

## First Real-World Evidence Demonstrates Cala Trio's Effectiveness in Essential Tremor with Individually Calibrated, Non-Invasive Stimulation

- *Cala Health announces real-world evidence from three months of home-use by patients prescribed Cala Trio to treat their essential tremor*
- Motion sensors used to calibrate therapy and measure tremor physiology before and after each session showed that 57% of subjects improved at least two-fold on all sessions, with 93% improving at least two-fold when tremors were most severe

**Burlingame, CA – September 14, 2020** -- Cala Health, Inc., a bioelectronic medicine company developing wearable therapies for chronic disease, today presented data demonstrating that Cala Trio™ therapy is safe and effective in improving tremors in patients with essential tremor (ET) when used at home, unsupervised, and under real-world conditions. These findings further validate the [previously reported results](#) from the landmark PROSPECT study, the largest therapeutic clinical trial in ET. The results from this new real-world evidence, which provides additional objective data on typically subjective patient-reported symptoms, were presented as a [poster](#) at the International Parkinson and Movement Disorder Society's MDS Virtual Congress 2020, being held from September 12-16.



"Patients with ET often need to choose between living with tremors that negatively impact their daily lives or risk unwanted side effects from pharmacologic therapy – our mission is to change that equation and improve lives," said Kate Rosenbluth, Ph.D., Founder and Chief Scientific Officer of Cala Health. "As a bioelectronic alternative, Cala Trio offers a new approach for managing tremors without the systemic side effects of pharmacologic treatments or the brain surgery needed for implanted devices. The real-world evidence presented at MDS shows that excellent outcomes can be achieved with Cala Trio and that the device is easy for patients to use in their everyday lives – not just in controlled clinical trials."

### **About the Real-World Data**

Forty-four patients used Cala Trio for symptomatic tremor relief in hand tremors during three months of non-supervised home use. Tremor severity was quantified using tremor power, which was computed from motion sensor data, and assessed before and after each of the first 40 Cala Trio™ therapy sessions, as well as every subsequent seventh session. Motion data resulting in tremor power measurements included 1,751 therapy sessions.

Results from this first real-world evidence show that therapy sessions following their most severe tremors, 93% of patients experienced at least a two-fold improvement (50% reduction) in tremor power. Additionally, 57% of all patients experienced at least a two-fold improvement in tremor power over all sessions. Of the 18 patients who completed a survey after 90-days of use, 61% reported improvement in their ability to eat, drink, and write, and 56% reported improvement in quality of life. Three of the 44 patients reported minor adverse events (skin irritation or electrical burns) that resolved with a pause in treatment and without medical intervention.

Sylvia Hooks, a 73-year-old former professional tennis player, and an avid golfer, has been living with ET for more than 30 years. She had taken daily medication for years to alleviate her tremors as well as had a consultation with her doctor about deep brain stimulation. Sylvia has been using Cala Trio since its approval in 2018, and no longer needs daily medication to treat her ET. "Many people fail to appreciate the psychological and emotional toll that ET takes on people living with this condition every day," [she said](#). "I felt frightened that I couldn't do simple tasks. It was also frustrating and embarrassing to have friends and family wanting to butter my bread because it was painful for them to watch me struggle. Cala Trio continues to make it easier to play golf, and it makes it more comfortable to eat in front of others."



Rohit Dhall, MD, MSPH, Associate Professor of Neurology and Director of Neurodegenerative Disorders at the University of Arkansas and lead author on the real-world data publication commented, "Adults with ET have limited treatment options, and Ms. Hooks' experience before commencing therapy with Cala Trio is typical of many patients. Patients with ET and the physicians who treat them need to know that a different option exists: a medication- and surgery-free therapy that can be administered easily at home and can improve tremor symptoms and quality of life. This evidence is an important step forward, and I hope that these real-world results will encourage the widespread adoption of this innovative bioelectronic therapy for ET."

### **About Essential Tremor (ET)**

Essential Tremor (ET) is the most prevalent tremor disorder and one of the most common neurological disorders, affecting an estimated seven million people in the United States. It is a chronic condition that causes involuntary and rhythmic shaking and typically worsens over time. ET can affect almost any part of the body, but the trembling most often occurs in the hands, making everyday activities such as eating, writing, or getting dressed extremely difficult. ET is often confused with Parkinson's disease, although it is eight times more common. A key difference is that hand tremors caused by ET happen with goal-directed movement (with intention), whereas Parkinson's disease tremors occur mostly at rest. Current ET treatments include mostly off-label use of medications or brain surgery.

### **About Cala Trio™**

Cala Trio™ is the first non-invasive targeted therapy that reduces hand tremors for adults living with Essential Tremor (ET). Prescription therapy is a simple, wrist-worn device that is calibrated to treat a patient's unique tremor symptoms. When activated, Cala Trio gently stimulates the nerves in the wrist to disrupt the tremulous activity in the brain, without the need for invasive brain surgery or medication. The easy-to-use and effective Cala Trio can be prescribed through an in-person consultation or telemedicine appointment. Therapy is conveniently delivered to the patient's home, and Cala Health educates patients via—phone, video, user portal.

### **About Cala Health, Inc.**

Cala Health, an award-winning bioelectronic medicine company, is transforming the standard of care for chronic disease while putting patients first. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation, and its vertically integrated commercial model is reshaping the delivery of prescription therapies. Cala Health's lead product,

Cala Trio™, is the only individualized, non-invasive, wrist-worn prescription therapy for essential tremor. New therapies are under development in neurology, cardiology, and psychiatry. Cala Health is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology. For more information, visit [CalaHealth.com](http://CalaHealth.com).

**Contacts**

Media Contact:

Erich Sandoval

[Erich.Sandoval@FinnPartners.com](mailto:Erich.Sandoval@FinnPartners.com)