Developers guidance

Ongoing research and service evaluation of your digital technology

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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)

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After placing your digital technology on the health and social care market, you may need to produce more evidence to prove its cost and clinical effectiveness. You should plan for this upfront to prevent the delay or further development of your digital technology.

Providing ongoing evidence to support your digital technology

NICE and adopters need to determine the cost and clinical effectiveness of your technology. They do this by looking at the evidence you have generated. This is an essential part of placing your digital technology on the market.

Although preferable, sometimes you may not be able to generate evidence early on. If this is the case, you will need to produce further evidence after your digital technology has launched.

Further research and service evaluation often takes place after you've placed your technology on the market. For example, you may need to do this after you have obtained your UKCA mark.

Planning for research and evidence generation

It is important to plan ahead to produce the best possible evidence to support your digital technology.

Not planning upfront may result in missed opportunities to generate the evidence needed. This could delay or limit further deployment of your technology.

Step 1: knowing the level of evidence required

Determine the appropriate level of evidence you need to generate for NICE or adopters. Determine the appropriate study designs to generate this evidence.

Step 2: find out if you need research approvals

Determine whether you need approval from the Health Research Authority (HRA) for further research. Service evaluations and audits are not considered research and do not need specific research approval.

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Difference between research and service evaluation

There is an important distinction between research and service evaluation.

Service evaluation:

- involves the routine monitoring of data to review the technology's performance in the service it is deployed in
- is essential for adopters to determine the technology's impact on the performance and safety of their service
- does not usually provide appropriate evidence to assess the clinical and cost effectiveness of your technology in practice. So, you are likely to need to do further research in the post-market stage

Research:

- provides evidence to prove the clinical and cost effectiveness of your digital technology
- will require approval from the HRA
- is essential for placing your digital technology on the market

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