

Voice Biomarker AI in Mental Health

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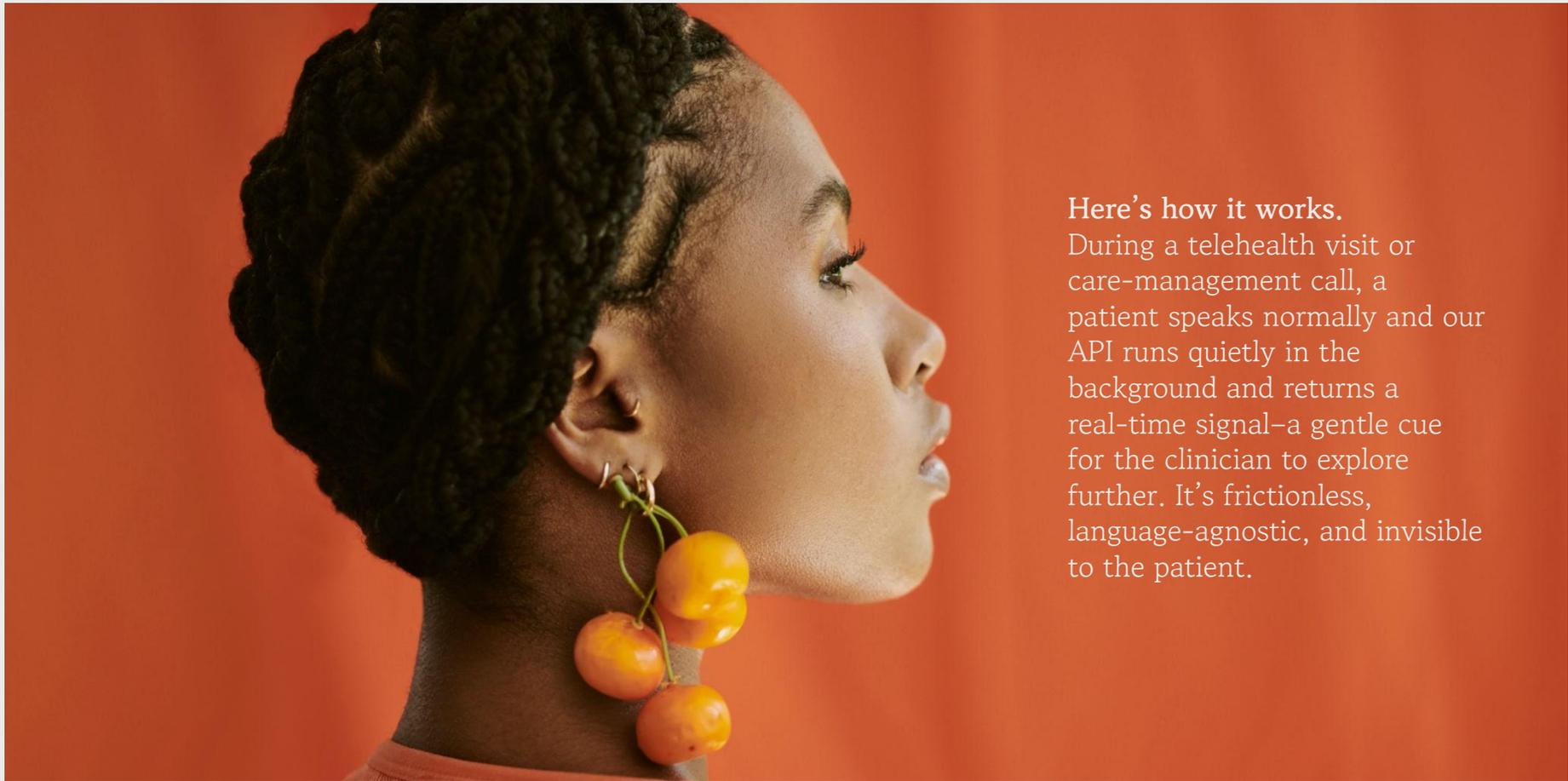
Developing foundational
models for human insights.

Depression and anxiety are the leading causes of disability worldwide, yet only **4%** of U.S. Primary Care visits are screened.

There's no vital sign for mental health—no objective measure, no quick check. When depression goes unseen, the cost of treating chronic conditions like diabetes or cancer can increase **2-8X**, and clinicians burn out trying to keep up.

What if **voice** could be that missing sign?

The human voice reflects emotional and neurological changes—subtle shifts in tone, energy, and rhythm. Kintsugi Voice analyzes 20-seconds of sound to detect signs of depression and anxiety, validated in prospective, double-blind pivotal study in its FDA De Novo submission, comparing our model against the SCID-5 clinician interview.



Here's how it works.

During a telehealth visit or care-management call, a patient speaks normally and our API runs quietly in the background and returns a real-time signal—a gentle cue for the clinician to explore further. It's frictionless, language-agnostic, and invisible to the patient.

Case Study

At Dreavita, a behavioral-health platform, Kintsugi Voice improved early detection and care-plan compliance.

They measured a 19-fold ROI and clinicians described it as a “sixth sense” for when patients were starting to struggle—or to heal.

“Kintsugi Voice standardizes rigorous assessment for improved patient screening. Voice analysis detects unseen stress and depression, enabling tailored treatment and better patient outcomes.”

————— Andrea Piazza, LMFT, Founder/Owner, Dreavita



FDA

The FDA is a capital-intensive lift for startups, often spanning multiple years and millions of dollars of commitment from public and private funding.

CMS

Even after clearance, **payment delays** create barriers. CPT 96127 already covers brief behavioral assessments, but CMS alignment often trails years behind. Without early FDA-CMS coordination, innovation in healthcare is punished instead of rewarded.

Startups

AI is critical **leverage**: thousands-fold productivity gain in a system short on clinicians.

FDA Lookback

2022

FDA Pre-sub 1

Alignment on De Novo designation, ground truth discussion

1 hour meeting

2023

FDA Pre-sub 2

Alignment on IFU, ground truth, pilot results and pivotal trial design considerations

1 hour meeting

2024

FDA Pre-sub 3

Alignment on lower bound Sn/Sp performance, SAP, and pivotal adjudication process

1 hour meeting

2025

FDA Pre-sub 4

Alignment on clinical utility, Precision and Human Factors studies design considerations

1 hour meeting

We've worked with the FDA for 4 years through multiple pre-submissions for our De Novo submission. The process has been thoughtful and rigorous. Given the high unmet need for validated tools, enabling additional resources to shorten feedback cycles would keep oversight strong while supporting progress more aligned with the pace of technology.

From first prototype to clinical use, this journey has taken 7 years.
In that time, depression rates and suicide deaths have continued to rise.



The science is ready; the system needs to move faster.

“ ”

Don't let the pursuit of perfection delay the delivery of progress.

If our AI model was **perfect** to the SCID-5 ($k=0.28$), this would be lower bound 75/75 Sn/Sp with 95% CI. Today's mental health screening happens in less than 4% of primary care visits, an indeterminate rate of 35% and 65% yield is still a 15X increase in real, usable screening impact over the status quo—a **huge public health win**.

Key Takeaways

01

Objective Screening, Triage, and Monitoring

AI can lower costs and improve care by making mental health triage measurable and fast.

AI is not replacing clinicians—it's **amplifying** them. If we get this right, checking mental health could become as routine as checking blood pressure.

02

Shorter Feedback Cycles

Aligning regulation with the iterative nature of AI would improve **innovation time and cost** to market.

Additional resources to expedite interactions due to the high unmet need for better tools.

03

Don't Let Perfect Block Better

Innovation often stalls from **process**, not science.

Thank You!