DermaSensor

AI-powered skin cancer detection at the point of care for rural health

- **52%** Reduction in missed cancers[12]
- **21-33%** Fewer unnecessary biopsies[9, 10]
- **61-77%** Fewer unnecessary referrals[11]

The rural skin cancer crisis

Skin cancer is the most common cancer in the U.S., yet rural patients face a compounding access crisis that delays diagnosis, drives worse outcomes, and strains limited dermatology capacity.

- **Less than 10%** of dermatologists practice in rural areas[3]
- **Average dermatology wait is 34.5 days** nationally — often months in rural settings[4]
- **Over 70% of skin cancers[1,2]** are first evaluated in primary care settings where physicians lack specialized training or objective diagnostic tools for skin lesion assessment

What DermaSensor brings

- **Clinical evidence package:** Nine peer-reviewed publications, FDA pivotal study data, and outcome benchmarks
- **Grant narrative support:** Template language positioning DermaSensor within applicable RHTP initiative categories
- **Implementation support:** Clinical training, workflow integration guidance, and dedicated account support
- **Outcomes reporting tools:** Data and reporting frameworks aligned with RHTP performance metrics
- **Partnership documentation:** Ready-to-execute MOU for collaborative RFA submissions requiring partner agreements

Result

Underdiagnosis

Skin cancers are missed and treatment is delayed, increasing mortality risk and late-stage presentation.

- PCPs detect skin cancer with lower sensitivity than dermatologists, missing approximately 1 in 5 cases of melanoma and keratinocyte carcinomas[2]
- Rural patients are 1.15×[6] more likely to present with later-stage skin cancer
- Five-year melanoma survival exceeds 99% when detected early but drops to ~35% at late stage[5] — making timely point-of-care evaluation lifesaving

Over-referral

Only 4-5% of lesions referred or biopsied by PCPs for melanoma are actually melanoma,[7] thereby increasing morbidity, healthcare costs and straining dermatology access.

Unmet need

This diagnostic gap creates a clear need for tools that support PCPs in accurately triaging suspicious lesions at the point of care — reducing missed cancers and unnecessary referrals.

DermaSensor — device overview

DermaSensor™ is the first FDA-cleared AI-powered skin cancer risk detection device designed for primary care providers.

Regulatory: *FDA-Cleared Class II De Novo; FDA Breakthrough Device. Software-aided adjunctive diagnostic devices for use by non-dermatology providers of lesions suspicious for skin cancer.*

How it works

- Apply handheld non-invasive device to suspicious lesion
- FDA-cleared AI algorithm analyzes spectral data and delivers skin cancer risk results in seconds
- Instant output: "Monitor" or "Investigate Further" (refer), with the latter results including a 1-10 confidence score for malignancy likelihood
- ~15 minutes of training — rapid deployment across any site and provider

CLINICAL DATA	DERMASENSOR ADVANTAGE
~96% sensitivity across all 224 skin cancers; ~97% NPV – with consistent sensitivity and specificity across all Fitzpatrick skin types[8]	Enables rural PCPs to identify high-risk lesions with confidence across all patient populations, supporting equitable early detection at the point of care and reducing the risk of missed diagnoses.
False negative rate decreased by more than half, from 18.0% to 8.6%[12]	Fewer cancers go undetected at the primary care level, enabling earlier-stage diagnosis.
Ruled out 21–33% of benign biopsied lesions biopsied by physicians and 61-77% of benign lesions suspicious to patients[9, 10, 11]	Reduces unnecessary referrals and biopsies – preserving limited dermatology capacity for high-risk patients while lowering patient travel burden, wait times, and system costs.
82.0% → 91.4% PCP sensitivity improvement (p=0.003)[12]	Enables providers to make more appropriate management decisions — more cancers caught, fewer benign lesions overtreated.
Device AUC comparable to dermatologists (0.76 versus 0.75)[13]	PCPs can approximate specialist-level diagnostic risk assessment, extending high-quality care to rural settings for suspicious lesions.

RHTP funding alignment

The RHTP — a $50 billion, 5-year federal initiative — prioritizes:

- Technology-driven solutions for the prevention and management of chronic diseases
- Investment in technologies that promote efficient care delivery and access to digital health tools by rural facilities and providers
- Payments to health care providers for the provision of health care items or services
- Measurable, outcomes-driven interventions with trackable data

DermaSensor qualifies under multiple RHTP allowable categories including technology innovation, chronic disease prevention, and clinical equipment investment.

Estimated budgetary inputs

- **Estimated # of devices:** 1 device per 3 physicians
- **Annual subscription plan:** $4,788 per device per year for unlimited patients and unlimited scans
- **One-time device activation fee:** $499 per device
- **Optional device purchase plan:** $20,000 per device, 10% annual maintenance fee

Data tracking and analysis

RHTP performance measurement framework

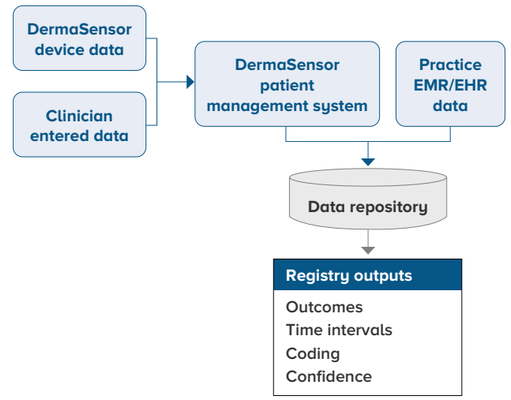
Target outcomes for RHTP reporting

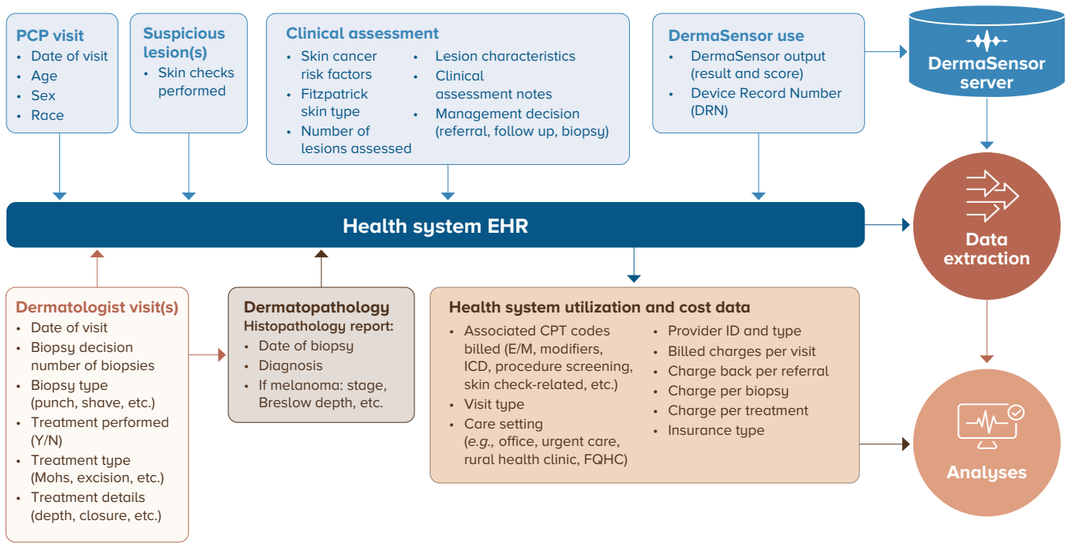
- **Missed skin cancers**
- **Time to diagnosis and treatment**
- **Cancer stage at diagnosis**
- **Unnecessary referrals**
- **Unnecessary biopsies**
- **Cost of care**

DermaSensor system and data architecture

DermaSensor's outcomes measurement approach is grounded in structured previously utilized registry protocols. Selected data from patients previously evaluated for skin lesions suspicious for skin cancer is collected and compared before and after clinician adoption of the DermaSensor device.

All device users automatically generate Device Record Numbers (DRNs), ESS recordings, and spectral scores for each scanned lesion. This data is complemented by non-PHI data from EMR/EHR systems, integrated into a common data repository, and analyzed across 3, 6, 9, 12, 18, and 24-month intervals following device adoption. This framework directly satisfies RHTP performance reporting requirements by generating measurable, trackable evidence of clinical and system-level impact.





Proposed outcome measures

Clinical detection and outcomes

- Skin cancer detection rate (aided versus unaided) — overall and by device score distribution
- Sensitivity and NPV of the aided versus unaided group
- Skin lesion procedure volume (*e.g.,* biopsies cryo) aided and unaided
- Patient visits with no referral that subsequently receive a positive skin cancer diagnosis (missed cancers)

Referral efficiency and utilization

- Device utilization (lesion and patient volumes)
- Total skin checks, referrals, and biopsies performed (aided versus unaided)
- Proportion of referrals resulting in a confirmed malignancy versus benign result (referral appropriateness)
- Proportion of biopsied lesions ultimately found to be benign (unnecessary biopsy rate)

Time intervals

- Time from initial PCP visit to dermatologist referral
- Time from referral to dermatologist assessment
- Time from assessment to biopsy and confirmed diagnosis
- Time from diagnosis to treatment initiation
- Comparison of above intervals between aided and unaided groups

Health economics and care experience

- Cost of care comparison between aided and unaided groups (billed charges per visit, referral, and biopsy)
- Clinician confidence pre- versus post-device adoption
- Relationship of physician confidence to proportion of malignant versus benign diagnoses
- Provider and patient satisfaction and ease of use

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DermaSensor Inc. is a medical device company that enables healthcare professionals to effectively check for skin cancer by leveraging cutting-edge technologies. The DermaSensor™ device is a cost-effective handheld tool that uses artificial intelligence and spectroscopy to non-invasively test skin lesions for skin cancer risk in seconds. By enabling quick and effective skin cancer checks, DermaSensor ultimately hopes to improve skin cancer detection and save lives. DermaSensor is currently FDA Cleared, and is available for sale in the U.S.

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