





# ECRC "INDUSTRY COLLABORATIONS WEBINAR SERIES Robotic Exoskeletons

April 25, 2025

Developing the most advanced robotics to tackle the world's toughest mobility challenges

# We envision a world where people who cannot walk are able to stand up and walk again.

We started with Atalante X, our **self-stabilizing exoskeleton** that enables patients with severe gait and mobility impairments to stand up and walk again **in rehabilitation**.

Soon we will release the first and only completely **self-balancing Personal Exoskeleton** designed **for everyday use**.



We are now a two-technology company with one vision

## Develop the most advanced robotics to enable people who cannot walk to walk again



Over a decade of R&D creating the most advanced robotics to rehabilitate and help people walk again





## KNOWLEDGE TRANSLATION

Clinical Practice, Payers, and Policy

## The current state of exoskeletons in clinical practice

#### What do we know?

- There is a rapidly growing diversity of devices<sup>1</sup>
- Exoskeletons are safe and effective<sup>2,3</sup>
- Exoskeleton-assisted walking has been shown to improve Spinal Cord Independence Measure (SCIM) – sensory and motor subscore<sup>4</sup>
- Potential positive impacts on spasticity, autonomic function, quality of life, cardiopulmonary health, and pain<sup>5</sup>

#### A clinician's perspective<sup>6,7</sup>

- Keys to success: patient and subsequent goal selection
- Reported \$\physical burden/fatigue while maximizing mobility and overall safety
- Anticipate greater benefit compared to standing alone
- Cost and barriers to implementation remain significant concerns
- Understanding value proposition for individuals with complete vs. Incomplete injuries

A growing body of research drives evidence-based physical therapy practice with robotic exoskeletons like Atalante



### Optimal Patient Outcomes

- Patient goal attainment
- Clinician goal achievement
- Facility-specific goals
- Reduce long-term healthcare utilization

# Navigating device cost – both for rehab and home devices - is a major step along the path from clinical research to widespread access



Overground robotic training - more cost-effective than conventional training for individuals with complete SCI<sup>6</sup>

6) Pinto D, Heinemann AW, Chang SH, et al. Cost-effectiveness analysis of overground robotic training versus conventional locomotor training in people with spinal cord injury. J Neuroeng Rehabil. 2023;20(1). doi:10.1186/s12984-023-01134-7

Budget impact analyses define anticipated economic impact based on clinical improvement or implementation costs



Medicare began reimbursing personal exoskeletons in 2024, covering at least 75 devices to date, with additional payors beginning to increase access



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# How do we accelerate adoption and continue on a path towards expanded patient access?



## WALK IN NEWYORK

A private PT practice that enables physical therapists to leverage advanced technology and generate clinical research

### Our goals

- Create a playbook to navigate barriers to tech adoption
- Create a dedicated space for personal exoskeleton training
- Collaborate with practicing clinicians on research studies



## CLINICAL OUTCOMES

Our Approach to Clinical Trials and Ongoing Research Studies

# The process for identifying "Indications for use" differs between the US and EU



**~**-

- Adult able to tolerate a stand-up position
- Within professional healthcare facilities
- Under the supervision of a trained operator



#### In the US:

- Individuals with hemiplegia due to cerebrovascular accident (CVA).
- Individuals with spinal cord injuries at levels T5 to L5 (SCI).



**In the EU**, not by diagnoses, but following functional impairments:

- Motor complete paraplegia.
- Motor incomplete paraplegia.
- Hemiplegia due to cerebrovascular accident or to any other cause of acquired brain injury.

# Our approach to clinical trials: Wandercraft sponsored trials accelerated Atalante's path to the field



Sources : ClinicalTrials.gov M4 study article : Kerdraon et al. 2021.

### Our approach to clinical trials: new era with 1st researches on the Personal Exoskeleton



Personal Exoskeleton prototype

- Designed for high-SCI users (T6 and above)
- With a **hand control interface** for those with limited hand functionality
- For home and community use
- With a trained companion



# First study on the Personal Exoskeleton, conducted in Walk in Paris center

ExoUser Study : Human Factors Validation Testing

**Population:** 6 SCI patients (C4-T5) + 6 companions

**Intervention:** 5 training sessions + 1 for usability evaluation, functional tests, and participants interviews

#### **Results**:

- Usability validated: All critical tasks\* successfully completed. Ex: donning/doffing, emergency extraction
- Training consisting of only 5 sessions deemed satisfactory and adequate to certify both users and companions.

Critical tasks = tasks required to be mastered to use the device safely and effectively in home and community settings



Simulated indoor/outdoor environments used during the study

# First clinical trial in the US on the Personal Exoskeleton: ongoing pivotal study is being conducted in two research facilities

Pivotal Study: Empowering mobility in people with SCI with a hands-free, selfbalancing personal exoskeleton

- Population: 24 SCI users + 24 paired companions, T6 and above, motor complete or incomplete
- Intervention: 9-10 visits over 3 to 4 weeks
- Objectives: Safety & Effectiveness. Two co-primary outcomes : Timed Up and Go (TUG) in 3min or less, ≥40m on the Six-Minute Walk Test (6MWT)



U.S. Department of Veterans Affairs

Spinal Cord Damage Research Center, James J. Peters VA Medical Center

Principal investigator: Ann M. Spungen



**Kessler Foundation** 

**Co-Principal investigator: Gail Forrest** 



- → Collection of **adverse events**
- → Monitoring of **vital signs**, **#steps, distance covered** and **up-right time** at each exoskeleton session
- $\rightarrow$  Level of companion assistance recorded on the different tasks and each Perf. Test

### Ongoing recruitment at the Bronx VA and Kessler Foundation



Do you have (or could get) a companion with good physical ability willing to attend the screening (1 to 2 visits) and 8 sessions at a center in the NYC area with

Are you 18 years or older?

Do you live in the US and speak English or are able to with the assistance of a translator?

If you said "Yes" to all the questions above and wish to learn more about this study, please contact us!



If you'd like more information or have any question about recruitment, please reach out to: clinicaltrials@wandercraft.health

### We would love to hear from you!

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Clinical Trials questions or wish to participate <u>clinicaltrials@wandercraft.health</u> Walk in New York (<u>winypt.health</u>) <u>Therapy@winypt.health</u>

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