

What is a trial?

A trial is a type of research study that aims to understand whether a new treatment or test is effective.

What is the NHS-Galleri trial?

The NHS-Galleri trial is a research trial to see how well the new Galleri test works in the NHS. The aim of the trial is to see if using the Galleri test alongside standard cancer testing in the NHS can help to find cancers at an early stage, when they are easier to treat. We would like 140,000 people age 50–77 to give blood samples and take part in this trial.

What organisations are involved?

GRAIL

GRAIL Bio UK Ltd. (GRAIL) is the main funder and organiser of this trial. It is a branch of GRAIL, Inc. in the United States that developed the Galleri test.



NHS England is a partner and will provide follow-up care related to the trial.



The Cancer Research UK & King's College London Cancer Prevention Trials Unit, a team of cancer researchers and trial managers at King's College London will coordinate this trial and analyse the results.

What information about me will be used during the trial?

A lot of different information needs to be collected about people when they take part in a trial. The trial team will collect the following types of information about you:

- Personal contact details, so we can stay in touch with you about the trial.
- Personal healthcare information, such as your GP and NHS records. This includes information about you held by national bodies like NHS Digital, Public Health England and the Office of National Statistics.
- Information you share by filling out the surveys the trial team gives you.

All of this information will be handled and stored securely, in compliance with the Data Protection Act (2018) and UK General Data Protection Regulation. Some of this information will be sent to GRAIL in the US. However, your personal contact details and any information that identifies you directly (like your name, NHS number, address, phone number and email address) will never be sent outside the United Kingdom.

What do I do next?

If you're interested in taking part, please follow the steps on your invitation letter or visit the website at www.nhs-galleri.org to find out more.

Thanks for your time and for reading this leaflet. We hope you consider volunteering to take part in the trial.

Taking part in the NHS-Galleri trial

What you need to know

The Galleri™ test is a new test that looks for potential signs of cancer in a sample of blood.

The NHS-Galleri trial will try to understand if this test works well in the NHS to find cancer early, when it is usually easier to treat.

Researchers need your help to find out whether the Galleri test could help people in the future.

How does the Galleri test work?

Through a simple blood sample, the Galleri test looks at DNA in your blood to determine if any of it may have come from cancer cells.

DNA is the genetic code (a sort of instruction manual) found in cells. When a person has cancer, the cancer releases small pieces of DNA into the bloodstream. Although the Galleri test does not look at the genetic code itself, it looks at the pattern of other markers on the DNA to flag a possible cancer signal.

If a cancer signal is found, the results can point to where in the body the cancer is. However, the signal does not mean that a person *definitely* has cancer. It just means that they *might* have cancer, and they will need to have some follow-up tests to check.

The Galleri test can pick up a signal for more than 50 types of cancer but does not detect all cancer types.

What is involved in taking part?

If you take part, you will be put into one of two groups. You do not have a choice about which group you are put into. The decision will be made by a computer, and you have a 50:50 chance (like flipping a coin) of being in either group. The two groups are:



1. Test group

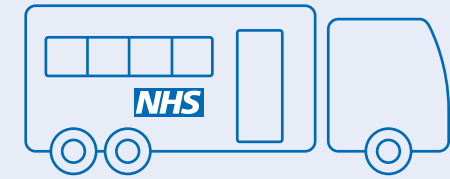
Half of the people who take part in the trial will be in this group. They will give blood samples and their samples will be tested with the Galleri test at GRAIL's laboratory in the US. In this group a **small number** of tests are expected to show a cancer 'signal'. Anyone with a cancer signal will be contacted about their test result and their GP informed. This will be approximately 30 days after their appointment. If your test shows that you have a cancer signal, you will be sent an appointment to see a specialist in the NHS for further tests (like scans or additional blood tests). Most people will not have a cancer signal result and will be tested again in years 2 and 3.



2. Control group

Half of the people who take part in the trial will be in this group. They will give blood samples, but their samples will be stored and tested in the future as part of the trial. They will not receive results, not even after the trial is finished. This is a standard procedure in trials, as it creates a comparison group (control group) that the researchers need for their analysis. This comparison group is an essential part of good research.

Everyone who takes part in the trial will give blood samples. You will be asked to do this up to 3 times over a 2-year period, usually with a year between appointments. At each appointment, you would give a blood sample and fill out surveys.



When you give your blood sample, it will be at a mobile clinic (similar to those used for breast screening and blood donation). This means the appointment will be somewhere local to you. Weekend and evening appointments will be available and clinics use COVID safe practices.

You yourself may not benefit from taking part but you will be helping with important cancer research.

Do I have to take part?

No. Taking part in this trial is voluntary.

If you volunteer to take part, you can also change your mind at any point during the trial. You can let the trial team know you do not want to take part anymore. You do not have to give a reason.

What happens to my blood samples after the trial is over?

Everyone will be asked if their samples can be used for research to further improve the Galleri test, and to develop other tests and see how well they work.