

## Newel Health Launches Groundbreaking Parkinson's Disease Study Leveraging Real-World Data for Enhanced Treatment Strategies

Initiates Recruitment for "NWL-SOT-CS-001" Clinical Study with Generous Funding from The Michael J. Fox Foundation

Salerno, Italy, December 14, 2023 – Shortly after presenting Soturi at Frontiers Health 2023, <u>Newel</u> <u>Health</u>, a leading digital therapeutic solution provider, is pleased to announce that three centers are involved in the recruiting and onboarding for its clinical study, "NWL-SOT-CS-001," aimed at leveraging Real-World Data to enhance Parkinson's disease treatment.

The study prioritizes free-living data collection to understand patients' daily challenges, symptoms' patterns, adherence to medication and the overall response to medication to validate algorithms for treatment optimization. With the recruitment phase started, the data collection phase is now underway, using the Soturi mobile app and a smart device for digital data capture over a 6-month period. Led by **Prof. Maria Teresa Pellecchia** at **University Hospital San Giovanni di Dio e Ruggi d'Aragona** in Salerno, Italy, alongside two centers in Rome, **Santa Lucia Foundation IRCCS Outpatient Clinic for Parkinson's Disease and Movement Disorders - Laboratory of Neuropsychiatry, and the Parkinson's disease research centre Institute for Research and Medical Care IRCCS San Raffaele, this innovative research initiative is generously funded by The Michael J. Fox Foundation for Parkinson's Research.** 

Prioritizing free-living data collection, the study bridges the gap between traditional clinical monitoring and the challenges faced by Parkinson's patients. By exploring medication's impact on symptom fluctuations, the study strives to develop a model for refining medication plans and reducing OFF periods. The Soturi mobile app, a key component, provides digital companion features, paired with a wearable smart device for seamless data capture over a 6-month period.

This study strategically complements Newel's R&D activities, addressing gaps in previous research. Actively recruiting for the next two months, it will culminate in the last patient's final visit in approximately eight months.

"This study aims to address a significant unmet need for individuals with Parkinson's disease: the accurate identification and remote monitoring of motor symptoms, motor fluctuations, and dyskinesia in real-world scenarios. Neurologists from three esteemed centers will collaborate to validate the clinical effectiveness of Soturi's digital health technology in providing real-time insights for optimizing and personalizing medication schedules for patients with Parkinson's disease," declares Prof. Maria Teresa Pellecchia, Principal Investigator, University Hospital San Giovanni di Dio e Ruggi d'Aragona.

"In the field of personalized management of Parkinson's disease, information gathered during conventional clinical visits often falls short. Recognizing the imperative to base insights on ecological data, we aim to provide a comprehensive understanding through accurate reports of patient symptomatology in everyday contexts, facilitated by data obtained from wearable devices," said Dr. Clelia Pellicano, Principal Investigator, Santa Lucia Foundation IRCCS Outpatient Clinic for Parkinson's Disease and Movement Disorders - Laboratory of Neuropsychiatry.

## PRESS RELEASE



"As the Clinical Trial Manager for Newel Health, I'm pleased to coordinate a clinical study that marks a significant step in implementing digital data and endpoint collection. This initiative is crucial as we transition towards studies that demand more Real-World Data, allowing us to capture the nuanced variability often missed in standard clinical studies' visits. By prioritizing free-living data and leveraging digital technologies, we aim to bridge the gap between traditional monitoring and the complex real-world experiences of Parkinson's disease patients, paving the way for more comprehensive and impactful research outcomes," said Giovanni Gentile, Clinical Trial Manager, Newel Health.

This study is funded by The Michael J. Fox Foundation for Parkinson's Research, Grant ID: MJFF-022711.

For more information or participation, visit:

- Newel Health Launches Groundbreaking Parkinson's Disease Study Leveraging Real-World Data for Enhanced Treatment Strategies
- <u>Michael J. Fox Foundation Trial Finder</u>
- ClinicalTrials.gov NCT05904288
- Michael J. Fox Foundation Grant MJFF-022711

## **About Newel Health**

Newel Health is an innovative company that aims to improve the lives of people that live with a health condition and support their doctors through the creation of beautifully designed and clinically validated digital medicine (DM) and digital therapeutics (DTx) solutions.

Born from an investment play by Healthware Ventures, the company has executed a series of strategic acquisitions of earlystage startups which now constitute a portion of its products' pipeline.

Its team of experts, comprised of professionals in digital, data, behavioral, and scientific fields, has extensive experience in the life sciences industry.

Newel Health's long history of industry partnerships and a focus on patient-centricity results in successful outcomes in these shared initiatives. The company also leverages commercial partnerships to expand its customer reach and to promote its vision of future health.

The company actively researches and develops new digital product concepts in additional therapeutic areas with the goal of entering new partnerships and extending its portfolio of DTx solutions.

Newel Health also owns H.Core, a proprietary rapid-development SaMD (medical device software) framework designed to accelerate the design, validation, production, and launch of DM and DTx solutions. Thanks to H.Core Newel Health provides its two flagship digital solutions:

**Amicomed**, a Hypertension Control program that helps people lower their blood pressure via analytic insights of longitudinal blood pressure measurements and highly personalized behavioral lifestyle modification programs.

**Soturi**, a suite of digital services and smart algorithms that personalize and optimize the medication and treatment plans for people living with Parkinson's disease.

For more information, please visit newel.health and follow us on LinkedIn and Twitter

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