

## The LIBRA Study (Leeds Investigation of BReast screening AI)

At your breast screening appointment, the images taken will be used in a research study unless you choose to opt out. If you do not wish for your images to be used in this way you must let us know. You can opt out at your appointment by telling the person who checks you in or the person who takes your mammogram.

You can find more information about the study in this leaflet, in the Frequently Asked Questions (FAQs) leaflet or at [www.kheironmed.com/libra-study/](http://www.kheironmed.com/libra-study/).

### What is the purpose of the study?

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Normally, mammograms (breast x-rays) are looked at by two qualified healthcare professionals (often called 'readers'), to decide if more tests are needed. In this study, a piece of new technology using artificial intelligence (AI) software (known as 'Mia') will also look at some mammograms in the background, in addition to the two readers. We want to see how the AI performs when compared to readers, and the impact of introducing AI into breast screening. For example, we'd like to understand if the AI might help us find more cancers and how humans may interact with the AI in the real world.

By taking part in this study, you will be supporting important research to help us decide the best way to detect breast cancer.

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

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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 study.**

Half of eligible women (1 in 2) will be chosen at random to have their mammogram looked at by our AI, as well as two readers. Your appointment will go ahead as normal and you will not need to have any extra x-rays. You will find out your results in the usual way.

### What happens if I opt-out?

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If you would like to opt-out, your data will then not be used for this research study and you will receive your mammogram as normal, without any additional input from the AI. Please let the person who checks you in or the person who takes your mammogram, know if you would like to opt out.

## What are the benefits?

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The long history of breast screening shows human readers miss a very small number of breast cancers on mammograms. It is possible a small proportion of women whose cancers may have been missed by human readers will benefit from earlier cancer detection by having AI involved. This is because AI and humans do not analyse mammograms in the same ways.

## What are the risks?

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Using 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 most people who need further tests will not be diagnosed with breast cancer. In the breast screening programme, about 4 in every 100 women are asked to come back for more tests after screening. Out of these 4 women, 1 will be found to have cancer. The rest will not have cancer and will go back to having screening invitations every three years.

There are some risks associated with breast screening. These include being diagnosed with and treated for breast cancer that would never otherwise have been found and would not have become life-threatening. This is the main risk of screening. Unfortunately, healthcare professionals cannot always tell whether a breast cancer that is diagnosed will go on to be life-threatening or not, so they offer treatment to all women with breast cancer. This means that some women will be offered treatment that they do not need. If there are choices about your treatment then you'll receive information and support to help you decide what is right for you. This risk is no more or less likely in this study.

You can read more about the risks and benefits of breast screening in the pink booklet you received with your breast screening invitation. This leaflet is also available online:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1031049/BSP01\\_plain\\_text\\_A4\\_PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1031049/BSP01_plain_text_A4_PDF.pdf)

### Where can I find further information?

You can find out more at this website: [www.kheironmed.com/libra-study/](http://www.kheironmed.com/libra-study/)

Or by contacting the research team:

By phoning: **0113 2063677** or **0113 2063666**

Or by emailing: [leedsth-tr.breastscreeningunit@nhs.net](mailto:leedsth-tr.breastscreeningunit@nhs.net)

**Please use the above contact details if you have any questions or would like to make a complaint.**

### Can I speak to an independent advisor?

Yes, you can contact Clare Bridge, Principal Radiographer at Seacroft Hospital:

By phoning: **0113 2063765** or **07768 028430**

Or by emailing: **clare.bridge1@nhs.net**

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

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If you do not opt out at first but later decide that you do not want to take part in the study after your mammogram is taken, we will keep all of your previously collected data. The AI will have already read your mammogram so it is not possible to withdraw your data from the AI. However, we will not collect any further information about you and will not include your data in the analysis of the study.

The option to withdraw from the study is only available for a fixed time (about 2 months after the final woman joins the study).

To withdraw from the study after your mammogram is taken, you can contact the research team using the contact details above in the blue box.

### Who has reviewed and approved this study?

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Research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and received favourable ethical opinion by South East Scotland Research Ethics Committee.

### How will we use information about you?

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We will need to use information from your breast screening records for this research project.

This will include assigning you a breast screening participant ID number which links your screening details and results to your mammogram image. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number, your breast screening participant ID, instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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

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You can stop being part of the study up to a fixed point (see “**What happens if I change my mind about taking part?**”), without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research 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

- At [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- Our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- By asking one of the research team
  - By ringing us on **0113 2063677** or **0113 2063666**
  - By sending an email to [leedsth-tr.breastscreeningunit@nhs.net](mailto:leedsth-tr.breastscreeningunit@nhs.net)
- By contacting Kheiron's Data Protection Officer, Joe Stock
- By sending an email to [privacy@kheironmed.com](mailto:privacy@kheironmed.com)

## Who will my information be shared with?

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In order to carry out the research, the de-identified data we collect may be shared with:

- Kheiron Medical Technologies who are the Sponsor of this study and manufacturer of Mia
- The Research Ethics Committee (REC) who approved the research
- Researchers at King's College London
- Other statistical consultants and researchers who are supporting the Sponsor with this study.

## Who is funding this study?

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The study 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 AI software and are Sponsoring this study, to evaluate the AI within breast screening programmes across the UK.

### Glossary of key terms:

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**Artificial Intelligence (AI):** Artificial intelligence or AI is the term used to refer to a computer system taught to mimic some human behaviours such as problem solving and decision making. There are lots of interesting uses of artificial intelligence, from speech recognition to learning to play complex board games. Using artificial intelligence to support the diagnosis of health conditions is another way of using this technology.

**Sponsor:** In clinical research, a Sponsor is the person or organisation who takes overall responsibility for the conduct and management of the research project. In this study, the Sponsor is Kheiron Medical Technologies who is the manufacturer of Mia.

**Pseudonymised or De-identified data:** This refers to data where identifying pieces of information are replaced with a code so that the data cannot be used to identify an individual unless more information is available. This method is often applied to data in research so that only the researchers who need to know who you are have the identifying set of data, but the rest of the research team will not know who you are.