

May 12, 2022 8:00 AM Eastern Daylight Time

Wysa Receives FDA Breakthrough Device Designation for AI-led Mental Health Conversational Agent

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New peer-reviewed studies demonstrate efficacy in managing chronic pain, depression and anxiety

BOSTON--(BUSINESS WIRE)--Wysa, a leading artificial intelligence (AI) based digital companion for behavioral health, has announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its AI-based digital mental health conversational agent for patients 18 years and older with a diagnosis of chronic musculoskeletal pain (defined as pain lasting longer than three months) and depression and anxiety.

The device delivers cognitive behavioral therapy (CBT) via a smartphone-based conversational agent to reduce the symptoms of depression and anxiety, reduce pain interference, and improve physical function.

The designation follows an independent peer reviewed clinical trial, published in [JMIR](#), that found Wysa to be effective for managing chronic pain and associated depression and anxiety, which was found to be more effective than standard orthopedic care, and comparable to in-person psychological counseling.

"We're thrilled to achieve this meaningful designation from the FDA and look forward to working closely with the Agency to continue development of AI-based cognitive behavioral therapy," said Jo Aggarwal, CEO and co-founder of Wysa. "Our mission is to help those in need of support with an always available platform, and

during these challenging times it's more crucial than ever to provide mental health options."

The FDA Breakthrough Device program is designed to help accelerate the development and approval of medical devices and products that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The FDA designation of Wysa's platform will enable Wysa to efficiently communicate with FDA's experts through various program options, facilitating the development of the product prior to the premarket review phase.

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Notes to editors:

Wysa has published peer-reviewed work in the domain of chronic pain which codified user-centric insights ([link](#)), examined the efficacy of the solution in a clinical trial ([link](#)), and future protocols which aim to study this novel solution further in chronic pain ([link](#)).

About Wysa:

Wysa is a global leader in AI-driven mental health support, available both to individuals and through employer benefits programs. Wysa is intended to support individuals with the help of an "emotionally intelligent" conversational agent. The bot uses evidence-based cognitive-behavioral techniques (CBT), meditation, breathing and mindfulness exercises, as well as micro-actions to help users build mental resilience skills. For employers, Wysa offers a workplace solution that caters to the full spectrum of mental health needs. This solution embeds into existing company benefits, such as Employee Assistance Programs (EAP) or external health care provider networks, and can be customized by geography or cohort. Currently, Wysa has facilitated over 400 million conversations in 65 countries across the globe. Wysa works with 20 enterprise partners and 7 million employees worldwide, with partners that include Accenture Global, Aetna International, NHS, L'Oreal, Cincinnati Children's Hospital Medical Center, and the Ministry of Health in Singapore.

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WYSA

RELEASE SUMMARY

AI-led therapy app for chronic pain, depression and anxiety receives FDA Breakthrough Device Designation. Independent research proves efficacy.

RELEASE VERSIONS

English

HASHTAGS

[#Wysa](#)

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OneDigital Resourcing Edge Partners with Wysa to Provide AI-Powered Mental Health Support for Employees

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