed care pathway or system process using the DHT will be **different to the current pathway or system process** described for standard 11.

Standard 13:
Describe the expected health, cost and resource impacts compared with current care or system processes

Describe the **anticipated health benefits** and other outcomes (such as system efficiency, care outcomes, or structural and procedural effects) associated with using the DHT.

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).

Demonstrating Performance

Standard 14:
Provide evidence of the DHT's effectiveness to support its claimed benefits

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.**

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

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/best practice** in the UK.

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

The company and evaluator should agree a plan for **ongoing data collection.**

Delivering Value

Standard 17:
Provide a budget impact analysis

Provide a **budget impact analysis** relevant to the setting the DHT is used in. This can be done using information about the **value proposition** given in response to standards 10 to 13, and the **outcomes from studies** shown in standard 14, or the **real-world evidence** in standard 15.

Standard 18:
For DHTs with higher financial risk, provide a cost-effectiveness analysis

A DHT with **higher financial risk** is where the **costs of commissioning, purchasing or implementing the DHT** are deemed to be **substantial** within the context of the relevant budget and system priorities.

When needed, a cost-effectiveness analysis in the form of **cost–utility or cost-consequences analysis** should be done to inform the budget impact analysis in standard 17.

Deployment Considerations

Standard 19:
Ensure transparency about requirements for deployment

The company should provide **clear descriptions of the data used in deployment** including the minimum infrastructure requirements for deploying the DHT.

Standard 20:
Describe strategies for communication, consent and training processes to allow the DHT to be understood

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.**

Standard 21:
Ensure appropriate scalability

The company should ensure that **load testing** has been done, to show that the DHT can **perform to the scale needed.**

Section D:

Early deployment standards for evidence-generation programmes

NICE acknowledges that 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 create the early deployment (ED) subset of standards, they have **removed standards** that are likely to only be met by DHTs at a **later point** in their evidence-generation plan.

Notably Standards **14, 15, 17 and 18**.

REFERENCES:

NICE National Institute for Health and Care Excellence

Evidence standards framework for digital health technologies

Corporate document

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www.nice.org.uk/corporate/ecd7

Hope you found this helpful!