NHS AI and Digital Regulations Service for health and social care

Developers guidance

# Evidence generation when your digital technology is relevant to a national screening programme

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## This is best practice guidance

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

## This Guide covers:

- United Kingdom

## From:

- UK National Screening Committee (UK NSC)

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If you're developing screening tests for the NHS, you will need to generate specific evidence which meets a higher bar.

# Why are screening services different, and why should I generate specific evidence for them?

The NHS website lists the NHS population screening programmes. The advice below refers to screening programmes provided by the NHS only, not to private providers.

Many digital technologies can be used in both diagnosis and screening pathways for the same disease areas. Take the use of mammograms in breast cancer as an example.

Mammograms are used in screening pathways for breast cancer, in which women in a specific age bracket are invited for breast checks. They are also used in diagnosing cancer when a patient presents with symptoms to their GP. This includes women outside the screening age bracket and men with breast cancer symptoms.

People coming for screening tests will be different from people showing up with symptoms. This means the technology may be more or less effective for these different groups. So, the evidence requirements will be different.

An NHS population screening programme may have different evidence requirements than, for example, a service for symptomatic patients in an NHS trust or clinical commissioning group. This is because screening programmes invite healthy people in for a screening test. Because getting it wrong can lead to a healthy person coming to harm, the NHS population screening programmes set high evidence standards before making changes. So, you may have to generate evidence which meets a higher bar. If you do not think this through early on, you will likely have problems. These include:

- getting the marketing authorisation for your technology with the appropriate intended use so that it can be considered in an NHS screening population. For example, if a programme uses nurse practitioners instead of doctors to do screening tests, your medical device's intended purpose will need to be for that type of care professional
- generating appropriate evidence for a national screening programme, which could result in your company's resources or time being wasted on misdirected research

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# What does the UK National Screening Committee do?

Screening programme policy is informed by the expert, independent advice of the UK National Screening Committee (UK NSC). It advises governments across the 4 UK nations on whether new screening programmes should be recommended, what should be included as part of established national screening programmes and whether they should be changed or not. This includes making any major modifications to them such as using a new test that includes AI or digital technology.

The UK NSC reviews peer-reviewed evidence for a technology's effect on the clinical pathway. It will not only take interest in technical accuracy but also downstream resource and impact implications, such as:

- the clinical impact of the screening test on other parts of the pathway such as screening uptake. For example, an invasive screening test might put some people off participating in screening
- the number of patients unnecessarily referred from the screening programme to treatment services, which risks overdiagnosis and overtreatment
- workload and resource requirements
- social and ethical issues. This includes whether a given screening test is more or less effective in a particular demographic group, especially if it is a marginalised group
- patient and clinical acceptability

# What do I need to do?

## Step 1: Determine whether your digital technology is relevant to national screening programmes and might be evaluated by the UK NSC

The UK NSC evaluates any proposed alteration that constitutes a 'major change' to a screening programme. This might include:

- introduction of an alternative screening test to replace the current primary screening test
- introduction of an additional test in the pathway
- evidence of altered cost effectiveness or cost

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The UK NSC does not need to review changes when a technology is used to improve the operational delivery of the existing screening programme pathway (for example, improvements to administration processes). This is because these do not alter the patient's pathway of care.

However, these are not always 'black and white'. For example:

## Step 2: Learn about the UK NSC's evidence requirements and processes

You can learn about this by reading:

- this blog from Public Health England
- section 5.4 of the UK NSC evidence review process

You should also review the UK NSC recommendations on population screening for a condition using previously evaluated technologies. These set out the state of the science at the point of publication and highlight areas in which further research is needed. For example, the UK NSC published a review on use of AI in breast cancer screening. This was followed up with an article in the Lancet addressing important considerations in research into the use of AI in breast cancer screening.

## Step 3: Plan your evidence generation

If you intend to do research within an NHS screening service, you should seek advice from a programme-specific research advisory committee (RAC). RACs advise on the feasibility of proposed changes to a screening programme and review evidence-generation plans. They are hosted by the NHSE Public Health Commissioning and Operations Team.

If you are developing technology with a value proposition relevant for diagnosis of a disease in symptomatic patients and for use in asymptomatic people in a screening pathway, you should research the evidence requirements for both pathways.

You should also make sure this aligns with your technology's intended use. For example, a screening programme might have nurse practitioners screen patients because this is clinically and cost effective. But if the intended use of your technology as per its marketing authorisation is for consultant doctors in secondary care only, it cannot be used by nurse practitioners. If so, you might need to do another clinical trial to get this marketing authorisation.

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## Step 4: Determine the type of proposal you need to submit

Consider whether you are:

- proposing a new topic
- requesting an early update for a topic
- suggesting a modification to an existing screening programme

Check the UK NSC recommendations to determine the current status, if any, of the topic.

## Step 5: Submit your evidence and proposal to the UK NSC

The UK NSC previously invited stakeholders to submit proposals during a 3-month period between 1 July and 30 September each year.

This open call for topics process has been updated and now follows a 2-year cycle.

- The next open call is scheduled to run from 1 July 2026 to 30 September 2026 as announced in the UK NSC blog.
- An exceptions process will allow the UK NSC to consider proposals outside the new 2-yearly open call period if there is significant new evidence that meets specific criteria.

For more information read how to submit a proposal to the UK NSC

**When do I need to consider this?**

You need to learn about the screening programmes and the process for submitting for a major change during technology conceptualisation. This is because you should have a clear value proposition for your technology before you decide on its intended purpose, which then informs your approach for gathering evidence to apply for a UKCA mark.

But the work to demonstrate your value proposition and generate evidence for the UK NSC will start during the technology development stage.

For examples of UK NSC evidence reviews, see:

- use of AI in breast cancer screening: rapid review and evidence map
- automated grading in diabetic eye screening: rapid review and evidence map

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