KHEIRON
MEDICAL TECHNOLOGIES

Mia®: AI in breast cancer screening and safety considerations.

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Contents

- Introduction to Kheiron and Mia
- Safety considerations and initiatives

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Introduction

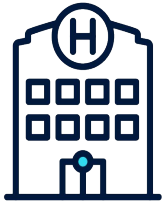
Kheiron Medical Technologies

- Small/medium UK AI startup founded in 2016
- Focus on breast screening
- Clinical rigour and robust evidence generation

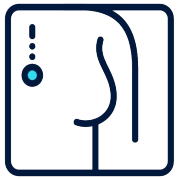
"Giving any woman, anywhere a better fighting chance against breast cancer"

Introduction

Challenges in breast screening programmes



High stress, cognitive load, burnout



Unnecessary recalls, poor participant experience

Shortage of trained breast radiologists

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Mia™

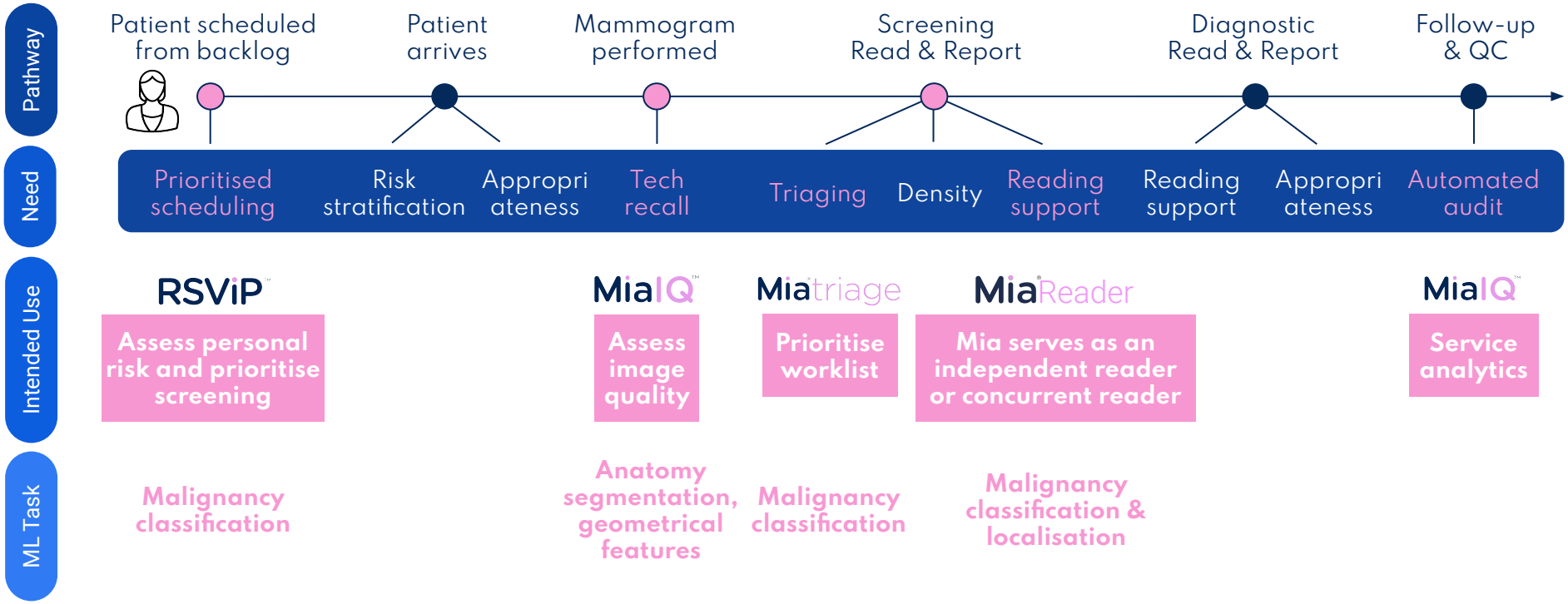
By Kheiron Medical

Giving **any** woman, **any**where a better fighting chance against breast cancer

Mia® is our breakthrough AI platform for breast screening. A suite of solutions, Mia is designed to empower radiologists and screening services to deliver confident, accurate and timely results to any woman, anywhere.

Introduction

Breast cancer screening solutions along the clinical pathway



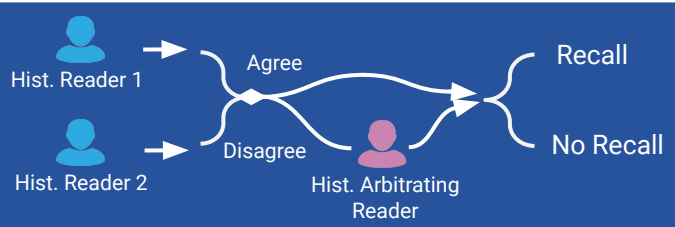
Introduction

Mia as an independent reader

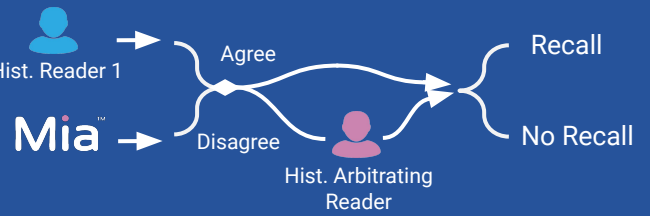
Case-Wise Recall Suggestion

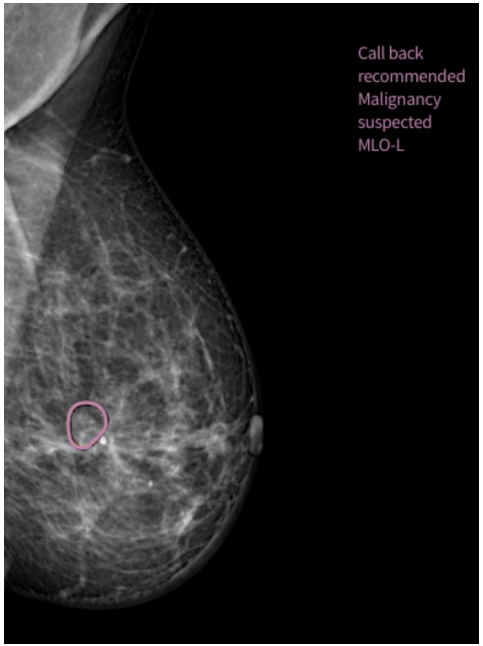
Mia™ suggests a decision for the entire case, just like asking a radiologist

Historical Double Reading



Double Reading with Mia™





Introduction

First winner of UK Government's AI in Health and Care Award 2020

- Evidence generation – national policy
- Independent evaluation
- Clinical confidence – trusted by Radiologists and readers
- Genuine patient and public involvement and support
- Generalisability
- Retrospective Study
- Prospective Study
- Safely deploy Mia into NHS Breast Screening

The AI in Health and Care Award

Congratulations to innovators

NHS

NIHR | National Institute for Health Research

ACCELERATED ACCESS COLLABORATIVE

KHEIRON MEDICAL TECHNOLOGIES

Safety considerations and initiatives

KHEIRON
MEDICAL TECHNOLOGIES

Safety considerations

Data protection

- **Pseudonymisation** of patient information before extracting from sites or being handled by Mia
- Worked closely with **data protection consultants** to generate data protection positioning and supporting documentation
    - Supporting NHS Trust IG teams to ensure comfort and compliance
- Involvement in ICO workshops to held **drive the agenda on information governance in AI**
- **Strict security and privacy processes** and procedures to ensure that pseudonymised patient information is handled safely
- **Appropriate consent models** as and when prospective data will be used for research

KALEIDOSCOPE
Data Privacy Consultants

ico.
Information Commissioner's Office

Information Security Management ISO 27001 Certified

Safety considerations

Regulatory and standards compliance

- **CE marked** - class IIa medical device
- **ISO 13485** (quality management system standard for medical devices), **14971** (standard for risk management) and **62304** (standards on software lifecycle process/development) compliant
- Protocols designed to comply with NHS Digital standards, **DCB0129 and DCB0160**
- Protocols designed to comply with **CONSORT-AI, SPIRIT-AI and DECIDE-AI guidelines**

Safety considerations

Deployment methodology

1. Understand

Understand your clinical and business objectives, workflow, processes & technical environment.

2. Connect

Connect your systems to the Mia cloud & configure your workflows. Test end-to-end.

3. Validate
(live data first, historical data if required)

Check Mia's performance with local population & data.

4. Train

Train clinical & administrative teams to work confidently with Mia.

5. Launch
(live data)

Put approvals, processes and communications in place. Go live.

6. Monitor
(live data)

Continuously monitor performance and impact.

Mia goes live, used within clinical care setting

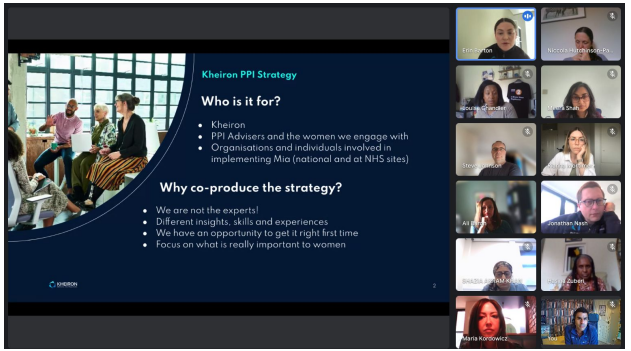
Safety considerations

Patient and Public Involvement (PPI)

By engaging with the people who are impacted by breast cancer we are able to focus our products on solving the problems they care about.

Our PPI efforts have been cited as **industry leading** and include:

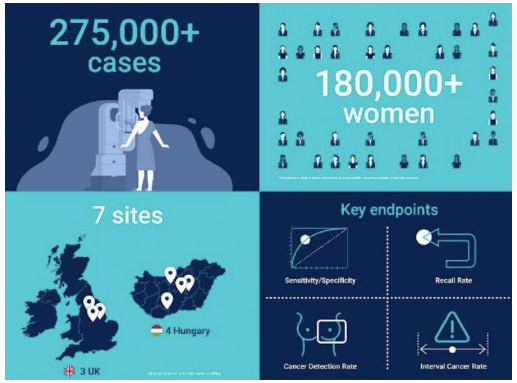
- **A PPI Advisory Board** curates the insight, knowledge, and experience to guide product development and deployment
- **Literature review and interviews** to enlighten our understanding of attitudes and beliefs around the adoption of AI in screening
- **Collaboration with PPI Leads at hospitals to** ensure all views are represented in what we deliver
- Co-designing **high quality information materials** to educate, inform, and engage women about our work



Safety considerations

Generalisability

- Previous run trial was across 7 sites and two countries using;
    - **unenriched data**, representative of real world screening populations & **clinically relevant** endpoints
- AI Award will build on this across the UK
    - including building **prospective evidence and monitoring processes**
    - government funded UK wide collaborative partnerships
- Reducing algorithmic bias
    - partners that cover all **ethnicities and demographics**
- Global partners and **active research**
    - RSNA panel - importance of **inclusivity and diversity** in healthcare AI

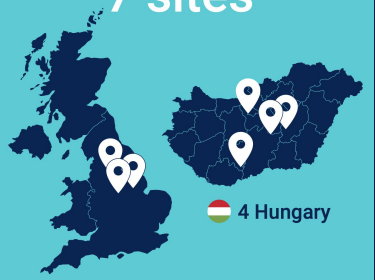


Clinical evidence – retrospective study

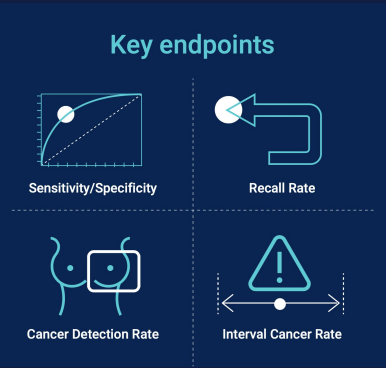
250,000+ cases

180,000+ women

7 sites



Key endpoints



20+ stratifications

INCLUDING:

Vendor

Consistent performance demonstrated across 4 mammography device manufacturers

Invasivity

Insights into performance for aggressive cancers

Prevalent/Incident

Performance on first screening visit

Tumor Size

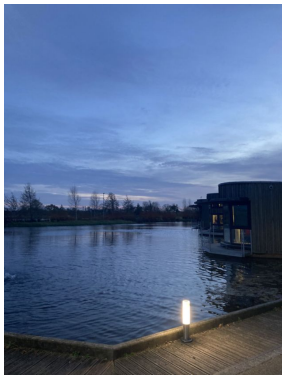
Safety considerations

Case study work with NHS Digital and AAIP

- Involvement as a case study in the **Safety Assurance FRamework for Machine Learning in the Healthcare Domain (SAFR)** project
- Including a detailed review of the **Assurance of Machine Learning in Autonomous Systems (AMLAS)** framework
- Contextual review of the CIEHF **Human Factors and Ergonomics in Healthcare AI**
- **Clinical Risk Management Training - Assuring AI in Healthcare** Training day

ASSURING AUTONOMY INTERNATIONAL PROGRAMME

NHS Digital



Thank you

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