

Real-world monitoring as the missing piece for deploying independent AI readers in mammography.

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PURPOSE

Evidence is not enough.

AI evidence for mammography screening is now compelling — but evidence from controlled clinical studies does not equal safe real-world deployment. The monitoring gap between trials and practice remains the critical unsolved challenge.

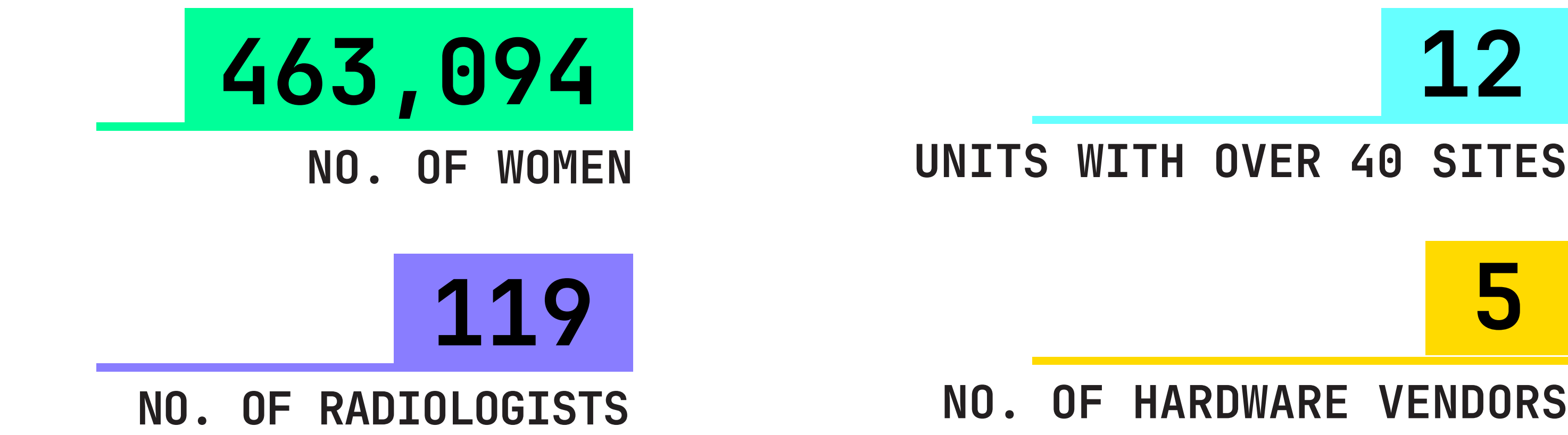


For all >6M reads that have ever been diagnosed on the Vara platform, we have tracked AI predictions, radiologist decisions and clinical outcome data.

BACKGROUND

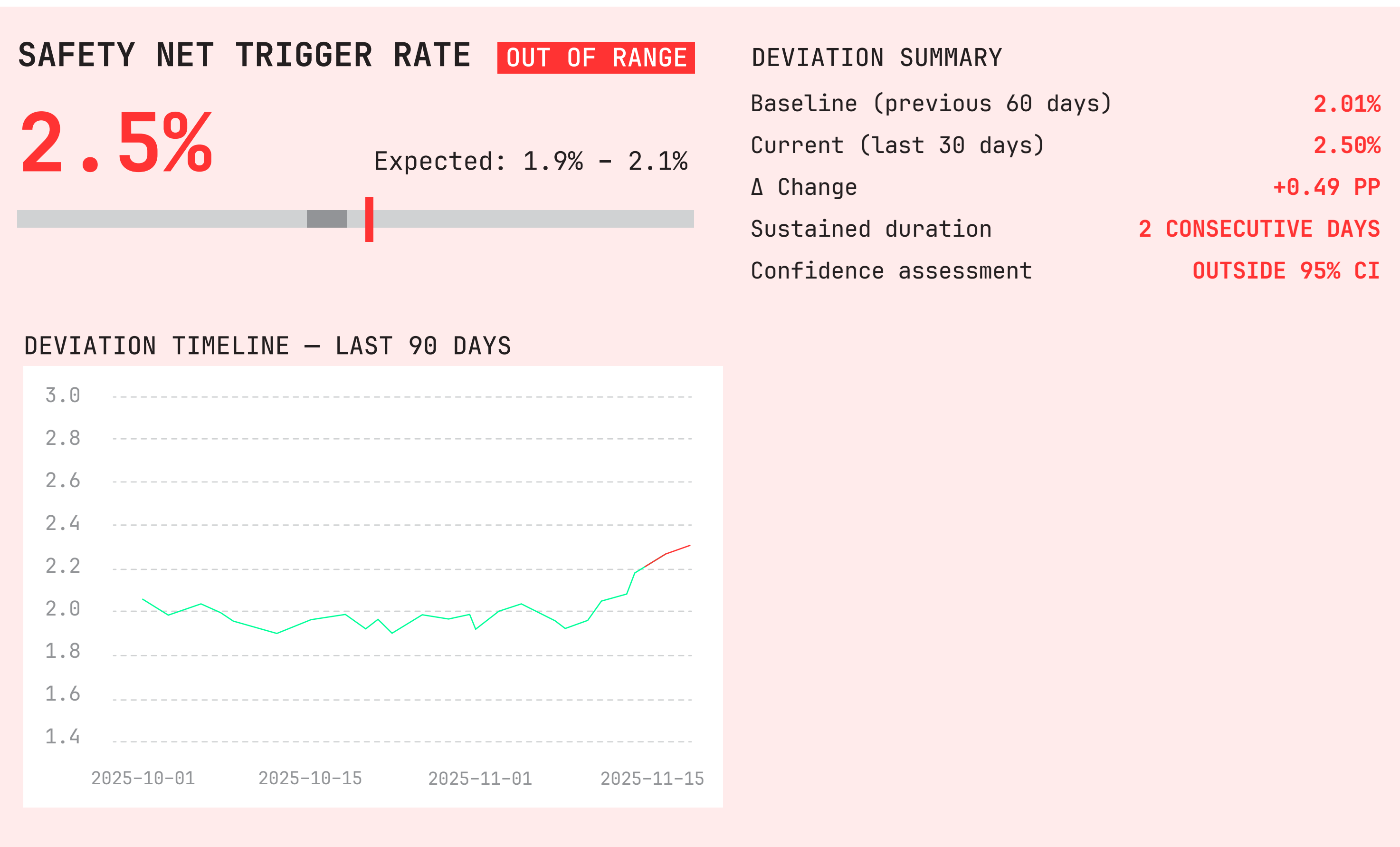
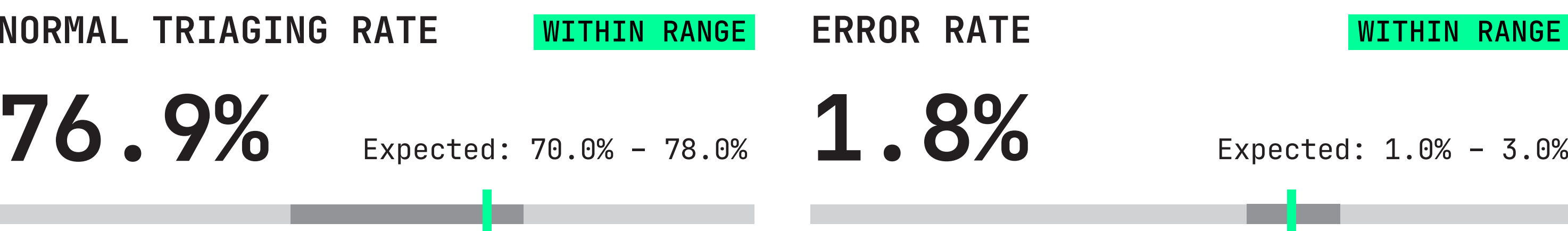
PRAIM study-nationwide visual representation of size

PRAIM (Nature Medicine, 2025) is the largest nationwide prospective study of AI in breast cancer screening, showing a +17.6% increase in cancer detection across multiple hardware vendors. Real-time monitoring was built into the deployment from day one.

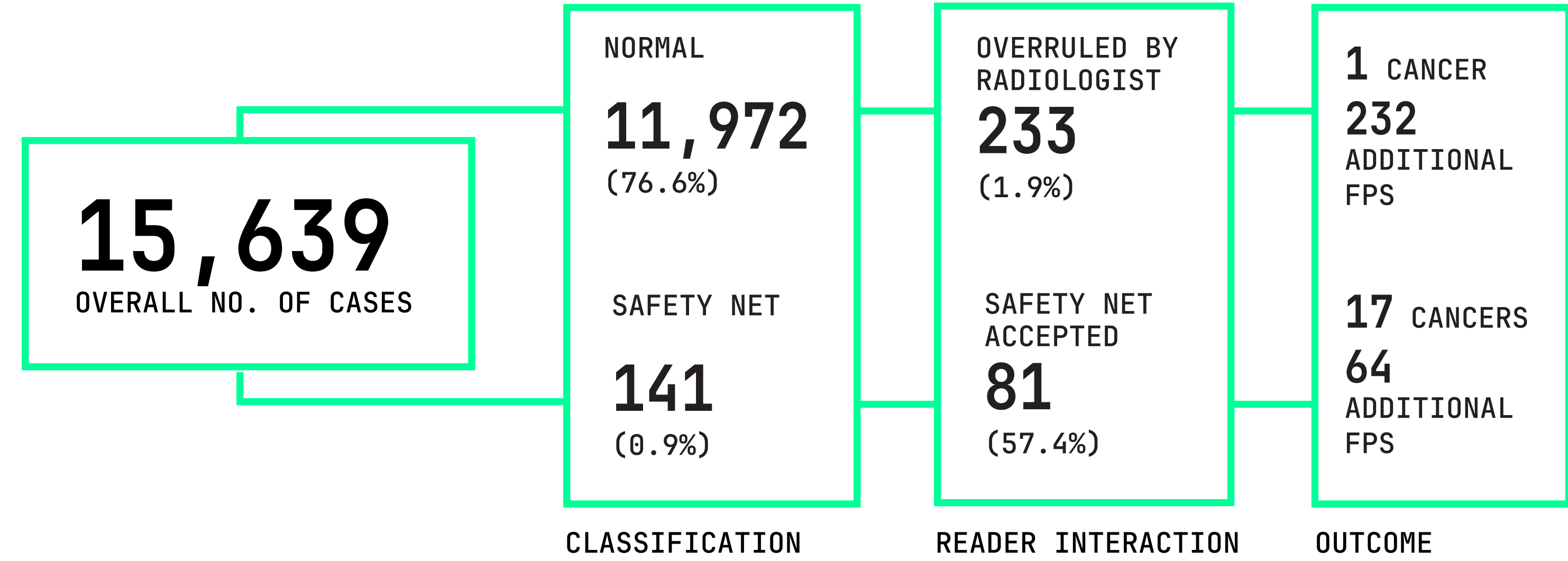


METHODS & RESULTS

Distribution Shifts / Performance Drifts



Biopsy Feedback Loop



Radiologist Interaction

RADIOLOGIST	TOTAL READS	SAFETY NET AI PROPOSAL ACCEPTED (%)	STATUS
RAD-018-A	3,523	53.6% (15/28)	Ok
RAD-024-K	4,298	90.0% (18/20)	Over-reliance (agreement)
RAD-031-M	3,177	9.5% (2/21)	Over-skepticism (disagreement)

CONCLUSION

Monitoring is a deployment condition.

FOR SCREENING UNITS

Deploying AI without monitoring is like a new mammography unit without technical QA.

The technology may be validated — but the specific implementation is not. Safety in practice is determined on day 1, not in year 3 of post-market surveillance.

FOR REGULATORS

MDR approval should require monitoring frameworks as a deployment condition.

Not only as post-market surveillance. AI manufacturers are responsible — at every single unit, not only at showcase centres.

FOR GUIDELINE DECISION-MAKERS

Screening capacity can be secured with AI — but only if safety in practice is guaranteed.

This is an infrastructure and process investment, not just a technology purchase. AI manufacturers must deliver this transparency.