Developers guidance

Designing clinical studies and choosing evaluation methods for 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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You need to regularly evaluate your digital technology to show adopters and assessors it's effective and safe.

Supporting your digital technology through evidence

Adopters, health technology assessors and regulators need evidence that shows your technology:

- works in practice
- is clinically effective
- is cost effective, and
- is safe

Spend time thinking about your study designs and evaluation methods. This will help produce the best possible evidence to support your digital technology.

Not planning upfront may result in inappropriate evidence generation. Or, it could result in missed opportunities to generate the most relevant evidence.

Gathering relevant evidence at each stage of the technology's lifecycle

You need to evaluate your digital technology at various stages throughout its lifecycle. The type of evaluation will vary at different stages. Thinking about this early on helps you produce the most relevant evidence at each stage. For example:

- during technology conceptualisation, you may do proof-of-concept evaluation studies
- during technology development, you may do a validation study and a clinical investigation
- during post-market stages, you may do a real-world evidence study. This will show how well your technology works in practice. Follow guidance on how to generate trusted real-world evidence in NICE's real-world evidence framework.

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Steps to designing clinical studies and choosing evaluation methods

Step 1: Level of evidence

Determine the level of evidence required by adopters, health technology assessors and regulators. For more information, see:

- submitting evidence to get a UKCA mark
- generating evidence for health technology assessment
- generating evidence for adopters

Step 2: Designing your evaluation

Design your evaluation and choose your evaluation methods. See information from the Office for Health Improvement and Disparities on how to design your evaluation and choose your evaluation methods.

Step 3: Feasibility of evaluation

Think about feasibility. You may need to weigh:

- the effectiveness of data collection methods, with
- the time and resources needed to do them

Try to get the most out of your studies by answering different questions at once, if possible. For example, capture cost-effectiveness evidence at the same time as safety and performance data.

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