The LIBRA Study
Frequently Asked Questions (FAQs)
(Leed's 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 information sheet you received with your appointment letter or at www.kheironmed.com/libra-study/

About the study

What is the name of this study?
The study is called 'LIBRA' which stands for 'Leeds Investigation of BReast screening AI'.

Who is organising this study?
The study is Sponsored by the Kheiron Medical Technologies, and they have overall responsibility for the conduct of the research. Kheiron is the manufacturer of the AI software. You can find out more about Kheiron at www.kheironmed.com

The Chief Investigator, the medical professional who leads the study, is Dr Nisha Sharma, Director of Breast Screening and Clinical Lead for Breast Imaging at Leeds Teaching Hospitals NHS Trust.

Which screening services are taking part in this study?
Only the Leeds/Wakefield Breast Screening Programme managed by Leeds Teaching hospital NHS Trust is taking part in the LIBRA study.

How many people will be involved?
The study plans to recruit about 7,000 women to take part in the research. This is the number needed to correctly evaluate the AI software in breast screening.

About the Artificial Intelligence (AI) Software

Who developed the AI?
The AI software, known as 'Mia', has been developed by Kheiron Medical Technologies. Kheiron's aim is to help readers detect cancers earlier, while helping radiology departments run more efficiently and

manage patient care more effectively. You can read more about Kheiron on their website: https://www.kheironmed.com/

What do we already know about the AI?
The AI software, known as 'Mia', has been carefully developed over a number of years by Kheiron's machine learning experts. Mia has already been evaluated in three previous research projects, where previous data from breast screening appointments was used to assess how the AI would perform if used live by the breast screening clinics.

In the first study, Mia looked at 3854 mammograms from one breast screening clinic. It was found that Mia could read mammograms at the recommended human performance guidelines. This study provided evidence that Mia is safe to use.

In the second study, Mia looked at a very large number of mammograms, over 275,000 cases. This was across seven breast screening sites in two countries. Again, this study showed that using Mia within double reading breast cancer screening can maintain the standard of care expected from human readers and potentially save some of the workload for breast screening clinics.

Mia has also been evaluated on a set of over 58,000 mammograms from NHS Grampian in Scotland. Again, Mia performed well on this dataset compared to the human readers and identified a number of extra cancers previously missed by human readers.

How have the patients and public been involved in developing the AI?
Kheiron has set up a Patient and Public Involvement (PPI) Advisory Board which includes women of breast screening age, some of whom have experienced breast cancer themselves. Staff at Kheiron work closely with the PPI board to jointly plan some of the work that Kheiron does, including designing and producing materials for research studies like this one.

Our PPI Advisory Board also helps us plan which healthcare problems we should try to tackle and how they would like to see AI applied in practice.

Taking part

What are the criteria for taking part in this study?
If you do not opt out of the study, you will be included in the research providing the following criteria are met to ensure that the study is right for you:

1. You are attending your mammogram for routine breast screening purposes (i.e. you were aged between 50 and <71 years of age when offered your appointment)
2. You are identified as female in the breast screening records
3. You do not have cosmetic or medical breast implants
4. You are not at known high risk of breast cancer
5. The images taken during your mammogram can be read by the AI

Do I have to take part?
No. You are welcome to opt out of taking part in the study without any change to your normal mammogram appointment. If you would like to opt out, please inform the person who checks you in or the person who takes your mammogram.

What happens if I do not opt out of the study?
If you do not opt out of the study, you will continue to have your mammogram as normal. Afterwards, the qualified healthcare professionals from the breast screening team (often called 'readers') will look at your mammogram and consider if more tests are needed.

All women in the study will have their mammograms looked at by readers as normal. At random, half of the women in the study will also have their mammogram looked at by the AI.

If you are in the group whose mammograms are looked at by the AI software (called Mia), the human readers will review the AI opinion and take it into consideration before making a final decision about your mammogram. It is always a human who makes this final decision, as it would be for your usual mammogram appointment.

You will be informed of the results of your mammogram by letter. You may be recalled for further tests and you can find more information about this 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

How will a decision to opt out be recorded?
If you decide to opt out of the study, this will be recorded on the National Breast Screening System (NBSS) which is used to keep information on your mammogram. This means your data will not be shared for the purposes of this research and you will not be included in the study.

Can I request to have my mammogram read by the AI?
No, you cannot request to have your mammogram read by the AI software. This is a randomised controlled trial which means that some women (50%) will have their mammogram looked at by the AI plus usual reading by healthcare professionals, whereas some women (50%) will have their mammogram read by healthcare professionals as per the standard of care. Evaluating the AI software in this way means we can better understand the benefits and safety of using AI in breast screening.

Whether your mammogram is looked at by the AI or not will be chosen at random if you decide to take part in the LIBRA study. It is not possible to request to have your mammogram read by the AI outside of the study.

Will I be paid for participating in the study?
No, participants will not be paid for taking part in the study.

If I choose to opt out or withdraw from the study, will it affect my participation in the standard breast screening programme in any way?
If you choose to opt out of the study, you will continue to receive your mammogram as normal and standard care as part of the breast screening programme. The AI software will not be involved in reading your mammogram or any decisions made about further tests required.

If you choose to withdraw after your mammogram has been taken, your mammogram may have already been read by the AI software as part of the study. However we will not collect any more data

about your mammogram once you choose to withdraw. You will continue to receive standard care from the breast screening programme.

Data, privacy and ethics

Who is responsible for study conduct and data management?
The Sponsor, Kheiron Medical Technologies, is ultimately responsible for the conduct of the study and for keeping your data secure and confidential. You can find out more about the work that Kheiron is doing by exploring their website: www.kheironmed.com

The day to day conduct of the study is managed by the Chief Investigator, Dr Nisha Sharma, who is the Director of Breast Screening and Clinical Lead for Imaging at Leeds Teaching Hospitals NHS Trust.

What data will be collected during the study?
The data needed to carry out the research includes demographic information (e.g. things like your date of birth, sex and ethnicity), information about your mammogram and any follow up appointments needed (e.g. things like the date of the appointment, the opinions of the readers who look at your mammogram and other clinical information), as well as taking some data from the mammogram image that is produced.

People who do not need to know who you are will not be able to see identifiable information about you. Your data will have a code number instead (often referred to as 'pseudonymised' or 'de-identified' data).

What rights do I have over the data collected?
Due to the purposes of the research, data subject rights may be limited. If you have a request or question about your data subject rights, you can contact Kheiron's Data Protection Officer, Joe Stock, using the email address privacy@kheironmed.com.

You have the right to make a complaint to the Information Commissioner's Office about the use of your data. You can contact them on 0303 123 1113 or by using their website https://ico.org.uk/global/contact-us/.

Please remember that you may opt out of the study if you do not want your data to be used for this research.

Where will my data be sent to and what security measures will be used?
In order to carry out the research, the data we collect may be shared with:

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

Data will always be kept within the EU Economic Area (EEA) and we will be handled in line with guidance from NHS Digital. You can find out more about this here: https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/nhs-and-social-care-data-off-shoring-and-the-use-of-public-cloud-services

Will my GP be told if I am part of this study?
No, we will not contact your GP to let them know if you take part in this study or opt out.

What happens to my research data after the study?
The results of the research will be written into reports and papers which may be published in scientific journals and conferences. We will write these reports in a way that no-one can work out that you took part in the study.

Leeds Teaching Hospitals NHS Trust will keep a copy of the research data along with your original breast screening ID number. Kheiron, the Sponsor, will only keep a coded copy of your research data, without any identifying information. The Sponsor will keep the research data collected for a minimum of 10 years in case it needs to be checked.

Further help and information

Who should I contact in the event of medical questions or problems during the study?
You can contact the research team if you have any questions or problems:

You can find out more at this website: www.kheironmed.com/libra-study/

By phoning: 0113 2063677 or 0113 2063666

Or by emailing: leedsth-tr.breastscreeningunit@nhs.net

You are also very welcome to talk to the staff at your mammogram appointment if you have any questions.

What happens at the end of the study?
At the end of the study, the data collected will be analysed to understand how human readers interact with AI and the benefits AI can bring to breast screening.

The results will be written up into a report to be published in a scientific journal.

Will I receive information on the study results once the study is over?
We will not contact participants individually to inform them of the study results. However we will provide updates on the LIBRA study page on the Kheiron website: www.kheironmed.com/libra-study/ and at the breast screening clinic.

What insurance and indemnity provisions are in place for the study?
Kheiron is responsible for insurance and/or indemnity to meet the potential legal liability of the sponsor for harm to participants arising from the management or design of the research. For the potential legal

liability of investigators/collaborators arising from harm to participants in the conduct of the research, NHS indemnity scheme or professional indemnity applies.

Glossary of Key Terms

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.

Chief Investigator: In clinical research, a Chief Investigator is the overall lead researcher for the project and takes on the day-to-day responsibility for the project's conduct.

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.