

## The GEMINI Project

### (Grampian's Evaluation of Mia in an Innovative National breast screening Initiative)

The mammogram images taken at your breast screening appointment will be used in a technology evaluation unless you choose to opt out. If you do not wish for your images to be used in the evaluation you must let us know. You can opt out before your appointment by contacting us using the details in the blue box on the third page, or at your appointment by telling the person who checks you in, or by telling the person who takes your mammogram.

You can find more information about the project in this leaflet, or at <https://www.nhsgrampian.org/about-us/innovation-hub/gemini/>.

### What is the purpose of the evaluation?

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Normally, mammograms (breast x-rays) are looked at by two or more qualified healthcare professionals (often called 'readers'), to decide if more tests are needed. In this evaluation, a piece of new technology using artificial intelligence (AI) software, called 'Mia', will also look at your mammogram, in addition to the standard two human readers. We want to see how the Mia AI performs when compared to readers, and if it improves breast cancer detection.

By taking part in this project, you will be supporting an important evaluation to help us improve the ways we detect breast cancer.

We expect using the Mia AI will result in a small number of women having further follow up tests in order to detect more breast cancers.

### What happens if I do not opt out of the evaluation?

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When you arrive at your appointment, the person who checks you in can answer any questions you may have. **You can also let them know if you do not want to take part in the project.**

Your appointment will go ahead as normal. You will **not** need to have any extra x-rays or a longer appointment. After your mammogram, the readers will look at your mammogram and decide if more tests are needed.

Following the two human reader review, the Mia AI will look at your mammogram and suggest whether more tests are needed. If the human readers and the Mia AI have different opinions, your mammogram will be sent for an extra review by a further human reader. The human readers will assess the Mia AI opinion before they make a final decision on whether further tests are needed. We do not expect the readers and the Mia AI to differ in their opinions very often and only a very small number of women are expected to be offered a follow up visit as a result. However, it is possible that the Mia AI may find some subtle changes that human readers cannot see. It is always

a human who makes the final decision, which is the same as it would be for your usual mammogram appointment.

You will receive a routine letter from the breast screening clinic after your appointment to tell you the outcome of your mammogram. Some people may also receive a phone call and a letter from the project team. There may be a short delay in receiving your results but NHS Grampian expects to contact you within three weeks of your appointment.

The breast screening clinic will inform your GP of your participation in the project.

### **What happens if I opt out?**

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If you would like to opt out, your mammogram will not be reviewed by the Mia AI and you will receive your mammogram as normal. Please tell the person who checks you in, or the person who takes your mammogram, if you would like to opt out. You can also inform us before your appointment by using the contact information in the blue box below.

### **What may be the benefits?**

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If your mammogram is looked at by the Mia AI, you may benefit from an additional check. If there are signs of breast cancer, finding them early means treatment is more likely to be successful and it is less likely you will be recommended to have a breast removed (mastectomy).

### **What are the risks?**

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Using the Mia AI to look at mammograms could mean that more women are called back for further tests. You may feel anxious about having further tests, but not all women who are called back will be diagnosed with cancer. In the breast screening programme, about 5 in every 100 women are asked to come back for more tests after screening. Out of these 5 women, 1 will have cancer. The other women will not have cancer and will continue to receive their regular screening invitation every three years in line with the normal screening service.

There are risks associated with breast screening which you can read more about in the booklet included with your breast screening invitation. This might include being diagnosed with, and treated for, a cancer that may not spread and may not cause you harm. Unfortunately, healthcare professionals cannot always tell whether or not the cancer will spread in the future and so you may have to make some difficult decisions about going forward with treatment. While treatments save lives, they can also cause serious long-term side effects. If there are choices about your treatment then you'll receive information and support to help you decide what is right for you.

## What happens to my personal information?

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The NHS will ensure that any information collected about you during the project is held securely and in a way which protects your privacy. The NHS will work with health data science experts from the University of Aberdeen to fully assess the performance of the Mia AI. Before this assessment begins your data will be de-identified to protect your privacy. The evaluation will then be carried out in the Grampian Data Safe Haven (DaSH). DaSH will provide secure access to de-identified data and only for a limited number of individuals who are part of the following groups:

- Approved Scientists from The University of Aberdeen
- NHS Grampian
- Approved researchers from Kheiron Medical Technologies who are the manufacturers of the AI software
- Other statistical consultants and researchers who work with the project team

We may publish results of the project however it will not be possible to identify any individuals from these publications. All personal information will be de-identified before being analysed. All results will be fully checked by Grampian Data Safe Haven personnel to ensure there is no risk of identifying any screening participants ahead of results being released for publication.

### Where can I find further information?

You can find out more at this website: <https://www.nhsgrampian.org/about-us/innovation-hub/gemini/>

By phoning: **01224 550570**

Or by emailing: **[gram.nhsggemini@nhs.scot](mailto:gram.nhsggemini@nhs.scot)**

## What happens if I change my mind about taking part?

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It is only possible to opt out of having your mammogram read by the Mia AI before your mammogram is taken. If you have any worries about the evaluation work after your mammogram appointment you can contact the project team using the contact details above.

## How will we use information about you?

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We will need to use information from your breast screening records for this project. You will be assigned a breast screening participant ID number which will link your screening details and results to your mammogram image. People who do not need to know who you are will not be able to see your name or contact details. We will keep all information about you safe and secure.

The scientific team who are assessing the Mia AI results will only be able to access de-identified data so they will not know who you are and it will not be possible for them to work out that you took part in the project.

### **What are your choices about how your information is used?**

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You can stop being part of the project up to a fixed point without giving a reason (see “What happens if I change my mind about taking part?”), but we will keep information about you that we have already collected. We need to manage your records in specific ways for the evaluation to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

### **Where can you find out more about how your information is used?**

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You can find out more about how we use your information

- By asking one of the project team
  - By ringing us on 01224 550570
  - By sending an email to [gram.nhsggemini@nhs.scot](mailto:gram.nhsggemini@nhs.scot)
- By contacting Kheiron’s Data Protection Officer, Joe Stock
  - By sending an email to [privacy@kheironmed.com](mailto:privacy@kheironmed.com)

### **Who is funding this project?**

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The project is funded by the AI in Health and Care Award from a group of government research bodies: the National Institute for Health Research (NIHR), the Accelerated Access Collaborative (AAC) and NHS England (NHSE). This grant money was awarded to Kheiron Medical Technologies, who make the Mia AI software, to evaluate the AI within breast screening programmes across the UK.

### **The GEMINI project is supported by:**

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