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CASE STUDY · MARLUC SYNOPSIS

MASAI trial: AI-supported mammography screening in Sweden

IMPLEMENTED 2021–2026 · HEALTH AND LIFE SCIENCES · SWEDEN · BAND C · PARTLY PROVED

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A randomised trial inside the Swedish national screening programme tested AI that sorts mammograms into single or double reading. Radiologists' reading workload fell by 44% and more cancers were found at screening. The final result on interval cancers met the non-inferiority test; the lower rate is not shown to be statistically significant, and long-term outcomes are not yet known.

ABOUT THIS SYNOPSIS

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Facts and figures are as reported by the sources listed below, which may be incomplete, self-reported or out of date. Check the original source before relying on any figure.

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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. MarLuc grades what has changed in practice so far.

AI used: Deep-learning image analysis in breast screening: the Transpara system gave each mammogram a risk score from 1 to 10, sent most to one radiologist and the highest-risk to two, and marked suspicious areas.

Implemented: 2021–2026. Grade: band C, Process change, Partly proved.

Headline result, as reported: In a randomised trial of 105,915 Swedish women, AI-supported mammography screening cut radiologists' screen reading by 44% and found 29% more cancers; the interval cancer rate was non-inferior (1.55 against 1.76 per 1,000)

1 · The case

The facts, as reported by the 5 sources listed at the end. Where a source is silent, the field says "Not reported".

Organisation

Lund University, with Skåne University Hospital and the Unilabs Mammography Unit, Malmö. Academic and clinical research team at Lund University, Skåne University Hospital and the Unilabs Mammography Unit in Malmö, running a trial inside the Swedish national breast screening programme. Women aged 40 to 80 were eligible; four screening sites took part. Canvas block: 4. Operations and process. Also 5. People and skills.

Business challenge

The challenge. Per the authors, European guidelines recommend that two radiologists read every mammogram, yet some cancers still go undetected in screening, and there are health professional workforce shortages. Retrospective studies had suggested AI could improve accuracy and cut reading workload, but no randomised trial had tested it.

How it was addressed. Women were randomly allocated 1:1 by the picture archive system to standard double reading or AI-supported screening. The AI system (Transpara version 1.7.0) gave each examination a risk score from 1 to 10. Scores 1 to 9 went to a single radiologist and score 10 to two radiologists, and the radiologists saw the scores and computer-aided detection marks for the highest-risk examinations. [1] [2] [3] [4] [5]

Who implemented it

Lund University (University or research lab): Designed and ran the trial with Skåne University Hospital and the Unilabs Mammography Unit in Malmö..
ScreenPoint Medical (Software vendor): Supplied the Transpara AI system used for triage and detection support..
The MASAI authors are academic and clinical; vendor involvement in the trial design is not reported in the sources opened.

Technology (SEAM pillar E)

SEAM types: T8 Predictive / ML models. Deployment: Not reported. Vendors and products: ScreenPoint Medical, Transpara version 1.7.0.

Where it was built in: Used in the reading workflow of the Swedish national screening programme at four sites (Malmö, Lund, Landskrona, Trelleborg). Examinations were randomised through the picture archive and communications system; the AI risk score decided single or double reading and AI marks were shown to the radiologist.

What changed

Before: two radiologists read every screening mammogram. In the trial: one radiologist read most examinations and two read those the AI scored as highest risk, with AI marks as support. Radiologists were not replaced. [1] [2] [3] [4] [5]

What it cost

Not reported

What it saved

Workload: 61,248 screen readings against 109,692, a 44.2% reduction (2025 paper); 44.3% in the 2023 safety analysis. Detection: 6.4 against 5.0 cancers per 1,000, ratio 1.29, with recall and false-positive rates not significantly higher. Interval cancers: 82 of 53,043 (1.55 per 1,000) against 93 of 52,872 (1.76 per 1,000), non-inferior. Sensitivity 80.5% against 73.8%. Cost saving: Not reported. [1] [2] [3] [4] [5]

Governance and control

A prespecified safety analysis was run before the main results, a human radiologist read every examination, and the AI version was fixed. Lund University says many Swedish regions have begun to implement AI-supported screening; that is the lead researcher's statement and the sources opened do not name the regions.

S2 · Accountable owner · Claimed
Lund University names Kristina Lång as study lead; the trial is registered as ClinicalTrials.gov NCT04838756. [1] [3]

A1 · Safe use · Evidenced
The peer-reviewed 2023 paper reports a prespecified clinical safety analysis at 80,000 women, with a lowest acceptable cancer detection rate of more than 3 per 1,000. [3]

A2 · Human in the loop · Evidenced
AI triaged examinations to single or double reading by radiologists; the authors say the approach "still requires at least one human radiologist". [3] [5]

A3 · Monitoring and assurance · Evidenced
The papers report a prespecified safety analysis, then protocol-defined analyses of detection and of interval cancers after two years of follow-up. The lead author says continuous monitoring should be in place when AI is introduced. [2] [3] [4] [5]

A4 · Vendor AI · Evidenced
The papers name the exact product and version (Transpara 1.7.0, ScreenPoint Medical, Nijmegen). Funding came from the Swedish Cancer Society, the Confederation of Regional Cancer Centres and Swedish government clinical research funding. [2] [4]

A5 · Agent controls · Not reported
No agents described.

A6 · Standards and regulation · Evidenced
Randomised, registered, population-based trial inside the Swedish national screening programme, with a prespecified 20% non-inferiority margin for the primary outcome. [2] [3]

What worked, what did not, what is unproven

WORKED

– Screen-reading workload fell by about 44% in both the 2023 and 2025 analyses.

– Cancer detection rose from 5.0 to 6.4 per 1,000 (ratio 1.29, 95% CI 1.09 to 1.51) without a significant rise in recall or false positives.

– The primary outcome, interval cancer rate, met the prespecified non-inferiority test (ratio 0.88, 95% CI 0.65 to 1.18).

– Sensitivity was higher with AI (80.5% against 73.8%, p=0.031) at the same specificity (98.5%).

DID NOT

– The interval cancer result is a non-inferiority finding. The confidence interval (0.65 to 1.18) includes 1 and p=0.41, so the 12% lower rate is a descriptive difference, not a demonstrated reduction.

– The authors say the study does not support replacing health professionals with AI.

UNPROVEN

– Whether earlier detection lowers breast cancer deaths: no mortality data are reported.

– Results in later screening rounds and cost-effectiveness; the lead author says further studies are needed.

– Whether the results hold with other AI systems, other mammography devices, other countries and less experienced radiologists; the authors list these as limitations.

– Whether the extra in situ cancers found (68 against 45) are clinically relevant; the papers report the counts and grades, and the long-term effect is not known.

Timeline

Apr 2021 Trial begins randomising women at four screening sites in southwest Sweden [4]

Dec 2022 Recruitment ends with 105,934 women randomly assigned [4]

Aug 2023 Lancet Oncology safety analysis of the first 80,033 women: workload down 44.3%, detection similar; trial not halted [3]

Mar 2025 Lancet Digital Health screening-performance analysis: 29% more cancers detected, workload down 44.2% [4]

Dec 2025 All participants complete two years of follow-up [1]

Jan 2026 Lancet publishes the primary interval cancer result [2]

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: Not applicable. Grade: C, Process change. Proof: Partly proved. Level of change: Process change.

Process change (Level 2, band C). The screening process was redesigned around AI triage and proved in workload and detection, in a randomised trial. Whether routine practice has changed rests, in the sources opened, on the lead researcher's statement.

The SEAM view and lessons learnt

This is the strongest kind of evidence in the library: randomised, pre-registered, peer reviewed and publicly funded, with a safety stop-rule written in advance. The result is a workload saving and better early detection, with the human reader kept in place. The gap that remains is outcome: interval cancers are a proxy and the trial was not designed to show fewer deaths. For a larger organisation, the transferable point is to fix the safety limit and the primary measure before the first patient and to keep a person responsible for each decision.

1. Test the AI against the current method in live operations before rollout.
2. Set the safety limit and the primary measure before the trial starts.
3. Keep a trained person reading every case and monitor results after rollout.

Evidence

Score 3 of 4. Independent: peer-reviewed randomised trial (Lancet Oncology 2023, Lancet Digital Health 2025, The Lancet 2026), publicly and charity funded. Limits: one AI product, one country, no mortality data.

Evaluation method. Randomised trial: 1:1 population-based, single-blinded, non-inferiority screening-accuracy trial (NCT04838756), with prespecified safety, screening-performance and interval cancer analyses.

Sources disagree. Lund University and the Lancet press release describe a 12% reduction in interval cancers; the paper reports a non-inferior ratio of 0.88 with a confidence interval that includes 1. Lund University says 19% fewer large interval cancers, where the paper and press release give 38 against 48, which is 21%.

Status. Complete: primary results published January 2026. The lead author says follow-up studies on later screening rounds and cost-effectiveness are needed.

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/masai-ai-mammography-screening-sweden

[1] Lund University: AI support in breast cancer screening: Fewer missed cancer cases
https://www.lunduniversity.lu.se/article/ai-support-breast-cancer-screening-fewer-missed-cancer-cases

[2] The Lancet (2026) via PubMed: Interval cancer, sensitivity, and specificity comparing AI-supported mammography screening with standard double reading without AI in the MASAI study
https://pubmed.ncbi.nlm.nih.gov/41620232/

[3] The Lancet Oncology (2023) via PubMed: AI-supported screen reading versus standard double reading in the MASAI trial, clinical safety analysis
https://pubmed.ncbi.nlm.nih.gov/37541274/

[4] The Lancet Digital Health (2025) via PubMed: Screening performance and characteristics of breast cancer detected in the MASAI trial
https://pubmed.ncbi.nlm.nih.gov/39904652/

[5] EurekAlert: Lancet press release on the final MASAI results
https://www.eurekalert.org/news-releases/1114399

Lund University, with Skåne University Hospital and the Unilabs Mammography Unit, Malmö website: https://www.lunduniversity.lu.se

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