Title: Use of Real-World Data to Evaluate Clinical and Patient Outcomes by Use of a Prescription Digital Therapeutic (delivered via mobile app) for the Treatment of Insomnia and Depression

Technology of Interest: mHealth for Insomnia, Prescription Digital Therapeutic*

Disease Area: Mental Health – Insomnia/Depression

Duration: 12 months

Network Collaborator(s): Yale New Haven Hospital; Mayo Clinic

Leveraging patient-generated health data, this project will assess the impact of a mobile-delivered, prescription digital therapeutic (PDT)* device (Pear-003) delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) for real-world patients with chronic insomnia and depression.

Insomnia is one of the most prevalent health concerns and imposes a significant physical, behavioral, and financial burden on patients’ lives. Up to 50% of the general adult population experience insomnia symptoms, with 12-20% meeting criteria for chronic insomnia. Adults suffering from insomnia also have a higher likelihood of comorbid conditions such as depression, resulting in a reduced quality-of-life and higher rates of morbidity and mortality. CBT for insomnia is the recommended first line treatment for chronic insomnia, but many patients encounter treatment barriers, including a limited number of trained providers. The goal of this Test-Case is to conduct a multi-center randomized controlled trial to collect and evaluate real-world data alongside clinically-validated measures of insomnia and depression to yield a multidimensional analysis of patient benefit from a mobile-delivered CBT-I prescription digital therapeutic.

Using Hugo, a participant-centered mobile health research platform for data collection and aggregation, this study will gather and collate patient-reported outcomes, healthcare utilization data, and data from personal digital devices. 70 patients with chronic insomnia and sub-clinical depression will be randomly allocated to receive the PDT device delivering CBT-I or usual care and will be followed for 21 weeks. Primary study endpoints include self-reported online ratings of insomnia severity and self-reported depressive symptoms. Secondary endpoints include rate of healthcare utilization, change in sleep outcomes, and change in patient-reported outcomes of sleep quality. In addition, this study will determine the feasibility of connecting in-house PDT devices to other mobile health (mHealth) devices.

*Planned; this product has not yet been reviewed and approved by the FDA.