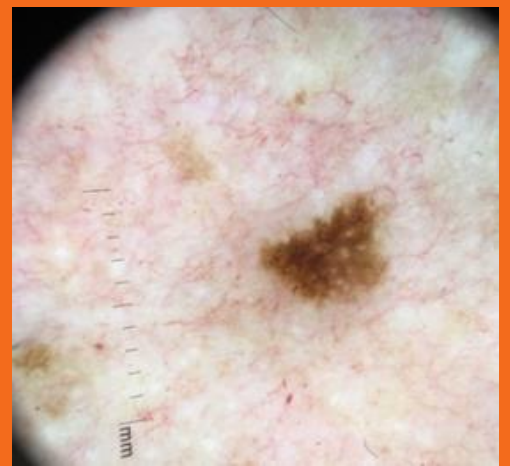
Bostel Technologies

Skin Cancer diagnostics by an AI decision support tool



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Avi Dascalu MD, PhD, CDO, Specialist in Dermatology
dasc17@gmail.com; Phone: +972.544.306.331

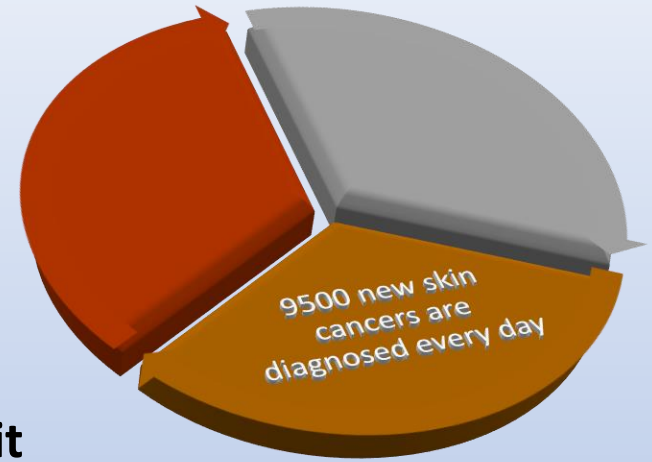
Problem: Skin Cancer detection is a diagnostic challenge

Skin cancer is common:

- **Melanoma (MM)** - 200,000 adults, 8000 deaths, 1:38 lifetime risk (US/yr.)

- **Non Melanoma Skin Cancer (NMSC) –** total 5.4 million cases (US/yr.)

- **1 in 5 Americans** will develop skin cancer during their **lifetime**. The average **wait time** for a dermatology appointment is **34.5 days**

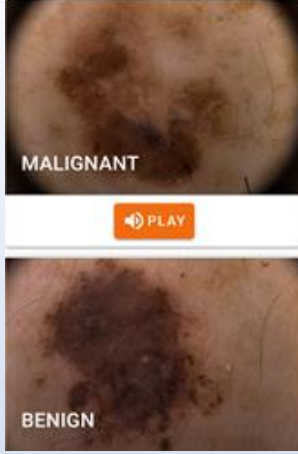


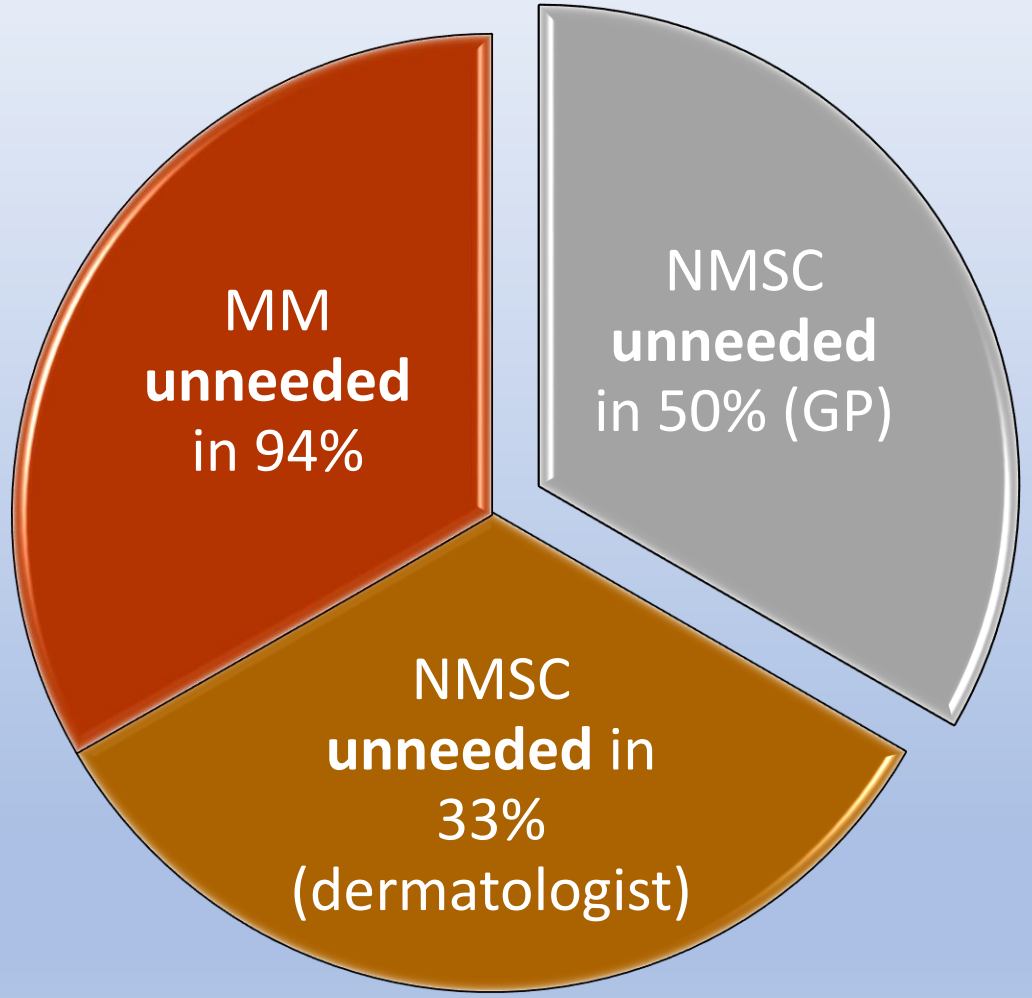
High annual costs

- The annual direct costs are **$2.5 billion/yr.** for MM treatment and **$6.5 billion** for NMSC treatment.

(Cancer Causes Control 2023;34:205-212).

Problem: Low diagnostic accuracy and unneeded biopsies





(Cancer Causes Control 2023;34:205-212).

Operational Team

Bruce N. Walker, PhD: Professor of Psychology & Computing, Georgia Institute of Technology (Atlanta), **President**

- Human-Computer Interaction, sonification, and multimodal user interfaces. President. Co-founder.

Avi Dascalu, MD, PhD: Specialist in Dermatology, **CDO**

- Image and sound analysis, clinical development. Co-founder.

Ankur Kalra, MEng: Hop Labs, Atlanta, GA, **CTO**

- CEO of an artificial intelligence software and machine learning development laboratory.

Benny Shachar, CPA, MBA: CFO

Eli O. David, PhD: Consultant

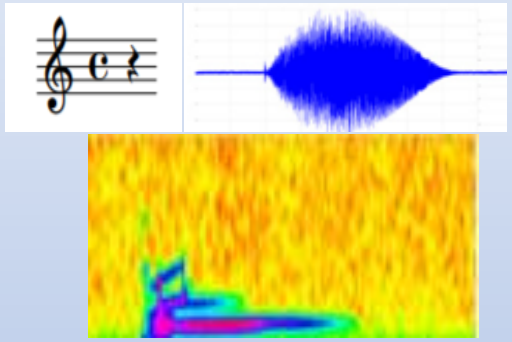
- Deep learning and evolutionary computation.

James M. Rehg, PhD: Consultant

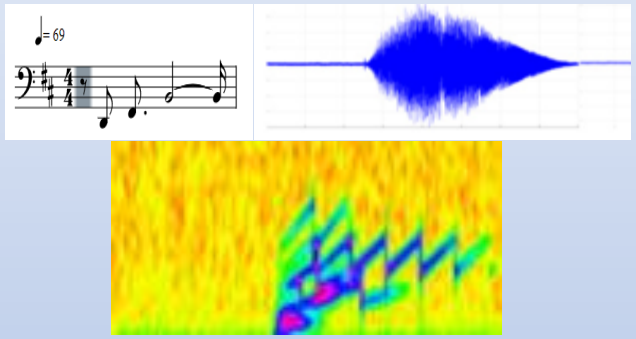
- Deep Learning. Principal, Amazon Scholar at Amazon Lab126. Professor of Computer Science and Industrial and Enterprise Systems Engineering at University of Illinois Urbana-Champaign

Solution: AUDIO diagnostics technology

Benign



Malignant



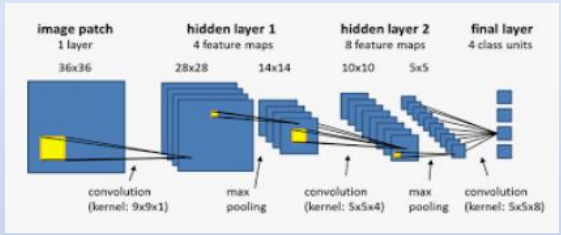
SONIFICATION TECHNOLOGY highlights hidden malignant structures, to be processed by divergent VISUAL and Audio CNN's, resulting in superhuman accurate diagnostics

✓ **Prospective clinical study,** IRB-approved, monitored, **NCT03362138** , N=75 subjects.

Sensitivity 93.3%

Specificity 68.3%

Solution: Deep Learning 4 seconds precise diagnostics



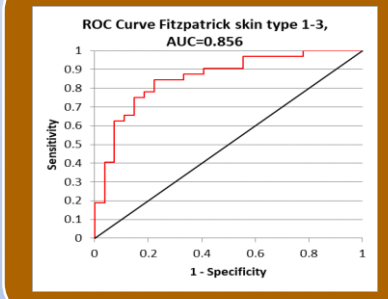
- Image is captured by dermoscope and processed on cloud

- **General Practitioner - 1st FDA submission,** In-office and telemedicine

  1 billion GP's US annual visits and a 45:1 density as compared to dermatologists

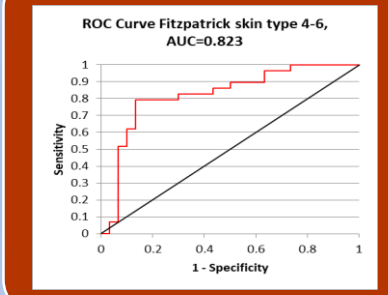
Competitive Advantage:

Unique **sonification** technology which extracts malignant features, i.e. **the signal out of the noise**, enhancing sensitivity.



Demographic free

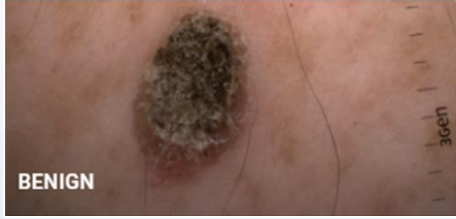
The only available technology of dark skin diagnostics

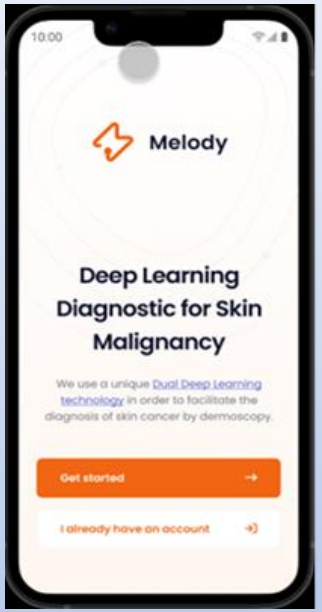


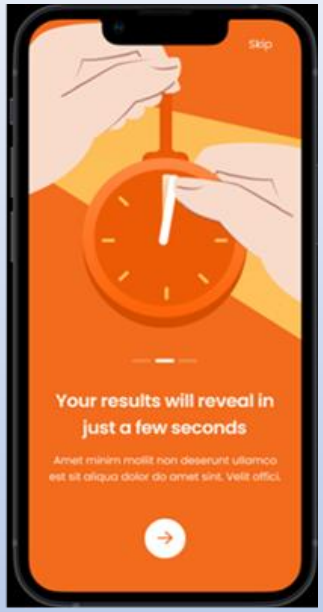
An **operational** low cost technology

US Patents: *11,298,072 and 16/311,372.*

Product: Application and diagnostic www site







Cited in BJD and *Nature* Editorial as **one of only 11 clinical trials of AI in medicine that is randomized and conforms to new guidelines for AI clinical research.**

Topol, E.J. Welcoming new guidelines for AI clinical research. Nat Med 26, 1318–1320 (2020). https://doi.org/10.1038/s41591-020-1042-x.

Br J Dermatol. *2021* Mar;184(3):381-383. doi: 10.1111/bjd.19616.

Validation: Key publications in *The Lancet , ICAD and JoCR*


Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.ebiomedicine.com

EBioMedicine
Published by THE LANCET

Research paper

Dermoscopy diagnosis of cancerous lesions utilizing dual deep learning algorithms via visual and audio (sonification) outputs: Laboratory and prospective observational studies

Walker B.N. [a], Rehg J.M. [b], Kalra A. [c], Winters R.M. [d], Drews P. [e], Dascalu J. [f], David E.O. [g], Dascalu A. [h,*]

ARTICLE INFO

ABSTRACT

1. Introduction


Contents lists available at ScienceDirect

EBioMedicine

journal homepage: www.ebiomedicine.com

EBioMedicine
Published by THE LANCET

Skin cancer detection by deep learning and sound analysis algorithms: A prospective clinical study of an elementary dermoscope

A. Dascalu [a,*], E.O. David [b]

ARTICLE INFO

ABSTRACT

1. Introduction


ICAD

HEARING ARTIFICIAL INTELLIGENCE: SONIFICATION GUIDELINES & RESULTS FROM A CASE-STUDY IN MELANOMA DIAGNOSIS

R. Michael Winters — GT Center for Music Technology, Georgia Institute of Technology, Atlanta GA, mikewinters@gatech.edu

Ankur Kalra — Hop Labs, Atlanta, GA, ankur@hoplabs.com

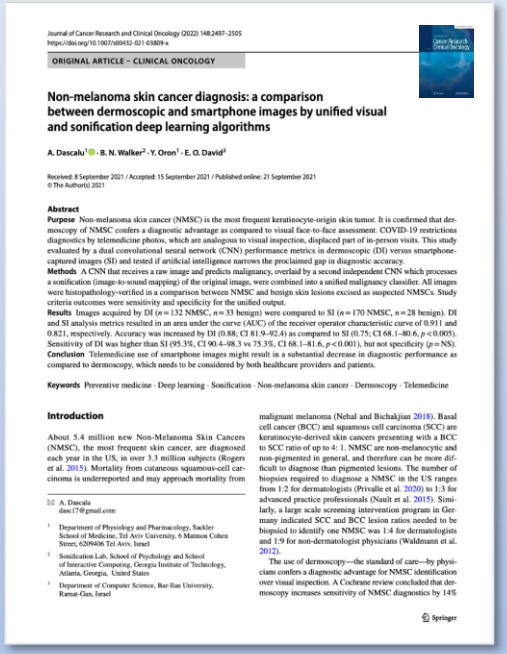
Bruce N. Walker — GT Sonification Lab, Georgia Institute of Technology, Atlanta, GA, bruce.walker@gatech.edu

ABSTRACT

1. INTRODUCTION

2. BACKGROUND CONTEXT

3. DESIGN PROCESS


JoCR

Journal of Cancer Research and Clinical Oncology

ORIGINAL ARTICLE – CLINICAL ONCOLOGY

Non-melanoma skin cancer diagnosis: a comparison between dermoscopic and smartphone images by unified visual and sonification deep learning algorithms

A. Dascalu [1] · B. N. Walker [2] · Y. Oron [3] · E. O. David [4]

Abstract

Introduction

Lancet EBioMedicine; February 2019, Volume 40, Pages 176–183 https://doi.org/10.1016/j.ebiom.2019.01.028

Lancet EBioMedicine; May 2019, Volume 43, Pages 107–113 https://doi.org/10.1016/j.ebiom.2019.04.055

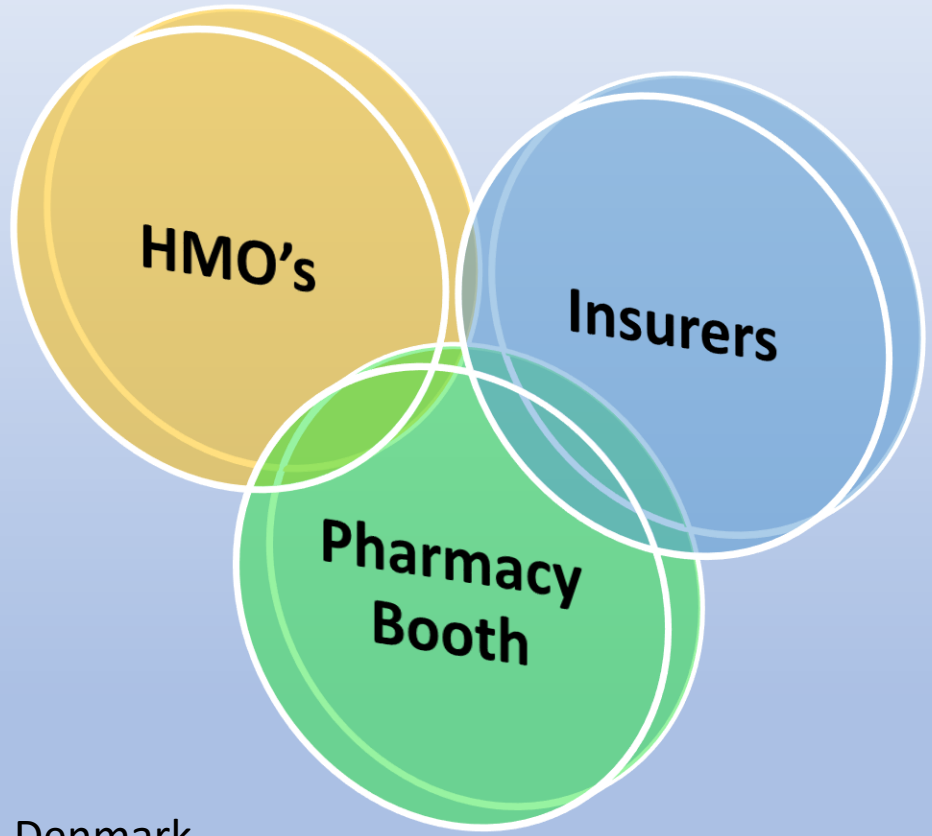
International Conference on Auditory Displays (ICAD); June 2019 http://hdl.handle.net/1853/61501

J Cancer Res Clin Oncol. 2021 Sep 21:1–9. https://doi.org/10.1007/s00432-021-03809-x

Business Model

A global, **B2B and B2B2C Cloud service**, FDA approved, performing skin cancer diagnostics by pay per package use of **GP's or Dermatologists**

Platform can be applied across 3 large diagnostic areas:



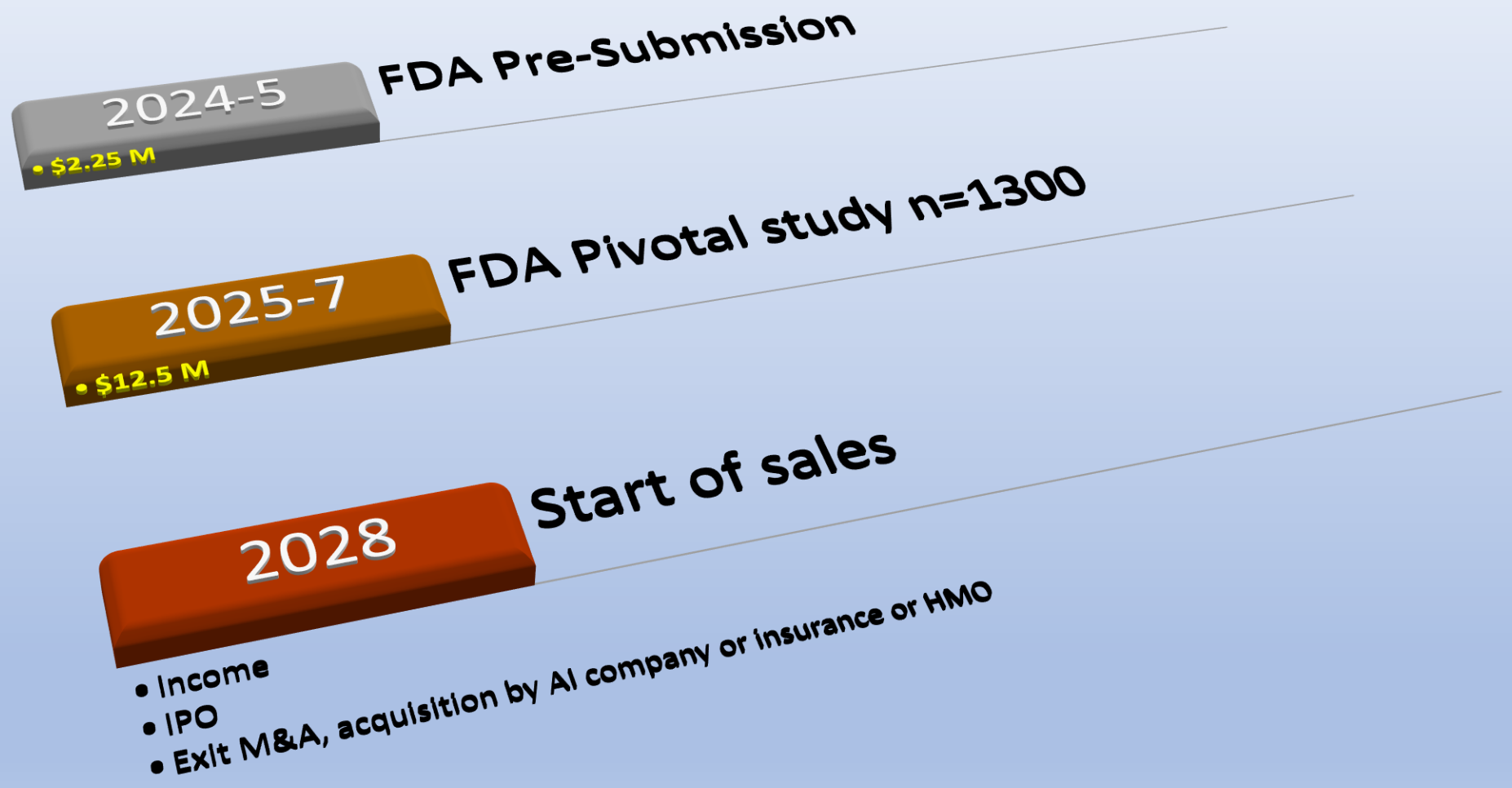
Target consumers model

- All subjects screened by GP's on an annual basis, alike regular blood pressure measurements
- Patient report of a suspicious lesion diagnostics

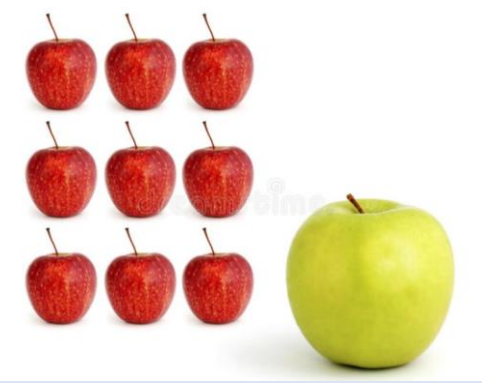
Implementation per continent

- CPT code reimbursement in US
- Statutory health insurer payment in Germany over age 35 yrs.
- Gate keeper countries GP reimbursement: UK, Netherlands, Norway, Denmark

Projections – Go To Market



Competitive Landscape for Sonification – Blue ocean



BosTel Technologies' skin cancer diagnosis algorithms are unique (sonification), more accurate, scientifically validated, patented (US) and **outperform** presently weak competitors. No sonification competitors.

I. Algorithm-based applications review

British J Medicine, 2020
DOI: 10.1136/bmj.m127 10 Feb 2020

CONCLUSIONS

Current algorithm based smartphone apps cannot be relied on to detect all cases of melanoma or other skin cancers. Test performance is likely to be poorer than reported here when used in clinically relevant populations and by the intended users of the apps. The current regulatory process for awarding the CE marking for algorithm based apps does not provide adequate protection to the public.

SYSTEMATIC REVIEW REGISTRATION

PROSPERO CRD42016033595.

II. Google Skin app performance, *JAMA Netw Open.* 2021;4(4):e217249

- Tool for PCP and Nurse practitioners
- "Most dermatologic cases are initially evaluated by nondermatologists such as primary care physicians (PCPs)"
- Sensitivity: - SCC 0.58
  - BCC 0.84
  - Melanoma 0.15

Always store inconvenient results in a Supplement

III. SkinVision has a **45% rate of non diagnostics** and **identifies melanoma by a 2700% higher rate** than trained dermatologists. [Sensitivity and specificity of SkinVision are likely to have been overestimated. JEADV 2020;34:e582; Over-Detection of Melanoma-Suspect Lesions by a CE-Certified Smartphone App, Cancers (Basel), 2022, Aug 14 p3829].

IV. Skin Analytics study addresses MM
doi:10.1001/jamanetworkopen.2019.13436.
Study looked for and identified **only BIG MELANOMAS (>76%),** which can easily be accurately identified by an unaided human eye.

Variable	Category	.	Percent
Lesion diameter (Geometric mean diameter=6.75 mm (6.49-7.02))	< 5 mm	110	20.0%
	5-9 mm	266	48.3%
	10-14 mm	155	28.1%

Work Plan – Pre Submission

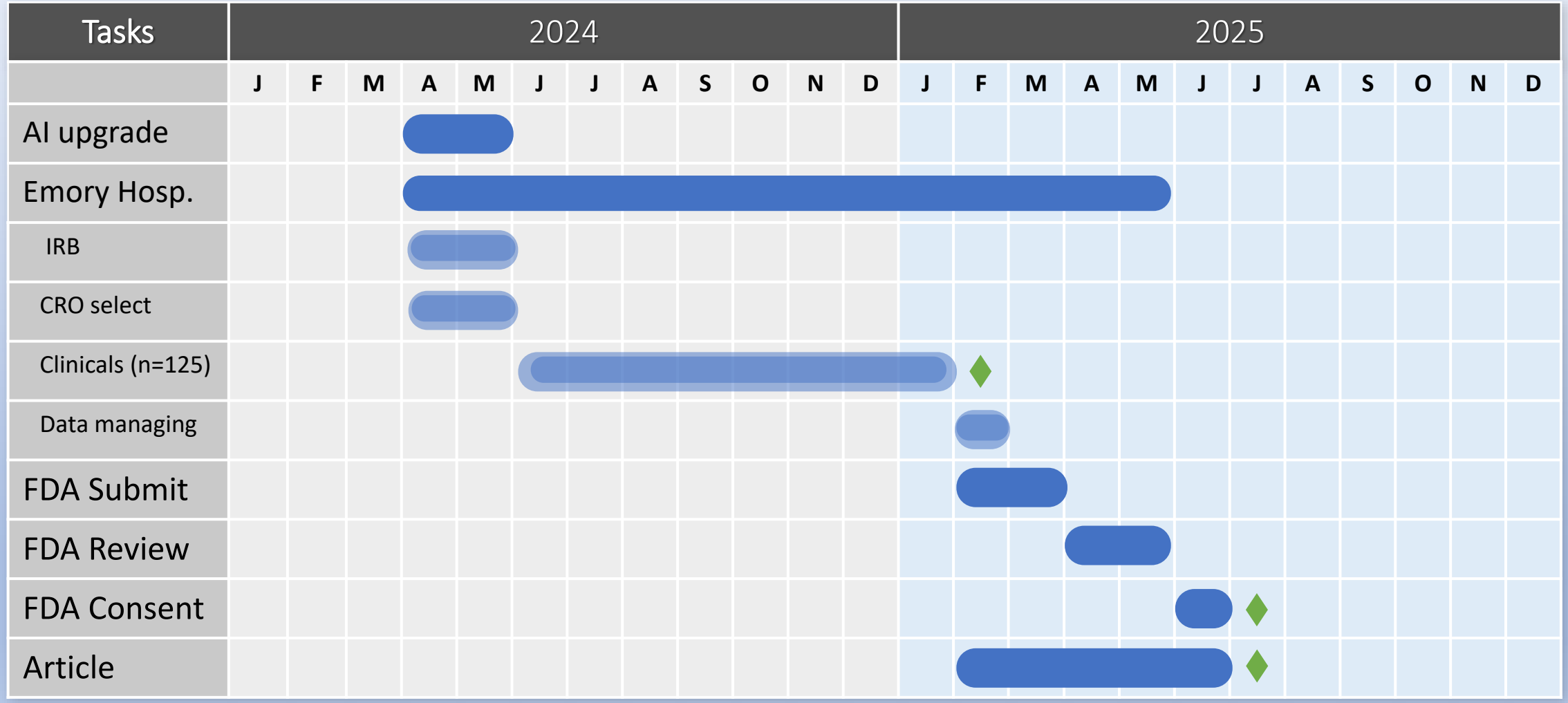
Budget FDA Pre-submission : $2.25 M, 9-12 mo.

- Final server upgrade - Hop Labs	0 - 2 mo
- Clinical study n=125 at Emory Hospital, IRB, **Prof Travis Blalock, PI**	0 - 6 mo
- Regulatory consultancy	0 - 7 mo
- FDA pre-submission and approval	9 - 12 mo

Milestones

- ✓ **Bostel – Emory Hospital** ongoing joint IRB.
- ✓ Joint article Bostel Emory
- ❑ EU patent admittance
- ❑ Study n=125,
- ❑ FDA approval of pre-submission

Pre-Submission usage of funds

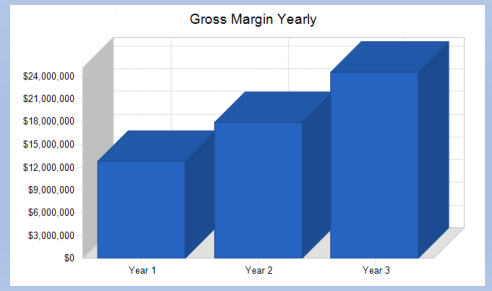


Financial forecast post FDA approval (2027) and start of sales

Table: Sales Forecast

Sales Forecast			
	Year 1	Year 2	Year 3
Unit Sales			
HMO	1,069,224	1,500,000	2,000,000
Insurance Company	290,024	400,000	600,000
Total Unit Sales	1,359,248	1,900,000	2,600,000
Unit Prices	Year 1	Year 2	Year 3
HMO	$10.00	$10.00	$10.00
Insurance Company	$10.00	$10.00	$10.00
Sales			
HMO	$10,692,240	$15,000,000	$20,000,000
Insurance Company	$2,900,240	$4,000,000	$6,000,000
Total Sales	$13,592,480	$19,000,000	$26,000,000
Direct Unit Costs	Year 1	Year 2	Year 3
HMO	$0.50	$0.50	$0.50
Insurance Company	$0.50	$0.50	$0.50
Direct Cost of Sales			
HMO	$534,612	$750,000	$1,000,000
Insurance Company	$145,012	$200,000	$300,000
Subtotal Direct Cost of Sales	$679,624	$950,000	$1,300,000

Pro Forma Cash Flow			
	Year 1	Year 2	Year 3
Cash Received			
Cash from Operations			
Cash Sales	$13,592,480	$19,000,000	$26,000,000
Subtotal Cash from Operations	$13,592,480	$19,000,000	$26,000,000
Additional Cash Received			
Sales Tax, VAT, HST/GST Received	$1,019,436	$1,425,000	$1,950,000
New Current Borrowing	$0	$0	$0
New Other Liabilities (interest-free)	$0	$0	$0
New Long-term Liabilities	$0	$0	$0
Sales of Other Current Assets	$0	$0	$0
Sales of Long-term Assets	$0	$0	$0
New Investment Received	$0	$0	$0
Subtotal Cash Received	$14,611,916	$20,425,000	$27,950,000
Expenditures	Year 1	Year 2	Year 3
Expenditures from Operations			
Cash Spending	$5,565,388	$7,590,700	$10,114,200
Subtotal Spent on Operations	$5,565,388	$7,590,700	$10,114,200
Additional Cash Spent			
Sales Tax, VAT, HST/GST Paid Out	$1,019,436	$1,425,000	$1,950,000
Principal Repayment of Current Borrowing	$0	$0	$0
Other Liabilities Principal Repayment	$0	$0	$0
Long-term Liabilities Principal Repayment	$0	$0	$0
Purchase Other Current Assets	$0	$0	$0
Purchase Long-term Assets	$0	$0	$0
Dividends	$0	$0	$0
Subtotal Cash Spent	$6,584,824	$9,015,700	$12,064,200
Net Cash Flow	$8,027,092	$11,409,300	$15,885,800
Cash Balance	$8,107,093	$19,516,393	$35,402,193



Opportunity: Technology-Ready for FDA approvals

Bostel Technologies is a company providing

- ✓ **Operational technology**
- ✓ **Unique audio sonification ability to detect malignant traces**
- ✓ **Backed up by 2 US Patents**
- ✓ **A prospective proof of concept study**
- ✓ **5 articles validation.**

Company is raising investment of a $2.25 M round for pre-submission.

Use of investment: Facilitate FDA class III PMA de novo pivotal studies.

Investment will promote Bostel's Audio-Visual AI in becoming the global reference site for skin cancer diagnostics.