Developers guidance

Understanding routes to NICE health technology assessment

Downloaded on December 4th, 2024

This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

United Kingdom

From:

 National Institute for Health and Care Excellence (NICE)

Last reviewed: 30 October 2023 Last updated: 02 November 2023



Understand how NICE does health technology assessments.

Planning for a NICE evaluation

NICE evaluates and produces guidance on many new products for the health and social care services in England. This includes digital health interventions, medical devices and diagnostics.

Your digital technology could be eligible for a NICE evaluation. Planning for a NICE evaluation in your evidence generation plans may:

- increase the likelihood of a positive recommendation by NICE. This will increase the likelihood of adoption of your technology across the NHS
- reduce delays in adoption of your technology
- help you create evidence generation plans that support your value proposition.

A key step in early planning is finding out about NICE's topic selection process.

Adopters may use NICE evidence standards when deciding whether to buy your digital technology. They may particularly use <u>NICE's evidence standards framework for digital</u> health technologies.

So it is important to consider these, even if your technology is not evaluated by NICE. For more details, see generating evidence for health technology assessment.

NICE evaluation: how it does it

NICE carries out evaluations through a range of programmes, which require different evidence. Each programme has a methods and processes manual that explains how guidance is developed.

The programmes relevant to digital technologies (including those driven by artificial intelligence) are the:

- <u>diagnostic assessment programme</u> for diagnostic technologies that are likely to improve patient outcomes. This includes digital health technologies, monitors and predictive tests
- <u>medical technologies evaluation programme</u> for technologies that deliver the same or greater benefit at a lower cost than existing technologies
- technology appraisal programme for technologies that are likely to incur extra cost for the NHS

 <u>interventional procedures programme</u> for procedures used for diagnosis or treatment

Each programme has an independent committee. It reviews the evidence for each technology and makes recommendations about using it in health and social care.

NICE's <u>topic selection process</u> makes sure technologies selected for evaluation reflect national priorities for health and care. Many technologies will not be eligible for a NICE evaluation. Typically, technologies will need to:

- have a CE or UKCA mark
- be a tier C intervention within <u>NICE's evidence standards framework for digital</u> health technologies, and
- have enough evidence to support the <u>value proposition</u>

<u>Early Value Assessment</u> (EVA) is a quick assessment of a digital technology for clinical effectiveness and value for money. It assesses technologies at an early stage in evidence generation and recommends promising technologies for use in the NHS, while further evidence is being collected. If your technology is recommended by EVA, NICE will help you plan for further evidence generation while it's in use. After the evidence has been collected, NICE will produce guidance stating whether the technology should be adopted.

Get your digital technology a NICE evaluation

Register with the <u>NHS Innovation Service</u> to find out if your technology could be eligible for a NICE evaluation.

Generate your evidence in line with NICE's evidence standards and methods guides, such as:

- the NICE health technology evaluations manual
- NICE's evidence standards framework for digital health technologies
- NICE's real-world evidence framework

Contact NICE at digitalhealth@nice.org.uk if you have a technology that fits the <u>EVA</u> criteria.

Consider using <u>NICE Advice</u>. As the NHS in England's health technology assessment body, NICE helps set the evidence standards you need to meet to gain nationwide

market entry. NICE Advice can help you demonstrate the value of your product and make valuable NHS connections, speeding up patient access to the best treatments and care.