

Evidence standards framework for digital health technologies: user guide

What are digital health technologies?

Digital health technologies comprise a wide range of products used in the health and care system including apps, software and online platforms that are intended to benefit people or the wider health and care system. They may be standalone or combined with other products such as medical devices or diagnostic tests.

Digital health technologies have the potential to empower people, allow more convenient care, reduce numbers of appointments, and help people who may be isolated from standard care. They are often highly scalable with low costs.

For the purposes of the evidence standards framework, digital versions of medical textbooks, teaching aids or similar resources are not considered to be digital health technologies.

The evidence standards framework is designed to be used for digital health technologies that are being considered for commissioning in the UK health and care system.

Why was the framework developed?

Evaluating digital health technologies in terms of their potential user and system benefits is challenging.

Digital health technologies are rapidly developed and iterated upon, with new versions being regularly released. There is generally less or lower quality evidence for digital health technologies compared with the evidence available for drugs or devices; this reflects their rapid development, and the challenges faced by smaller technology companies in accessing clinical trial expertise and research funding. In addition, there are specific issues with digital health technologies around data security, privacy and confidentiality, which are difficult to assess by non-specialists.

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These challenges have created barriers to digital health technologies being commissioned and inconsistencies across the UK in how these commissioning decisions are made.

The framework was developed to provide a set of evidence standards that should be used to show the value of digital health technologies in the UK health and care system.

NICE has been commissioned to produce this framework in order to support principle 8 of the [code of conduct for data-driven health and care technology](#) (generate evidence of effectiveness for the intended use and value for money) but will also be relevant for other principles.

What is the aim of the framework?

The framework describes the types and levels of evidence needed to show the effectiveness and expected economic impact of a digital health technology. It aims to establish consistent criteria against which digital health technologies can be assessed.

The framework has 3 components:

- Evidence for effectiveness standards, based on the functional classification of the digital health technology for its intended use(s).
- Evidence for economic impact standards.
- Supporting resources, including case studies.

The framework is not designed to describe an evaluation process for digital health technologies; evidence will still need to be critically appraised on an individual technology basis.

The evidence standards framework is not intended to assess the safety of digital health technologies, which is the responsibility of other frameworks such as the Medical Device Regulations or the NHS digital clinical safety regulations ([DCB0129](#) and [DCB0160](#)).

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Who will use the framework?

The framework has been designed with a range of intended users in mind, specifically:

- Technology developers, including commercial organisations of any size, when considering the appropriate evidence-generation plan for a digital health technology.
- Research funders and investors who are considering funding the development of digital health technologies.
- Evaluators and others, including commissioners.

What doesn't the framework cover?

The evidence standards framework is not suitable for all digital health technologies.

Because the framework has been designed for digital health technologies that are commissioned in the UK health and care system, it is less relevant to those that are downloaded or purchased directly by users (such as through app stores). The framework's relevance for technologies that are available free of charge to users will vary depending on the business model of the technology.

The framework may be used with digital health technologies that incorporate [artificial intelligence using fixed algorithms](#). However, it is not designed for use with digital health technologies that incorporate [artificial intelligence using adaptive algorithms](#) (that is, algorithms which continually change). Separate standards (including principle 7 of the [code of conduct for data-driven health and care technology](#)) will apply to these.

Does the evidence standards framework replace other existing guidance, standards or regulations?

The evidence standards framework is designed to be complementary to existing guidance, standards and regulations on the use of digital health technologies, including but not limited to:

- The [code of conduct for data-driven health and care technology](#)
- The EU medical device directives (and, when fully implemented, the Medical Device Regulations), and any associated guidance from the Medicines and Healthcare products Regulatory Agency. This [flow chart](#) helps developers of digital health technologies understand if their technology is considered a medical device. The International Medical Device Regulators Forum has produced [guidance](#) on clinically evaluating software as a medical device.
- The Care Quality Commission [regulation of digital healthcare providers in primary care](#).
- NHS Digital information standards on clinical risk management in health IT systems ([DCB0129](#) and [DCB0160](#)).
- NHS Digital's [digital assessment questions \(DAQ\)](#).
- Information governance requirements that are specific to each trust or local authority, which may include completing data protection impact assessments for each technology being commissioned.
- Public Health England's [public health profiles](#).
- Guidance from professional bodies on using digital health technologies.

What about data privacy and confidentiality?

The requirements in these areas are within the scope of the [digital assessment questions \(DAQ\)](#).

How does the evidence standards framework define risk?

Risk to service users

Functional classification (as described in section A of the framework) allows digital health technologies to be stratified by their potential risk to service users. Service users are patients, carers and people in the wider health and care system who may benefit from the technology.

In this context, risk is defined as the chance of harm coming to the service user from using the digital health technology. This could include:

- Unintended consequences of the technology.
- Consequences for the service user's health and wellbeing if the technology does not work as intended.
- Consequences for the service user's health and wellbeing if the care provided by technology is not of good quality.

Economic risk

The evidence for economic impact standards (section B of the framework) describe the levels of [economic analysis](#) that should be done for digital health technologies that present different levels of economic risk.

In this context, risk is defined as a chance of harm coming to the commissioning organisation from the digital health technology, specifically any harm associated with the expected cost and system impact of commissioning such a technology. This could include:

- Commissioning a technology that has a high initial cost in relation to the available budget.
- Commissioning a technology that needs services to be redesigned, and which would affect staffing, training or associated facilities.

How does functional classification work for technologies with more than 1 function?

Some digital health technologies may fit into more than 1 functional classification.

For these technologies, the highest risk function should be used to define its functional classification. For example, a digital health technology may provide both information on and treatment for a condition; of these 2 functions, providing treatment is the highest risk. So this would be classed as a tier 3b digital health technology.

Some digital health technologies have various levels of functionality depending on the level of service that is commissioned.

For these technologies, the highest risk function that is being considered for commissioning should be used to define its functional classification. For example, a digital health technology that provides health information, self-management tools and active monitoring could be classed as tier 2 (inform), tier 3a (self-manage) or tier 3b (active monitoring), depending on what level of service is being commissioned.

How can a technology be assessed if its functionality changes over time?

The rapid development of digital health technologies means that their functional classification may change over time.

If a digital health technology's functionality changes significantly, its functional classification may also need to be changed (such that different evidence standards may apply).

How does functional classification work for technologies that are used with other digital or medical devices?

Many digital health technologies work in combination with other hardware or software.

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If a digital health technology is used with otherwise standard medical or diagnostic devices, the evidence standard framework should be used only to assess the digital health technology itself.

If the digital health technology is an integral part of the product, the highest risk function of any digital component (such as apps, standalone software and online platforms) should be used to define the functional category. Any other relevant regulations still apply to the digital health technology, hardware and any other software components. These may include regulations such as CE marking of medical devices or NHS clinical safety standards.

What about health and fitness trackers and other similar apps?

The evidence standards framework has been developed to be used for digital health technologies that are being considered for commissioning in the UK health and care system. This includes health and fitness trackers and other similar apps if they are commissioned for use by people with specific health and care needs.

However, the framework may have the potential to be used more widely. For example, the framework could be applied to health and fitness trackers and other similar apps intended to be used by the wider public and which are offered for direct download or purchase.

How was the framework developed?

In developing this framework, NICE reviewed existing frameworks for categorising and assessing digital health technologies, as well as the published literature on digital health technology evaluation systems.

Between June 2018 and January 2019, the following stakeholders provided comments and feedback:

- industry representatives and developers
- healthcare commissioners

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- academic experts in health technology assessment and digital health technologies
- clinical experts with special interests in digital health technologies
- organisations responsible for promoting innovations such as Academic Health Science Networks and Digital Accelerators.

The standards were subject to a targeted consultation with relevant stakeholders.

NICE plans to publish details separately on how the evidence standards were developed. Selected studies and other publications that were used in the development of this work include:

- Murray E, Hekler EB, Andersson G et al. (2016) [Evaluating Digital Health Interventions: Key Questions and Approaches](#). American Journal of Preventative Medicine 51(5):843–51
- Nielsen SL and Rimpiläinen S (2018) [Report on International Practice on Digital Apps](#).
- Baumel A, Birnbaum ML, Sucala M (2017) [A systematic review and taxonomy of published quality criteria related to the evaluation of user-facing eHealth programs](#) Journal of Medical Systems 41(8):128
- Grundy QH, Wang Z, Bero LA (2016) [Challenges in Assessing Mobile Health App Quality: A Systematic Review of Prevalent and Innovative Methods](#). American Journal of Preventative Medicine 51(6):1051–9
- Consard Limited, Ruck A, Wagner Bondorf S, Lowe C (2016) [Second draft of guidelines - EU guidelines on assessment of the reliability of mobile health applications](#)
- Lewis TL, Wyatt JC (2014) [mHealth and mobile medical Apps: a framework to assess risk and promote safer use](#). Journal of Medical Internet Research 16(9):e210
- Khoja S, Durrani H, Scott RE et al. (2013) [Conceptual framework for development of comprehensive e-health evaluation tool](#). Telemedicine and e-Health 19(1):48–53
- World Health Organisation (2018) [Classification of digital health interventions v1.0 – A shared language to describe the uses of digital technology for health](#)

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- US Food and Drug Administration (2017) [Software as a Medical Device \(SaMD\): Clinical evaluation guidance for industry and Food and Drug Administration staff](#)
- Medicines and Healthcare products Regulatory Agency (2015) [Medical devices: conformity assessment and the CE mark](#)
- McNamee P, Murray E, Kelly MP et al. (2016) [Designing and Undertaking a Health Economics Study of Digital Health Interventions](#). American Journal of Preventative Medicine 51(5):852–60
- Husereau D, Drummond M, Petrou S et al. (2013) [Consolidated Health Economic Evaluation Reporting Standards \(CHEERS\) – Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force](#). Value in Health 16(2):231–50
- European Network for Health Technology Assessment (2015) [Methods for Health Economic Evaluations – A Guideline Based on Current Practices in Europe](#)
- Michie S, Yardley L, West R et al. (2017) [Developing and Evaluating Digital Interventions to Promote Behavior Change in Health and Health Care](#). Journal of Medical Internet Research 19(6):e232

What future priorities were identified for further development of the evidence standards framework?

NICE published the first version of the evidence standards framework in December 2018. Based on the comments and feedback, we made changes to the framework to incorporate stakeholder responses. These changes were mainly additional clarifications and further explanation of the evidence standards.

Stakeholders also identified wider questions related to the future development and implementation of the framework, which are reproduced here for information.

- Improving its applicability to digital health technologies used in social care.
- Ensuring that the framework aligns with the values and priorities of health and care system users. The rapid development timeline of the framework precluded substantial service user engagement and feedback.

- Monitoring the field of digital health and care to ensure that the framework is aligned with other standards and guidance for digital health technologies as they are published or updated. This could include standards around the use of artificial intelligence in health and care, commissioning standards for the NHS, or any future changes to technical standards set by NHS Digital.
- Continuing to investigate the potential of using [real-world data](#) and [evidence](#) in the framework.
- Continuing to investigate new study designs that may address some of the challenges of conventional trial design.
- Further exploring the challenges of digital health technologies whose function changes over time.
- Ongoing work will be needed by relevant stakeholders in mapping existing emerging standards for digital health technologies.
- Continuing to explore the concept of risk for digital health technologies as a basis for their functional classification.
- Continuing to explore how the evidence requirements for digital health technologies that use artificial intelligence can be determined.

Glossary

Artificial intelligence	<p>Artificial intelligence (AI) is an area of computer science that makes it possible for ‘machines’ to learn from new experiences, adjust outputs and perform human-like tasks. It is generally classified into:</p> <ul style="list-style-type: none"> • Narrow AI, which focuses on a specific task, or works within a narrow set of parameters such as reading radiology scans or optimising hospital workflows. • Strong or general AI, which refers to AI that can learn to do several different tasks. <p>AI can incorporate algorithms that do not automatically change over time (fixed algorithms) or algorithms that are automatically and continually updated (adaptive algorithms).</p> <p>Definition from The AHSN Network Accelerating Artificial Intelligence in health and care: results from a state of the nation survey.</p>
Digital assessment questions (DAQ)	<p>The Digital Assessment Questions (DAQ) is a self-certification tool that includes questions on clinical safety, data protection, security, usability and accessibility, interoperability and technical stability. The DAQ is aligned with the requirements of the General Data Protection Regulation (GDPR). The DAQ is used to assess all products featured in the NHS Apps Library. Further information can be found at the Health Developer Network.</p>
Economic analysis	<p>Study or analysis of the cost of using and distributing health or social care resources.</p>
Real-world data (RWD)	<p>An umbrella term for data regarding the effects of health interventions (for example, safety, effectiveness, resource use, etc) that are not collected in the context of highly-controlled RCT's. Instead, RWD can either be primary research data collected in a manner which reflects how interventions would be used in routine clinical practice or secondary research data derived from routinely collected data. Data collected include, but are not limited to, clinical and economic outcomes, patient-reported outcomes (PRO) and health-related quality of life (HRQoL). RWD can be obtained from many sources including patient registries, electronic medical records, and claims databases.</p> <p>Definition from imi GetReal glossary.</p>
Real-world evidence	<p>The evidence derived from the analysis and/or synthesis of real-world data.</p> <p>Definition from imi GetReal glossary.</p>