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CASE STUDY · MARLUC SYNOPSIS

PRAIM: AI in German mammography screening

IMPLEMENTED 2021–2023 · HEALTH AND LIFE SCIENCES · GERMANY · BAND C · PARTLY PROVED

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A prospective, observational study put AI support into routine German breast screening at 12 sites and compared it with standard double reading. Detection was 17.6% higher with a non-inferior recall rate. Radiologists chose whether to use the AI, the vendor funded the study, and outcomes after screening are not yet reported.

ABOUT THIS SYNOPSIS

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NOTICE WORDING LAST UPDATED 16 NOVEMBER 2026

AT A GLANCE

Frontier case: AI used for a scientific, medical or engineering breakthrough. The transformation is potential and unproven; MarLuc grades what has changed in practice so far.

AI used: Deep-learning image analysis in breast screening: Vara MG tagged very low-suspicion mammograms as normal and raised a safety-net alert on very high-suspicion ones that a radiologist had read as unsuspicious.

Implemented: 2021–2023. Grade: band C, Process change, Partly proved.

Headline result, as reported: In a real-world study of 463,094 women at 12 German screening sites, AI-supported double reading found 6.7 cancers per 1,000 against 5.7 with standard double reading, with a similar recall rate

1 · The case

The facts, as reported by the 2 sources listed at the end. Where a source is silent, the field says "Not reported".

Organisation

University of Lübeck and 12 sites of the German Mammography Screening Programme, with Vara. The German Mammography Screening Programme, which per the study release screens over 3 million women aged 50 to 75 each year. The study covered 12 sites, 119 radiologists and women aged 50 to 69. Canvas block: 4. Operations and process. Also 5. People and skills.

Business challenge

The challenge. Per the authors, screening could improve in sensitivity, leading to lower interval cancer rates, and in specificity, reducing false-positive recalls. Retrospective AI studies could not know the outcome for women flagged only by the AI.

How it was addressed. Radiologists in a reader set chose whether to use the AI-supported viewer. The AI tagged highly unsuspicious examinations as normal and raised a safety-net alert on highly suspicious examinations that the reader had read as unsuspicious. Both radiologists in the double reading kept their role and the final recall decision stayed with them. [1] [2]

Who implemented it

University of Lübeck (University or research lab): Led the study; Alexander Katalinic is named as principal investigator..
Vara (Software vendor): Supplied Vara MG, funded the study and took part in its design, analysis and writing..
Radiologists at the 12 participating screening sites used the software in routine work.

Technology (SEAM pillar E)

SEAM types: T8 Predictive / ML models. Deployment: Not reported. Vendors and products: Vara, Vara MG.

Where it was built in: An AI-supported viewer in the radiologists' reading workflow in the organised screening programme. It offered "normal triaging" of low-suspicion examinations and a "safety net" prompt on high-suspicion examinations that the reader had judged unsuspicious. Mammography hardware from five vendors was in use.

What changed

Before: two radiologists read each mammogram in a standard viewer. In the study: the same two readers, one or both using an AI viewer that tags likely normal cases and prompts a second look at likely cancers. [1] [2]

What it cost

Not reported

What it saved

Detection 6.7 against 5.7 per 1,000. Recall 37.4 against 38.3 per 1,000. Reading time in the AI group: normal-tagged examinations median 16 seconds against 30 seconds for unclassified and 99 seconds for safety-net examinations; control group reading time could not be measured. In a simulation where normal-tagged examinations were not read by radiologists, detection stayed 16.7% higher and recall fell by 15.0%. Cost saving: Not reported. [1] [2]

Governance and control

Radiologists kept the final decision and ethics approval and registration are documented. The study was funded by Vara, which also took part in its design and analysis, and three authors are Vara employees. Accountable programme owner and any post-study decision to adopt: Not reported.

S2 · Accountable owner · Claimed
The release names Alexander Katalinic of the University of Lübeck as principal investigator; Vara and the university shared the work. [1] [2]

A1 · Safe use · Claimed
Per the paper, women were informed about the AI software at each site and the study was approved by the University of Lübeck ethics committee. Safety limits beyond the non-inferiority design on recall are not reported. [1]

A2 · Human in the loop · Evidenced
The paper reports the safety net was triggered 3,959 times, shown 2,233 times and accepted 1,077 times, with the radiologist keeping the final recall decision. [1]

A3 · Monitoring and assurance · Evidenced
The authors report logging of AI predictions, reading times and outcomes, and changed their analysis plan after learning that radiologists were choosing when to use the AI viewer. [1]

A4 · Vendor AI · Claimed
Vara MG is described as a CE-certified medical device. The paper discloses that Vara funded the study, took part in its design, analysis and writing, and that three authors are Vara employees with stock options. [1]

A5 · Agent controls · Not reported
No agents described.

A6 · Standards and regulation · Evidenced
The protocol was registered (German Clinical Trials Register DRKS00027322) and approved by the ethics committee of the University of Lübeck (22-043). [1]

What worked, what did not, what is unproven

WORKED

– Detection was 17.6% higher than standard double reading, with the confidence interval above zero (+5.7% to +30.8%).

– The recall rate was non-inferior and slightly lower (37.4 against 38.3 per 1,000).

– Positive predictive value was higher for recall (17.9% against 14.9%) and for biopsy (64.5% against 59.2%).

– Detection was higher in all subgroups of screening round, breast density and age (between +12% and +23%).

DID NOT

– The study was not randomised: "PRAIM is an observational study with no random assignment of screening examinations to the AI-supported and standard-of-care groups".

– Radiologists chose when to use the AI viewer, which created a bias towards higher cancer prevalence in examinations read without AI. The authors changed the analysis plan and used propensity-score weighting to correct it.

– The recall difference (-2.5%, 95% CI -6.5% to +1.7%) is non-inferior, not shown to be lower.

UNPROVEN

– Effect on interval cancers and on stage at diagnosis: the authors say these "are subject to

– Effect on outcomes for women; the principal investigator says this will be the focus of future investigations.

– Whether results hold once radiologists are past the learning phase; the authors note the data come from early AI use.

– The workload simulation assumes AI-normal examinations are never read by humans. That was not done in practice.

Timeline

Jul 2021 Data collection starts at 12 screening sites in Germany [1]

Feb 2023 Data collection ends; 463,094 women screened [1]

Jan 2025 Nature Medicine publishes the results [1]

2 · Grade and SEAM assessment

MarLuc's opinion, made on the evidence above. How cases are graded: marluc.co.uk/case-studies/how-we-rate

Level of change and impact

Claimed: A. Grade: C, Process change. Proof: Partly proved. Level of change: Process change.

Process change (Level 2, band C). AI was built into the reading workflow at 12 screening sites. The release describes "transformative potential" (claimed A); that is potential and unproven.

The SEAM view and lessons learnt

This is a large, careful, real-world study, and it is the right second source beside a randomised trial. Its limits are plain in the paper: it is observational, self-selected by readers, and funded and co-written by the vendor. The finding is better detection at similar recall. Whether women live longer or have fewer advanced cancers is not shown. For a larger organisation, the transferable point is that real-world rollout data are useful, but a vendor-funded design needs independent analysis to carry the same weight.

1. Keep independent researchers in control of analysis when a vendor funds the study.
2. Record how staff choose to use the tool, because that choice can bias results.
3. Follow results through to interval cancers and stage at diagnosis as well as detection.

Evidence

Score 2 of 4. Partly independent: peer-reviewed prospective study in Nature Medicine with ethics approval and a trial register entry; observational, vendor-funded, with vendor employees as authors.

Evaluation method. Prospective, observational, multicentre real-world noninferiority implementation study with propensity-score adjustment; peer reviewed, registered as DRKS00027322.

Sources disagree. The abstract gives 463,094 women screened; the results text gives 461,818

3 · Original sources

Read these in full. To challenge a fact or a grade, use the contact form at marluc.co.uk or the link on https://marluc.co.uk/case-studies/praim-ai-mammography-screening-germany

[1] Nature Medicine (2025): Nationwide real-world implementation of AI for cancer detection in population-based mammography screening
https://www.nature.com/articles/s41591-024-03408-6

[2] EurekAlert: University of Lübeck press release on the PRAIM results
https://www.eurekalert.org/news-releases/1069807

University of Lübeck and 12 sites of the German Mammography Screening Programme, with Vara website: https://www.uni-luebeck.de

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