

NextStep Robotics Secures Phase II NIH NINDS Cooperative Agreement Funding



Baltimore Start Up NextStep Robotics Awarded Phase II NIH \$4.5 Million Cooperative Agreement to Bring its Stroke Recovery Device to Market.

NextStep Robotics, a University of Maryland, Baltimore start up tackling stroke rehabilitation, specifically foot drop, has been awarded Phase II of a Fast Track Cooperative Agreement application worth \$5.5 million by the National Institute of Neurological Disorders and Stroke.

Baltimore, MD (May 13, 2021) NextStep Robotics Inc., an early-stage company that has developed a personalized robotic therapy to help treat foot drop in recovering stroke patients, announces the National Institute of Neurological Disorders and Stroke has awarded the company Phase II of a Fast-Track Cooperative Agreement to complete a clinical trial testing the safety and efficacy of the device. This support for NextStep comes from National Institute of Neurological Disorders and Stroke of the National Institutes of Health under award number U44NS111076.

Phase I of this project completed development of NextStep's flagship AMBLE device, which shows promise to durably reverse foot drop for the first time. Phase II will allow the company to begin the clinical trial for the device. The trial, which will start this summer, will include 120 stroke survivors suffering from foot drop. Early success in a small cohort showed promising results, allowing 85% of subjects to either downgrade or discard their assistive devices, including canes, walkers, and ankle foot orthotics (AFO).

The trial will be conducted at the University of Maryland Rehabilitation and Orthopaedic Institute. Richard Macko, MD, Professor in the Department of Neurology at the University of Maryland School of Medicine and Co-Founder of NextStep Robotics, will be the Academic Lead for the project. Dr. Macko, who is one of the co-inventors of the device, has already obtained Institutional Review Board approval for the planned trial.

“When we look at the many life skills that a stroke survivor will be re-introduced to during rehabilitation, the ability to walk and re-establish balance is critical. Correcting drop foot through this advanced technology will help stroke survivors regain their mobility and take that significant next step in the recovery process.” – Cindy Kelleher, President & CEO, University of Maryland Rehabilitation & Orthopaedic Institute.

Led by Brad Hennesie, former University of Maryland, Baltimore (UMB) staff member turned entrepreneur, NextStep Robotics is based on intellectual property licensed from UMB; the robotic therapy has more than a decade of research behind it. It is the first effective treatment option for foot drop and helps stroke survivors and others regain mobility using clinically proven rehabilitation training. This treatment option serves a growing national need. With 5 million stroke survivors in the U.S. and 800,000 new strokes per year, this limit on mobility that inhibits people from lifting their toe while walking puts them at risk for a falls and limits their ability to

access their communities. Although the initial focus is on stroke victims, foot drop also afflicts people suffering from other maladies such as multiple sclerosis, diabetes, and Parkinson's disease, afflictions that are also increasing in incidence in the population.

NextStep Robotics gives clinics the ability to offer personalized robotics therapy through its adaptive software which provides an assist-as-needed approach. Worn by the patient, the easy-to-use robot is designed to be operated by any trained clinical staff, freeing up therapists with highly advanced training to provide hands-on treatment of patients' other rehabilitation needs.

The robot's unique training protocol is used to promote motor learning in just a few weeks. From a clinical standpoint, the robot serves as a training device, not an assistive device. One robot placed in a clinic can provide training to as many as 100 patients per year. Additionally, the device will be placed in clinics initially as an exercise device and the training protocol provides enough of an effect to elicit neuromuscular reeducation in its users allowing higher reimbursement rates than the usual gait training or therapeutic exercise.

Since it was founded in the spring of 2017 NextStep has been housed in the Maryland Development Center, created by Dr. Gil Blankenship of University of Maryland, College Park and nine UMB clinicians to develop technologies that come out of Baltimore area universities and hospitals.

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