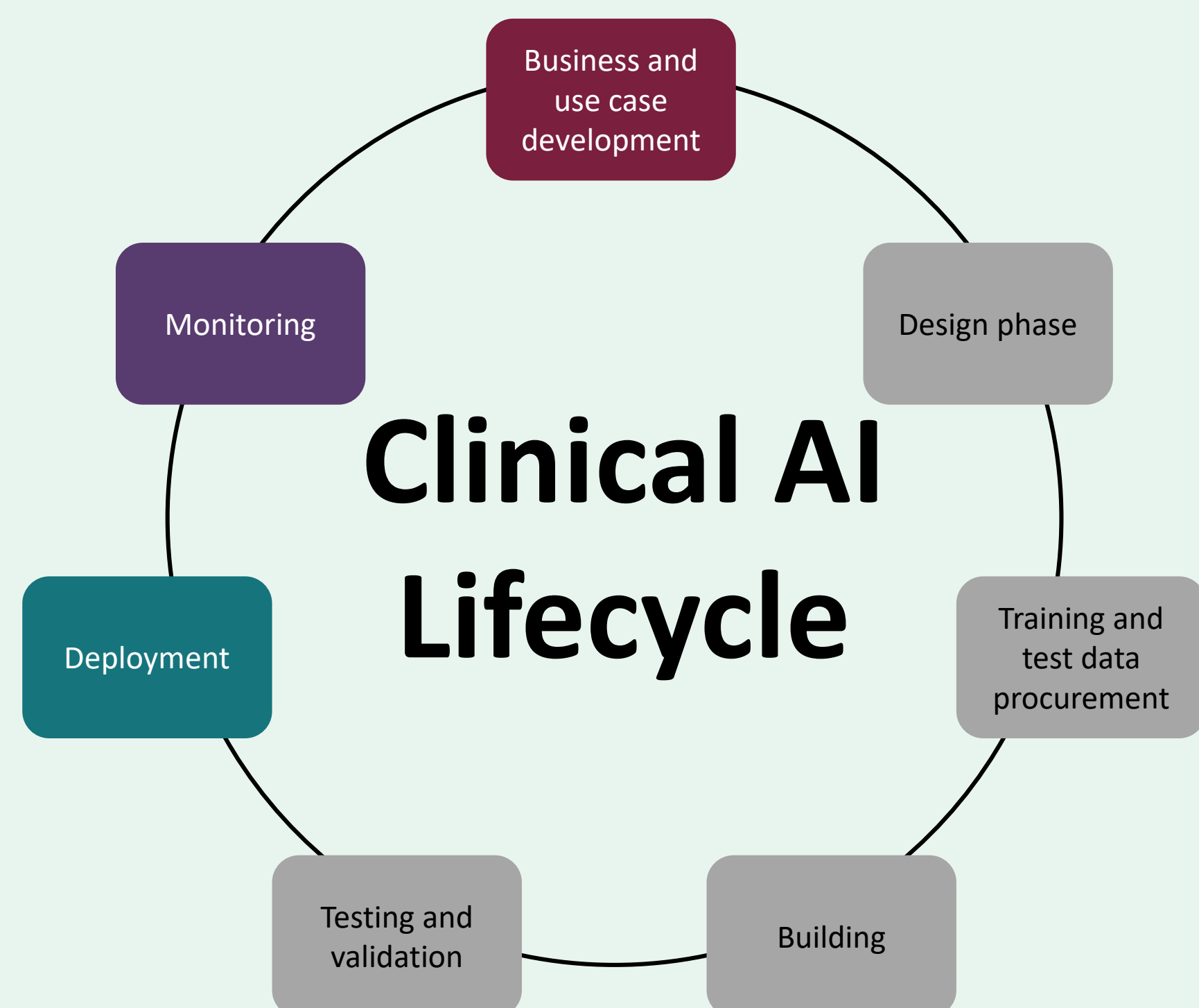


EDITH: From pixel to patient

The challenges of large-scale deployment of AI in breast screening

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What's gone before?

The Digital Mammography DREAM Challenge (2016-17)¹: Of 1,000 women screened, ~100 are recalled but only 5 diagnosed. Global open competition offering up to \$1,000,000 for the best AI model to reduce breast cancer screening recall rates.

iCAIRD (Imaging Centre of AI Research and Development, 2023)²: First evidence of real-world AI performance drift: recall rates shifted significantly following software updates, raising patient safety concerns about clinical AI monitoring.

GEMINI (2026)³: Prospective evaluation showing AI algorithms detect substantially different cancer populations - no single system is sufficient, and head-to-head comparison in a common framework is essential before widespread adoption.

These works demonstrate that clinical AI works in breast cancer screening in single, controlled environments. EDITH goes further, rising to the challenge of large-scale, multi-site deployment and monitoring:

- **Two intervention arms: triage then 2 human reads, one human and one AI read**
- **5 AI vendors, multiple PACS systems, a variety of mammogram machines**

Business and Use Case Development

2.28M screening mammograms generated in the UK per year.
At least 2 specialist readers needed per mammogram.
Some mammograms need additional arbitration reads.
Specialist breast radiology workforce is ageing, retiring, working LTFT, inequitably distributed across the UK.
Previous trials of AI in breast cancer screening have produced promising results but in small, controlled, single-site settings.

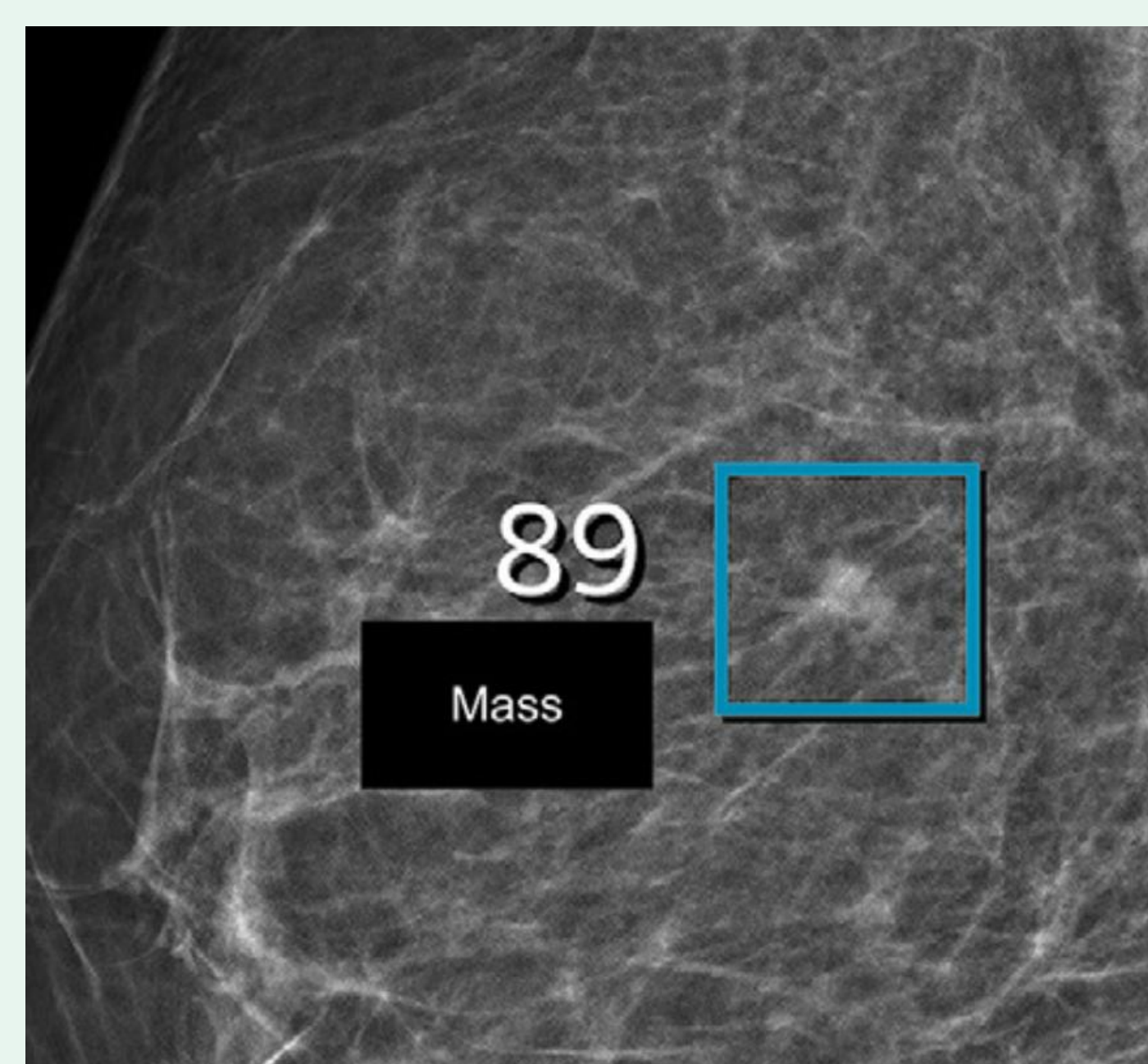


Figure 1: AI-detected suspicious lesion (blue square) on a screening mammogram⁴.

Deployment

The CHALLENGES:

Ethics approval granted in England applies to other UK nations.
Separate information governance approvals in UK nations.
Different breast cancer IT systems in place in each UK nation.
Ethnicity data is recorded differently across the UK.
Opt-out consent processes.
Multiple PACS systems in place across screening sites.

EDITH's solution:

Detailed explanation of ethics included in Scotland information governance application.
Iterative approach to information governance applications, with consistency across UK.
Harmonised approach to data item selection, data flow, and data use.
Ethnicity to be collected in line with each UK nation's census ethnicity categories.
Patient and public involvement has discussed participant consent and digital exclusion.
Large sample to generate data where algorithms only work with specific PACS.

Monitoring

The CHALLENGES:

Mammograms generated on different manufacturers' machines.
Mammogram machines may change during the trial.
Multiple AI algorithms, from a variety of commercial vendors.
Algorithms may be updated during the trial.
Need to monitor recall, cancer detection, and interval cancer rate.

EDITH's solution:

Real-time continuous monitoring system monitors recall rate and cancer detection rate at each trial site, to identify where rates are above or below pre-determined thresholds.
Procedures for reverting to standard of care in place if continuous monitoring system identifies problems. At trial conclusion, all mammograms will be compared against all algorithms (and all versions).

Large-scale, multi-site deployment of clinical AI is a systems problem.

The bottleneck for AI is no longer accuracy; it is now the challenges of deployment and monitoring.

EDITH is trialling large-scale deployment of breast cancer AI. Beyond that, EDITH is building a model for the deployment of clinical AI at scale across large and varied healthcare systems.

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