Agenda

12:00 Convenzis intro & housekeeping

12:05 Skin Analytics - Introduction

General AI versus AI for intended use. Can DERM be used by everyone?

12:15 Edge Health

Summary of the Whitepaper "Evaluating Pathways for AI Dermatology in Skin Cancer Detection". Published July 2024. Commissioned by NHSE's Outpatients and Transformation Recovery Programme. This will include key data on the performance of DERM.

12:40 Skin Analytics - Post Market Surveillance Processes

12:50 Q&A

13:00 Close

skin
analytics

Introducing our speakers

Dr Daniel Mullarkey
Medical Director
Skin Analytics

Yammi Yip
Analyst
Edge Health

Dr Dilraj Kalsi
Clinical AI Lead
Skin Analytics

Question 1

Since the early 90s, by what % have incidences of melanoma increased in the UK?

Question 1

Since the early 90s, by what % have incidences of melanoma increased in the UK?

Answer: 140%

The system is facing several critical challenges
Current pathways are unsustainable, and harm already exists

~700,000

USSC referrals per year and growing. Conversion rates remain flat.

~25%

of Consultant Dermatologist posts remain **unfilled**

~30%

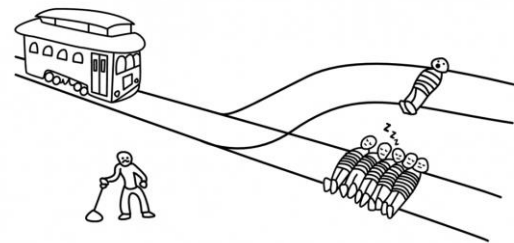of **MM and SCC** are found on routine referrals

Delays in routine pathways disproportionately affect Black, Asian and older patients
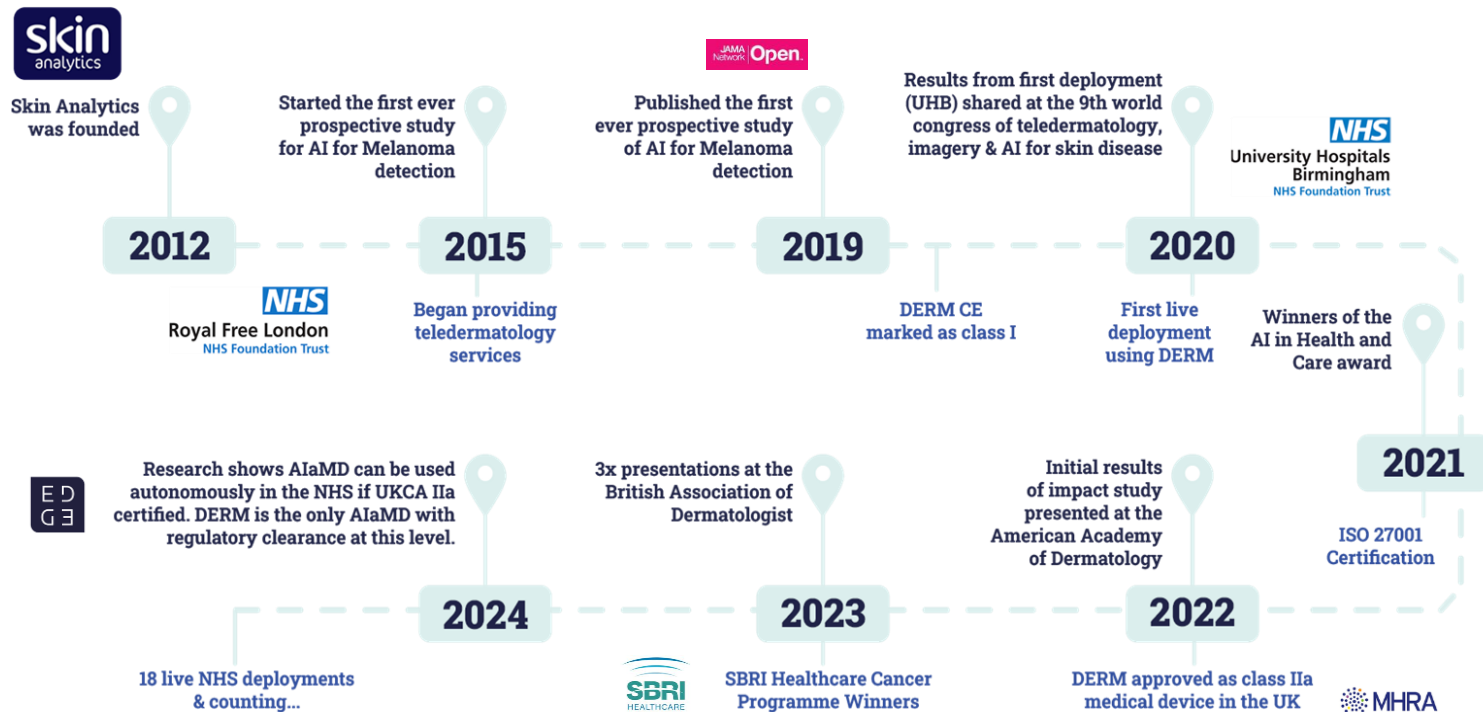
20%

improvement in 5-year melanoma survival for patients referred on the appropriate USSC pathway

>30,000

avoidable cases of cancer annually can be attributed to socio-economic deprivation

Building clinical AI is not an overnight project

Skin Analytics was founded

Started the first ever prospective study for AI for Melanoma detection

Published the first ever prospective study of AI for Melanoma detection

Results from first deployment (UHB) shared at the 9th world congress of teledermatology, imagery & AI for skin disease

NHS
University Hospitals Birmingham
NHS Foundation Trust

2012

NHS
Royal Free London
NHS Foundation Trust

2015

Began providing teledermatology services

2019

DERM CE marked as class I

2020

First live deployment using DERM

Winners of the AI in Health and Care award

Research shows AIaMD can be used autonomously in the NHS if UKCA IIa certified. DERM is the only AIaMD with regulatory clearance at this level.

3x presentations at the British Association of Dermatologist

Initial results of impact study presented at the American Academy of Dermatology

2021

ISO 27001 Certification

2024

2023

2022

18 live NHS deployments & counting...

SBRI HEALTHCARE

SBRI Healthcare Cancer Programme Winners

DERM approved as class IIa medical device in the UK

MHRA

DERM is the *only* AI for dermatology that is a UKCA Class IIa Medical Device
Outputs are optimised for management and risk akin to how clinicians think
"My top differential is SebK but I need to rule out Melanoma"

SBRI

Dermoscopic images are captured using approved hardware

DERM runs image quality checks & then provides instant assessment

Suspected Diagnosis	Post-referral use	Pre-referral use
Melanoma	Continue on USC pathway	USC referral
Atypical Naevus		
SCC		
BCC		Community / GPwER
SCC in situ		
Actinic Keratosis		
Benign - Vascular, SebK, Dermatofibroma, Naevus, Lentigo	Discharge with advice	Discharge with advice

Our AI pathways have been deployed in the NHS since 2020 have seen >120,000 patients

- Secondary Care

- Pre-primary Care / CDC

- Mixed
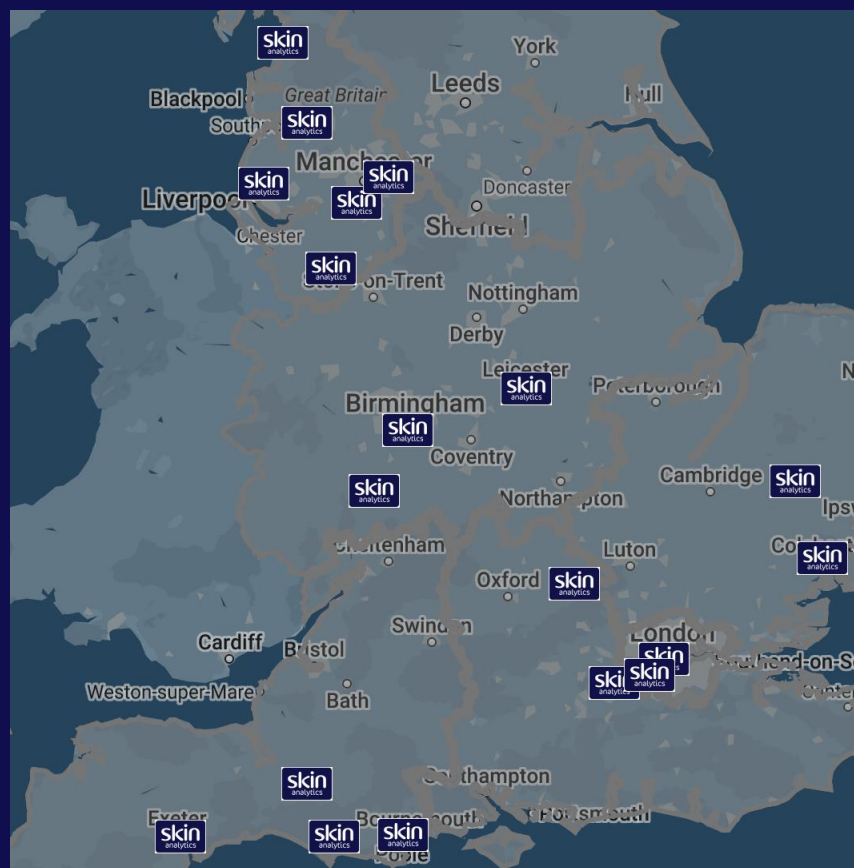
Question 2

Since 2020 our AI pathways have supported >120,000 skin cancer assessments. How many skin cancer patients (on average) might a dermatologist see in their career?

Question 2

Since 2020 our AI pathways have supported >120,000 skin cancer assessments. How many skin cancer patients (on average) might a dermatologist see in their career?

Answer: 49,000

References:
Levell N. Dermatology GIRFT Programme National Specialty Report [Internet]. Getting It Right First Time | NHS England & NHS Improvement. 2021 Aug. Available from: https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2022/07/DermatologyReport-Sept21o.pdf
https://www.england.nhs.uk/wp-content/uploads/2022/04/B0829-suspected-skin-cancer-two-week-wait-pathway-optimisation-guidance.pdf

Calculations: Based on 508 WTE derms in the UK (GIRFT) and ~700k skin cancer referrals a year (cancerdata) = ~1k cancer referrals a year in the NHS. Assuming an average NHS career is 35 years long.

What we'll cover today

1 Background

2 Dermatology Landscape

3 Standards of Care

4 Implementation Pathways and Budget Impacts

5 Post-Market Surveillance

6 Conclusions

Key Evaluation Objectives

- AI is being used in Dermatology across the NHS. There's a need to evaluate its standards and safety.

- NHSE Outpatient Recovery and Transformation Programme commissioned Edge Health to assess the use of autonomous AIaMD in urgent suspected skin cancer pathways

- There were three questions for our report to answer:

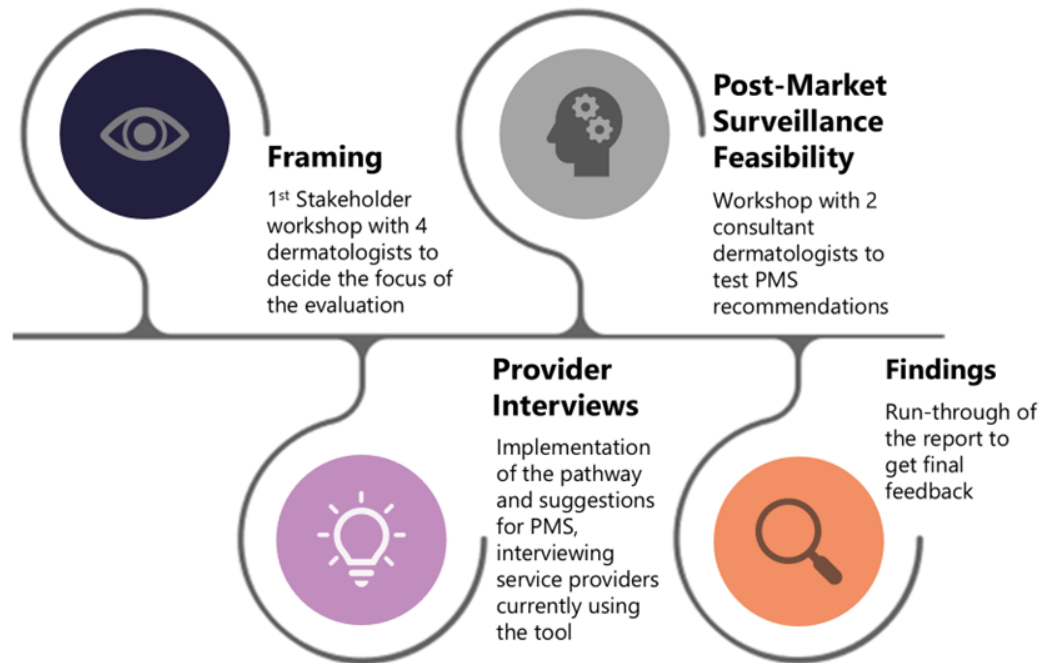|	
Is AIaMD safe to autonomously discharge benign lesions in suspected skin cancer pathways?	Assess documented clinical standards of care through meta-analysis and use them as a comparator for AIaMD performance in real world
How is AIaMD currently implemented? How do pathways differ and what are the costs and benefits associated with autonomous use?	Map pathways, carry out interviews with current providers, and high-level economic analysis of system-wide budget impacts
How can the safety of autonomous AIaMD be ensured in the long term?	Explore literature-based recommendations for Post-Market Surveillance (PMS) and provide an example practical methodology for future PMS

EDGE

Stakeholder Input

- We have engaged with multiple experienced consultant dermatologists

- These engagements informed the framing of this evaluation, validated our hypotheses and allowed us to sense-check the findings at each step of the evaluation

1. First Stakeholder Workshop
2. Provider Interviews
3. Post-Market Surveillance Feasibility
4. Report Run-Through

Framing

1st Stakeholder workshop with 4 dermatologists to decide the focus of the evaluation

Post-Market Surveillance Feasibility

Workshop with 2 consultant dermatologists to test PMS recommendations

Provider Interviews

Implementation of the pathway and suggestions for PMS, interviewing service providers currently using the tool

Findings

Run-through of the report to get final feedback

EDGE

1

Dermatology Landscape

Question 3

Over the past 10 years, what is the percentage increase in Urgent Suspected Cancer referrals in England?

Question 3

Over the past 10 years, what is the percentage increase in Urgent Suspected Cancer referrals in England?

Answer: 170%

Question 4

As of March 2024, how many patients are sitting on dermatology Referral to Treatment waitlists?

Question 4

As of March 2024, how many patients are sitting on dermatology Referral to Treatment waitlists?

Answer: 400,000

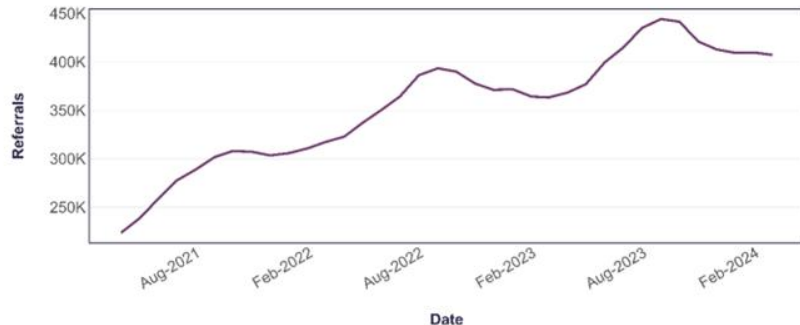# Background

- **Rising demand/capacity mismatch for Dermatology:** Growing patient demand and consultant shortages
  - 82% increase in the RTT waiting lists for Dermatology between April 2021 and March 2024, 170% increase in the rate of USC referrals in England in the last ten years
  - At least a quarter of all melanomas found through routine referrals, growing delays for patients with inflammatory skin conditions
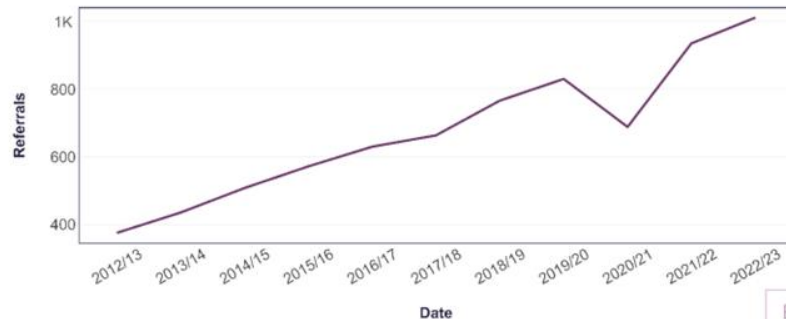 - Stagnant consultant dermatologist numbers with large WTE gap since 2021

Trends in RTT Waiting List Volumes for Dermatology

Analysis of Incomplete Pathway Patient Numbers Over Time

Trends in Urgent Suspected Cancer Referrals for Suspected Skin Cancer (England)

GP referrals per 100,000 across England
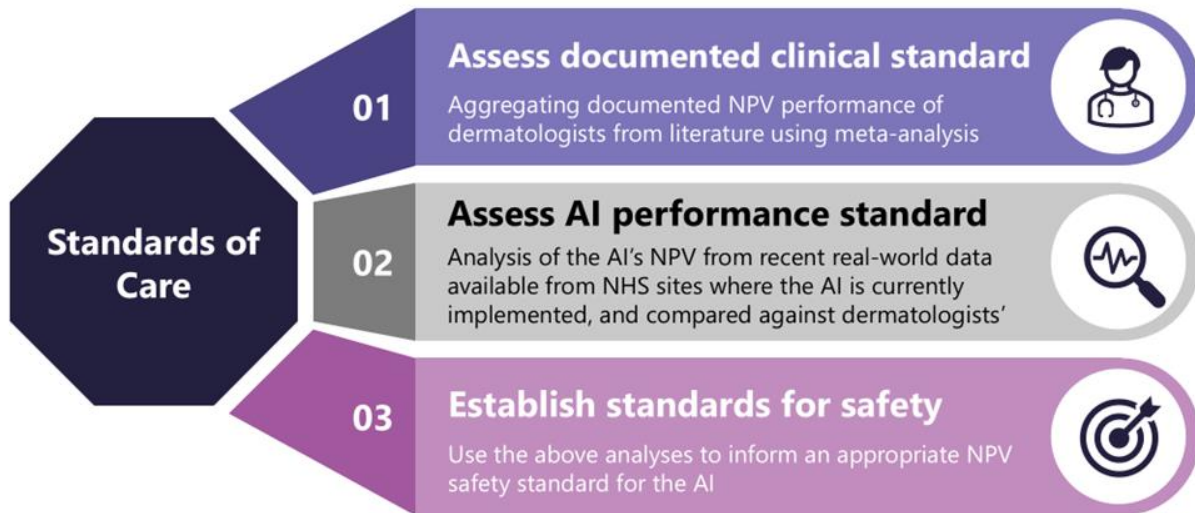
2

Standards of Care

Background

- NHSE's priority in integrating AIaMD within dermatology USC pathways is to identify benign lesions for discharge, allowing dermatologists to focus on more critical cases

- The key safety question is how effectively AIaMD can **exclude benign lesions** when triaging, therefore its performance should be assessed based on its ability to **accurately predict a benign diagnosis**
  - The relevant statistical measure for this is the **Negative Predictive Value (NPV)**

- Given the limited literature on non-melanoma skin cancers, this analysis focused on the detection of melanoma, which also aligned with stakeholder feedback from the first workshop

		Predicted	
		Positive How many melanomas	**Negative** How many non-melanomas
Actual	**Positive** How many melanomas	**True Positive (TP)** Patients' lesions diagnosed as melanoma that are confirmed melanoma	**False Negative (FN)** Patients' lesions diagnosed as not melanoma but are confirmed melanoma
	Negative How many non-melanomas	**False Positive (FP)** Patients' lesions diagnosed as melanoma but are not melanoma	**True Negative (TN)** Patients' lesions diagnosed as not melanoma which are not melanoma

$$NPV = \frac{TN}{TN + FN}$$

Standards of Care

Methodology Overview

- **Main Goal**: Establishing performance standards by comparing AIaMD with documented clinical standards in detecting benign skin lesions

- **Methodology Summary**: Semi-systematic review and meta-analysis of existing literature to assess clinical performance and independent analysis of AIaMD performance from real-world data to assess whether AIaMD meets current diagnostic standards.

Standards of Care

01 Assess documented clinical standard
Aggregating documented NPV performance of dermatologists from literature using meta-analysis

02 Assess AI performance standard
Analysis of the AI's NPV from recent real-world data available from NHS sites where the AI is currently implemented, and compared against dermatologists'

03 Establish standards for safety
Use the above analyses to inform an appropriate NPV safety standard for the AI

ED GE

Meta-Analysis Findings

- Each study is assigned an appropriate weight towards the final summary measure, considering their precision based on sample size, and the overall variability between the studies

- The analysis generated summary estimates for dermatologists' NPV performance in two settings: F2F evaluation and Teledermatology

Figure 1. Forest plot for the F2F evaluation meta-analysis
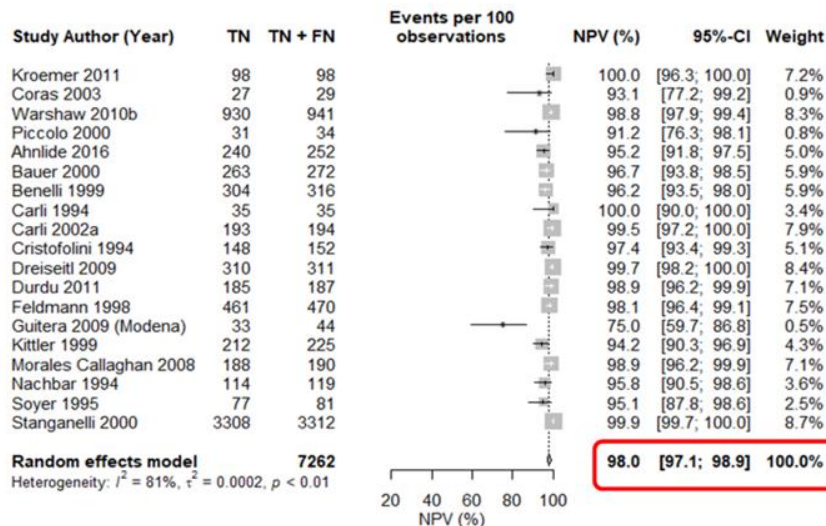
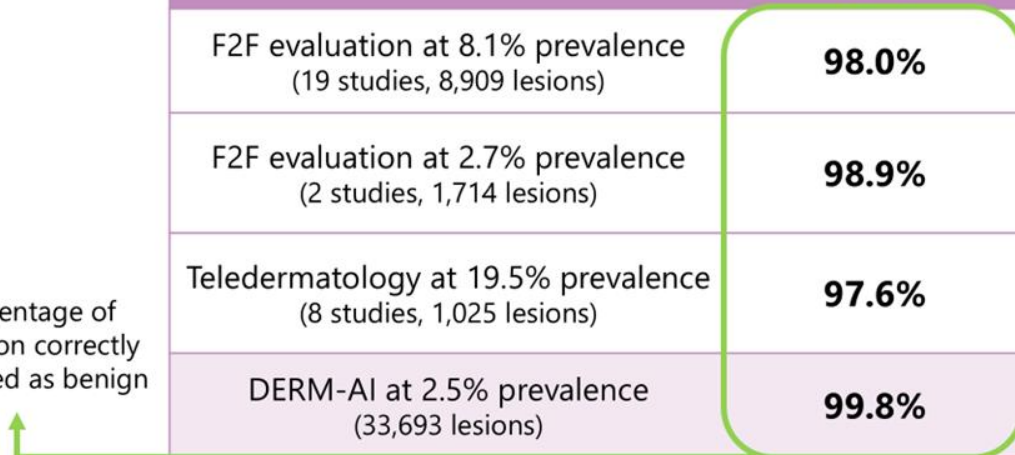| Setting	Prevalence of melanoma across studies	NPV [95% CI]
F2F evaluation (19 studies)	8.1%	98.0% [97.1%-98.9%]
F2F evaluation at lower prevalence (2 studies)	2.7%	98.9% [98.3%-99.5%]
Teledermatology (8 studies)	19.5%	97.6% [95.5%-99.6%]

AI compared to dermatologists

- DERM demonstrated an **NPV of 99.8%** at a 2.5% prevalence rate across 33,693 lesions, performing at least as good as dermatologists' **NPV of 98.9%** at a comparable prevalence

- Given the importance of NPV in the context of AI systems functioning as a triage tool in skin cancer pathways, a safety standard for **NPV at 99%** would be a sensible target

- This standard serves as a framework for future evaluation and validation, rather than a fixed benchmark

	NPV
F2F evaluation at 8.1% prevalence (19 studies, 8,909 lesions)	**98.0%**
F2F evaluation at 2.7% prevalence (2 studies, 1,714 lesions)	**98.9%**
Teledermatology at 19.5% prevalence (8 studies, 1,025 lesions)	**97.6%**
DERM-AI at 2.5% prevalence (33,693 lesions)	**99.8%**

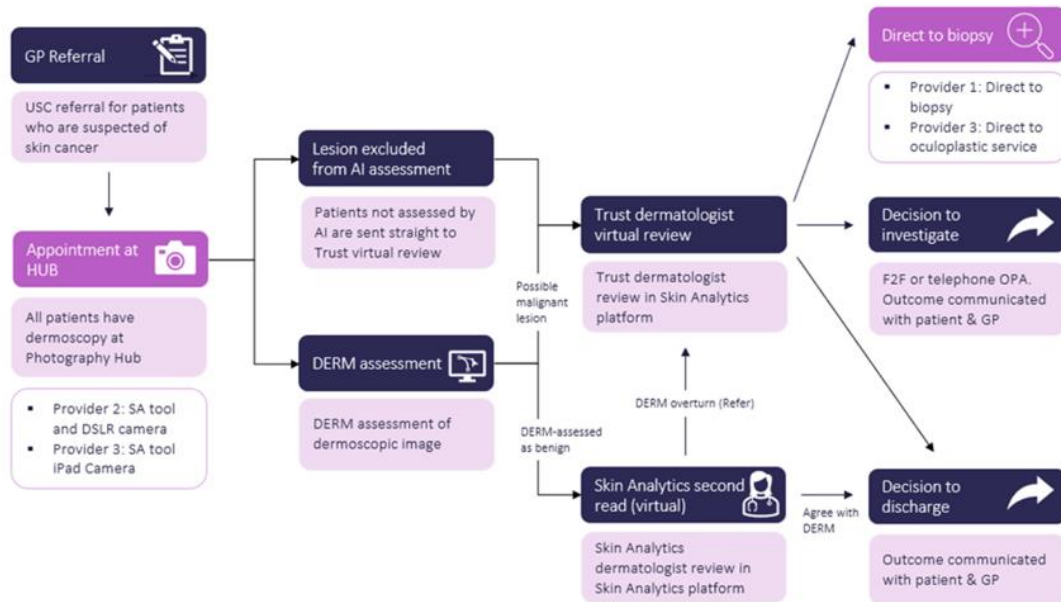The percentage of population correctly diagnosed as benign

ED G3

3

Implementation Pathway and Budget Impacts

AI Implementation Pathways and Current Use

- We have conducted a mapping of the current implementation pathways focusing on the post-referral model

- This was done via conversations with the manufacturer and semi-structured interviews with service providers (e.g. consultant dermatologists and transformation managers) to better understand the integration of AIaMD

- There are some variation in how the pathway was implemented across providers

Implementation Pathways

Map pathways, carry out interviews with current providers, and high-level economic analysis of system-wide budget impacts

Summary of Provider Interviews

Motivations

- **Address the escalating patient backlogs** and long **waiting periods** for USC referrals
- To enhance **both the efficiency and the quality** of patient care
- A logical progression to integrating AI from teledermatology services

Benefits

- Enhanced operational efficiency, reduced need for in-person reviews, and the potential for immediate patient discharge
- **20-25%** of patients discharged without a face-to-face review
- Some experienced **lower biopsy rates**

Challenges

- **IT challenges** such as **Wi-Fi connectivity and system integration**, caused delays in initial implementation
- **Integration with EPR system** and existing clinical portals is desired
- A **shift in case mix**, seeing **more complex** cases in F2F settings

Contracting and commissioning

- Contracting and commissioning could be complex for some providers
- Some faced delays in contract negotiations and procurement due to **evolving AI policies and funding complexities** at the ICB level.

Methods for service evaluation & surveillance

- Some providers were trialling a **text messaging system** to follow up with patients after discharge
- All providers are undertaking their own internal audits of the pathway

Implementation advice for other trusts

- Build **strong relationships with ICB and local GPs**
- **Ensure dedicated support staff**, are in place for AI implementation
- Adequate **job planning** for consultant dermatologists

High-level budget impacts

- As part of mapping the implementation pathways, we also carried out an economic analysis to estimate costs and potential savings at a system level

- This is to support decisions on implementation at scale and removal of second reads focusing on post-referral pathways

- Insights presented are preliminary, aiming to offer a high-level view of potential system-wide costs and savings

To complete this economic analysis, we have relied upon several high-level assumptions from various sources, including:

1. Data from Skin Analytics and Public Health England
2. Previous economic evaluation on the implementation of AIaMD at University Hospital Leicester
3. Units Costs of Health and Social Care (2023)

ED
G3

Our analysis covers three scenarios

- To provide a comprehensive view of costs and savings at various implementation stages, we proposed 2 scenarios and calculated their costs
  - Current Pathway
  - Scenario 1: AIaMD with second reads
  - Scenario 2: AIaMD with autonomous management of benign lesions

- We then estimated financial benefits in savings compared to the current pathway

- By comparing the costs and benefits of each scenario outlined above, we could calculate a **cost-benefit ratio**

	Total Costs	Total Benefits	Cost Benefit Ratio	Net Savings
Scenario 1	£763,324	£1,168,448	1.5	£405,123
Scenario 2	£679,482	£1,553,495	2.3	£874,014

This translates to system-level savings of up to £2.3 in savings for every £1 spent, if AIaMD is implemented autonomously

EDGE

4

Post-Market Surveillance

Strategy for PMS Recommendations

- Post-Market Surveillance (PMS) is a necessary process to monitor the real-world safety and performance of the AI after it's been deployed
- **Purpose of PMS**: to ensure continuous performance validation, risk management, and regulatory compliance through robust data collection and sharing in real-world settings
- We have first reviewed the regulatory requirements for AIaMD, then taken a dual approach to inform our recommendations:

1

PMS Best Practices

High-level recommendations on user & manufacturers actions covering:
- Performance Monitoring and Validation
- Data Collection and Sharing
- Risk Management and Regulatory Compliance

2

Example Practical PMS Method
- Determine an adequate sample size of lesions to be reviewed to determine NPV
- Simulation modelling to compare sampling lesions at different frequencies whilst considering practical constraints

ED
G3

PMS Roadmap

- Based on extensive literature review, we mapped actions needed for long-term monitoring of the safety of the AIaMD in post-deployment phase

- Responsibilities are shared between the manufacturers and the deployment sites
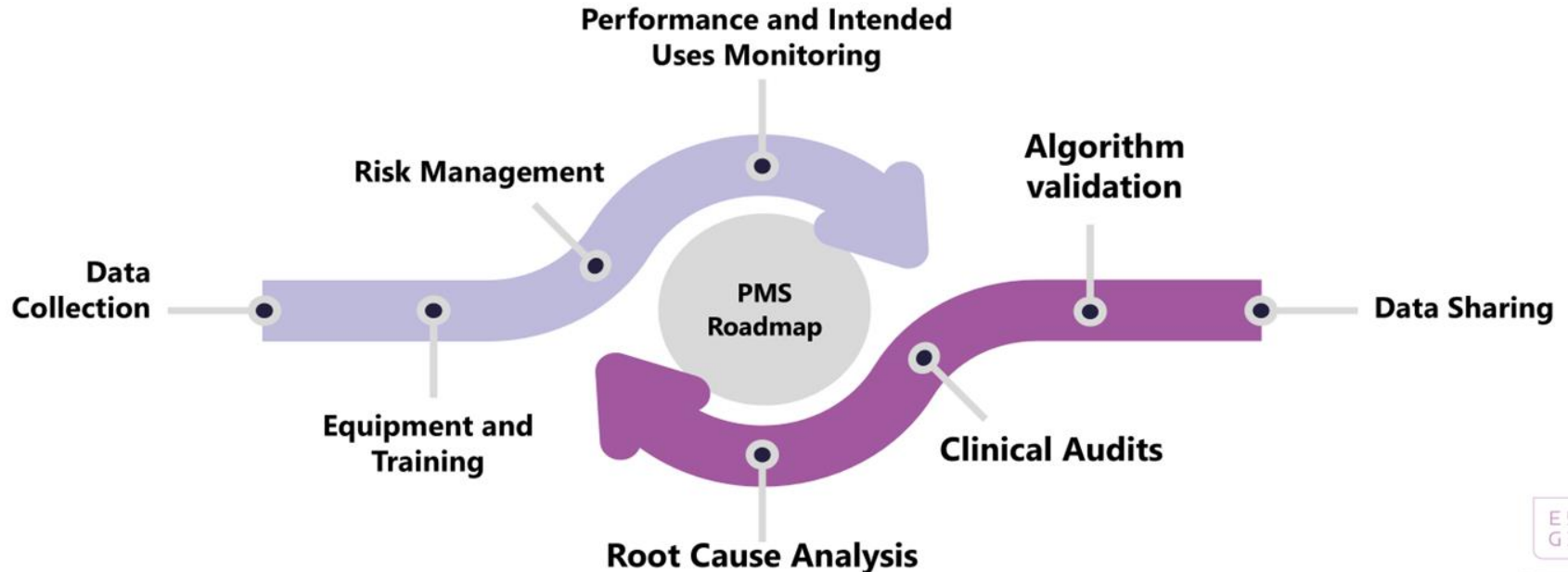
Example Practical Method for PMS

- Due to the sparse literature on practical clinical auditing methods, we outlined an example method to conduct audits

- Central to this method is monitoring whether AIaMD maintains an NPV above a pre-defined standard of 99%, supported by the clinical standard from the meta-analysis

- The actual implementation might vary depending on needs and practical constraints e.g. obtaining histology data

In practice, this involves two elements:

Sample Selection	Frequency of Auditing
Sample size must be sufficiently large to determine AI's NPV with the necessary statistical power and confidence levels. **Based on our statistical analysis, an adequate sample size would be 660 lesions.**	The optimal frequency of auditing is to detect any significant decline in NPV promptly, considering practicalities and resources available. **Based on our modelling, a greater frequency (3 or 4 months) of checking the NPV could detect an NPV drop quicker.**

EDGE

6

Conclusions

Conclusions

1	**AI could enhance the efficiency and effectiveness of skin cancer pathways**	Amid increasing melanoma incidence rates and consultant shortages in dermatology, AI technologies have the potential to reduce clinician workload by accurately identifying benign lesions for discharge
2	**AI performs to a level of safety comparable to dermatologists in skin cancer pathways**	AI technologies like DERM have demonstrated the potential to match dermatologists' standards in triaging benign lesions, indicating its potential to be integrated into the skin cancer pathways, while maintaining patient safety and care standards.
3	**There are potential positive economic implications from the use of the AI**	Economic analyses suggest that AI implementation could offer cost savings and reduced patient wait times, especially in autonomous scenarios.
4	**Providers hinted at wider non-quantified benefits from implementing the AI**	These benefits include operational efficiency, patient care improvements, and reduced necessity for face-to-face reviews.
5	**Adoption of AI necessitates a robust post-market surveillance strategy**	We have explored post-market surveillance methodology, with high-level recommendations informed by a literature review and an example practical auditing method to ensure patient safety and regulatory compliance.

EDGE

Practical PMS methods
How to ensure an AIaMD continues to perform

- Edge outline a potential methodology to conduct safety audits, exemplified through statistical analysis and simulation modelling

- NPV for melanoma at 98.9% among dermatologists for a similar disease prevalence to the DERM cohort, supports a recommended NPV standard exceeding 99%

- Key considerations for auditing

  - Sample selection

  - Frequency of auditing cycle

  - Obtaining histology and clinical diagnosis data for NPV calculation

AIaMD audits
Sample selection

- Lesions (and patients) diagnosed as benign, who would otherwise be discharged, instead reviewed as if under the high-risk pathway

- Sample size needs to be sufficiently large to ensure statistical power and confidence levels

- Sample size required to detect a drop of NPV from 99.8% (current DERM performance) to below 99% with an 80% power at a 2.5% significance level

- 660 lesions (approximately 570 patients)

AIaMD audits
Frequency of auditing cycle

- To detect any significant decline in NPV promptly, considering the practicalities and resources available

NPV Scenarios Dropping from 99.8%	Check every 3 months (91 days)	Check every 4 months (121 days)	Check every 6 months (182 days)
98%	109 days	174 days	280 days
97%	48 days	74 days	152 days
96%	45 days	64 days	122 days

Table 4. Results of simulating modelling, outlining the number of days to detect the drop of NPV performance across sampling frequencies and NPV scenarios with 660 lesions sampled

- Considerations - disease prevalence, feasibility of obtaining histology data, reduced benefits from avoided F2F appointments, added burden to analyse data for NPV and increased costs

Skin Analytics' approach
How we ensure DERM continues to perform

**Sample size -
at least 500 patients**

**Frequency of audit cycle
- every 6 months**

Key considerations

- Consecutive case sampling allows us to ensure **sensitivity** is consistent as well as NPV

- Ensures enough time for biopsies to have occurred by the time of analysis

- Minimises impact of audits on local service benefits and job planning

Post-Market Surveillance (PMS) recommendations and how we comply

PMS recommendation	Skin Analytics' standards & evidence
Data collection & Data sharing Requires strong NHS IT infrastructure and streamlined data sharing in line with data privacy regulation	• ISO 27001 • ISO 13485 • NHS DSP Toolkit • Cyber Essentials • DTAC compliant
Equipment, Training & Intended use monitoring Regular communication, training, SOPs and audits to ensure appropriate use of AIaMD and associated hardware	• In-person & online image capture training • Image quality & lesion suitability audits • DERM medical device resources for healthcare organisations
Algorithm validation & Risk management Clinical safety documentation updates with algorithm updates that are based on real-world performance with repeat attendance and adverse event monitoring	• DCB 0129 & support with DCB 0160 • Model card (available on request) • MHRA yellow card scheme
Performance monitoring, Service evaluation & Root cause analysis Regular AIaMD accuracy reporting including subpopulation analysis with false negative case reviews	• DERM Performance • Equality and Health Inequalities Impact Assessment (EHIA) • Clinical advisory case reviews

DERM is an artificial-intelligence (AI)-based skin lesion analysis device intended for use in the screening, triage and assessment of skin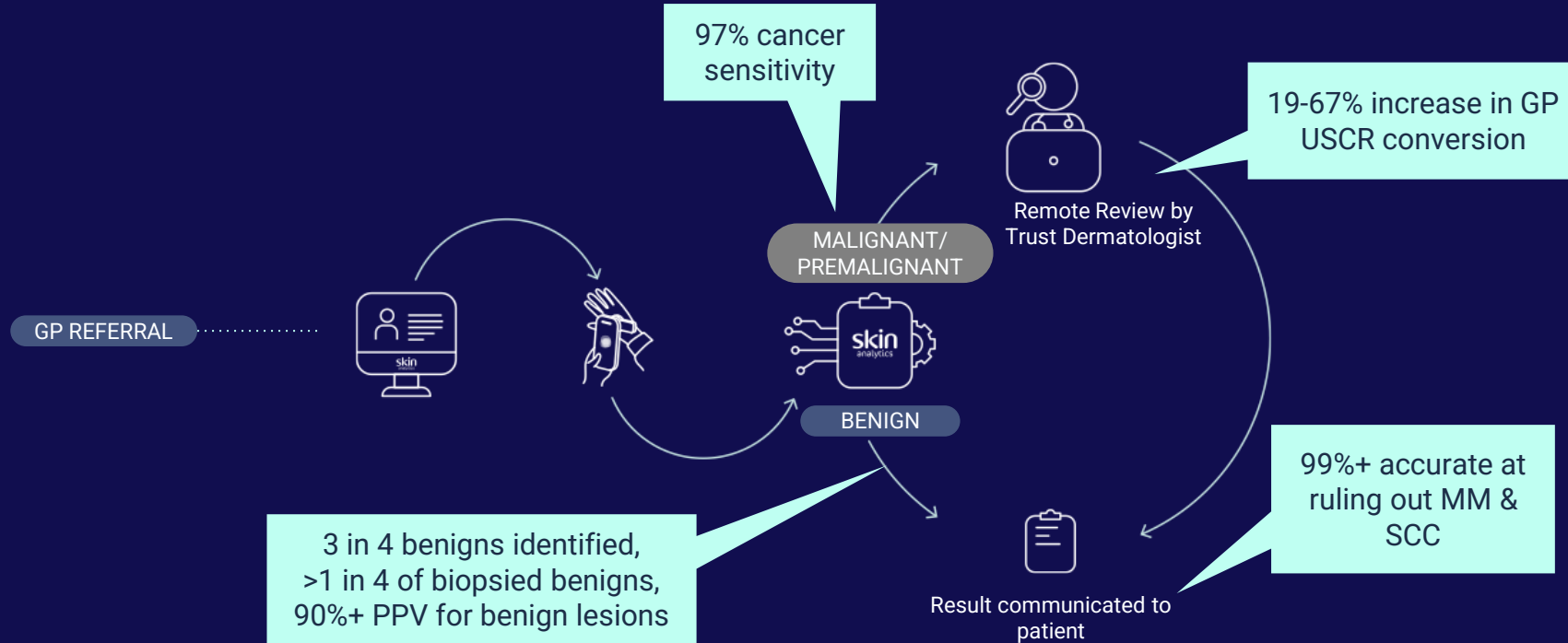 lesions suspicious for skin cancer. DERM will analyse a dermoscopic image of a skin lesion and return a suspected diagnosis and, if applicable, a referral recommendation for the lesion.

Category	Audit processes
Feedback	• Users are made aware of the local regulator's feedback scheme • Complaints, incidents and CAPA procedures, including trend analysis
AI input	• Image quality audit monitors for use of non-approved hardware • Audits of appropriate inclusion/exclusion of lesions
AI output	• Proactive monitoring that % of lesions labelled as MM/SCC/BCC is not below expected • Regular reports on DERM accuracy versus histology-confirmed cancers and histology/clinically-confirmed non-cancers • Follow-up for repeat presentations to close the loop • False negative root cause analysis - histology review, dermatologist panel, adversarial testing • Biannual case audits where a number of cases are routed to dermatologists to ensure performance is still to target

There are no specific requirements on the healthcare provider side, however the AI output analyses depend on you giving us access to the outcomes data including histology for us to conduct

DERM continues to perform in line with targets set according to specialist accuracy
Latest performance across 16 sites, ~53,000 outcomes and >6,000 confirmed cancers

97% cancer sensitivity

19-67% increase in GP USCR conversion

MALIGNANT/ PREMALIGNANT

Remote Review by Trust Dermatologist

GP REFERRAL

BENIGN

3 in 4 benigns identified, >1 in 4 of biopsied benigns, 90%+ PPV for benign lesions

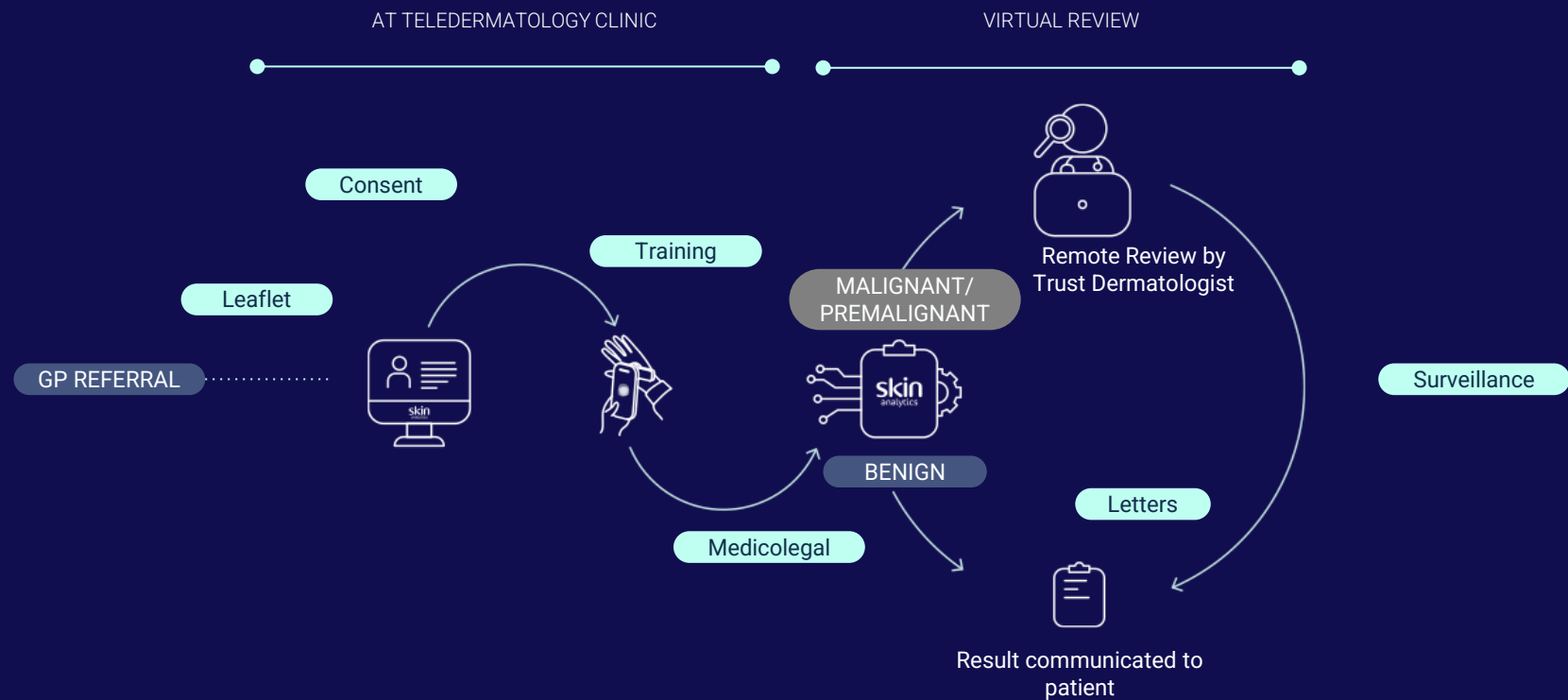99%+ accurate at ruling out MM & SCC

Result communicated to patient

Q2 2024 | 16 Sites | DERM Pathway Sensitivity & Benign Specificity

	Target	April 2022 - Apr 2024 Histology-confirmed sensitivity	
Melanoma	95%	95% (985/1037)	
Melanoma, invasive	95%	97.3% (547/562)	
SCC	95%	98% (1540/1571)	
SCC, excluding KA	95%	98.2% (1214/1236)	
BCC	90%	96.5% (3426/3551)	
All skin cancer		96.5% (6006/6224)[1]	
Bowen's disease (IEC)	90%	94.1% (620/659)	
Actinic Keratosis	90%	92.5% (1326/1433)	
Benign *Specificity*		*Inc. Clinically confirmed:* 75.2% (24408/32442)	*Histology-confirmed only:* 29.3% (1558/5318)

[1] includes 3x Merkel cancers appropriately routed into Trusts

skin analytics

Automated pathways | Step by step

AT TELEDERMATOLOGY CLINIC

VIRTUAL REVIEW

Consent

Training

Leaflet

MALIGNANT/
PREMALIGNANT

GP REFERRAL

Remote Review by
Trust Dermatologist

Surveillance

BENIGN

Letters

Medicolegal

Result communicated to
patient

Q&A - Ask us your questions

Dr Dan Mullarkey
Medical Director
Skin Analytics

Yammi Yip
Analyst
Edge Health

George Batchelor
Co-founder and Director
Edge Health

Dr Dilraj Kalsi
Clinical AI Lead
Skin Analytics

Rachael Dovey
Commercial Director
Skin Analytics

Thank you for attending.

You'll receive the webinar recording and the full Edge Health report in the coming days.

For more information, reach out to us at:

Skin Analytics:
enquiries@skinanalytics.co.uk

Edge Health:
info@edgehealth.co.uk