# Digital Health Industry Regulatory Case Study



# Making behavioral health radically accessible



### **About Woebot Health**

Woebot Health's fully automated platform accelerates access to quality, evidence-based mental health support. The heart of the platform is the always-available digital companion, Woebot. Woebot offers **personalized**, **evidence-based**, **AI-powered support** through chat-based conversations to help members cope with symptoms of anxiety and depression. Their configuration/integration capabilities and data reporting interface provide partners with valuable population insights. Woebot Health products include:

Woebot for Adults | Woebot for Adolescents | Woebot for Maternal Health





## The opportunity

Mental health needs in the US have skyrocketed, yet support continues to fail to meet demand. As many as 41% of adults report symptoms of anxiety or depression, but 56% of psychologists aren't taking new patients, and for those that are, 69% have wait times over 3 months. PCPs are often the first providers to encounter mental health concerns, yet the average PCP visit is only 18 minutes.



# The challenge

Addressing this gap requires a multifaceted approach that reliably **engages key and diverse stakeholders** (e.g., regulators, payers, providers, systems, clinicians, patients, families, and members) to deliver products that function across the full regulatory spectrum, from general wellness to FDA-cleared products.



### The approach

- Real-world deployment: Woebot Health is leveraging their 3+ years of real-world experience in clinically-mediated product deployments in healthcare ecosystems to continue broadening their portfolio of product offerings.
- FDA correspondence: Commitment to regulatory engagement and learning via communications with FDA.
- Research: 16 clinical trials conducted to date, with 1,800+ participants & leadership in DEIB-informed methods.
- Looking ahead: To develop a product portfolio that targets a wide range of mental health needs, Woebot is
  engaging with regulators to explore novel pathways to provide mental health support, as meeting unmet
  needs may require products that are widely accessible and cleared.



#### The success

- ✓ ISO:13485-certified quality management system demonstrates Woebot Health's use of the highest standards for software development.
- ✓ To accelerate the speed to support, improve member experience, and close gaps to supportive care, Woebot has provided 74M minutes of non-human emotional support to 1.5M individuals.
- 77% of patient-reported outcomes are collected outside of clinic hours, reducing clinician administrative burden and scaffolding partners' understanding of their populations.
- Woebot's behavioral health relational agent <u>creates a bond</u> that is comparable to that achieved between patients and human therapists in more traditional settings.

We're honored to take advantage of some of the greatest leaps in technology the world has seen. We're excited to see what advances we can make within the field of mental health itself. We'll continue doing what science does best: designing rigorous studies and sharing those results with the regulatory and broader community so we may build this new paradigm, together."

#### - Alison Darcy, Ph.D

Founder & President, Woebot Health

