Real-world performance of a CE Class III Artificial Intelligence as a Medical Device in the assessment of suspicious skin lesions

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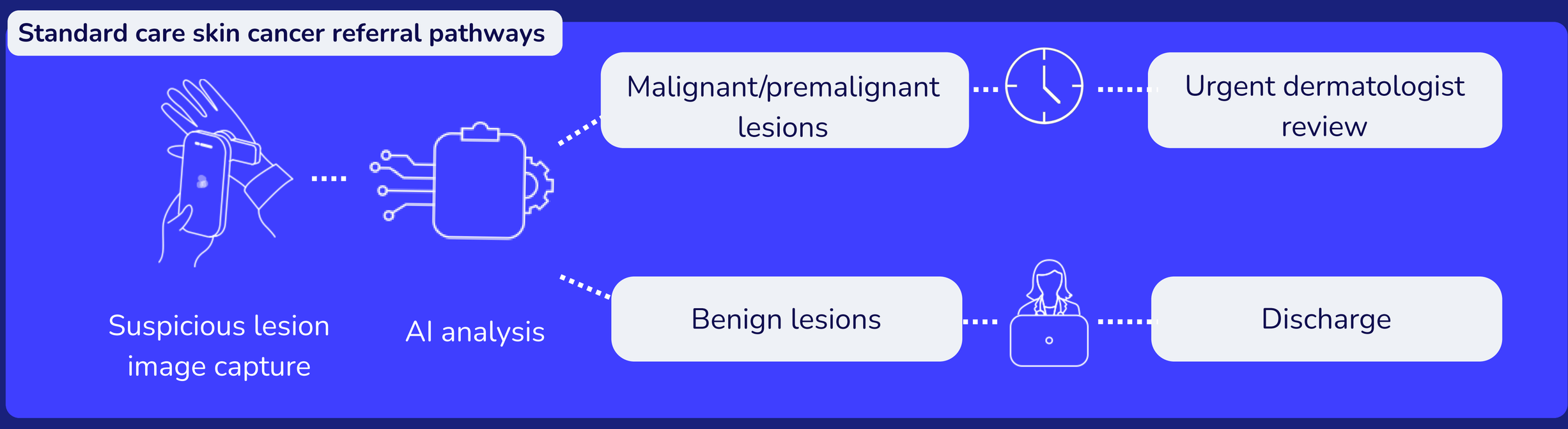
Aims

To evaluate the real-world performance of an Artificial Intelligence as a Medical Device (AIaMD) in the screening, triage and assessment of suspicious skin lesions.



Methods

- A prospective, multi-centre clinical performance review of a CE Class III AIaMD was conducted.
- Patients presenting to primary and secondary care services between December 2023 and November 2025 were eligible for inclusion.
- Histology outcomes were used as the reference standard for all malignant and pre-malignant lesions. Consistent with standard of care, dermatologist clinical diagnoses were also used for any non-biopsied benign lesions.
- To avoid verification bias, all lesions included in the study underwent second read review by a dermatologist.

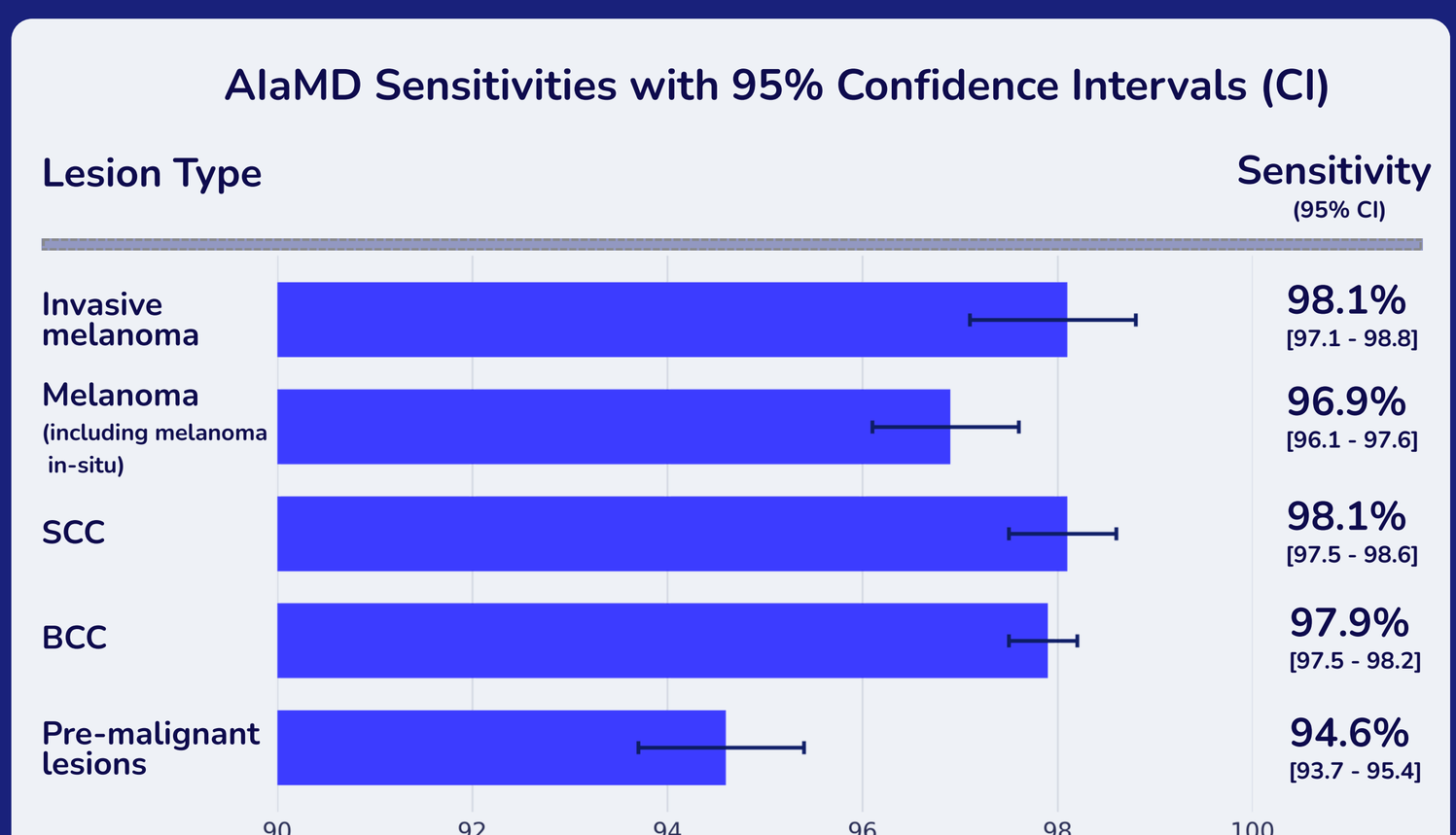
Results

150,854 patients evaluated across 6 primary care and 25 secondary care pathways were included.

Of 116,419 lesions assessed by the AIaMD, 90,236 (77.5%) had a ground truth outcome, including 1,889 melanoma, 2,334 squamous cell carcinoma (SCC), 5,420 basal cell carcinoma (BCC) and 2,651 pre-malignant lesions.

The AIaMD correctly identified 87.1% [86.8-87.4%] of clinically-diagnosed benign lesions and 23.7% [22.8-24.5%] of biopsy-confirmed benign lesions as benign.

The conversion rate (the proportion of referrals that result in a high-risk skin cancer diagnosis) improved in all sites: in primary care pathways up to **310%** and secondary care pathways up to **155%.**



Negative Predictive Value (NPV)

Melanoma NPV

99.9%

95% CI: [99.8% - 99.9%]

All skin cancers NPV

99.5%

95% CI: [99.4% - 99.6%]

Conclusion

Real-world post-market surveillance data demonstrate high sensitivity for identification of malignant, pre-malignant and benign lesions. Autonomous use of the AIaMD could safely prevent nearly 9 in 10 assessments for clinically-diagnosed benign lesions and avoid nearly 1 in 4 unnecessary biopsies.

~9 in 10
Assessments for clinically-diagnosed benign lesions could be prevented

~ 1 in 4
Unecessary biopsies could be avoided

1. All authors affiliated with the AIaMD manufacturer Skin Analytics Limited, London.