Contract code	SE712000CO2024017

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Technical specifications for contract: ABLE DailyExo Clinical Trial

By submitting a tender, the participating bidders accept the technical specifications established herein, which are considered the minimum compulsory requirements.

Any proposal that does not comply with the minimum requirements set out in these technical specifications will be excluded from the procurement procedure.

1. Subject of the contract

The purpose of these technical specifications is to establish the particular conditions that will govern the provision of the service for conducting a clinical study of the ABLE Daily* robotic exoskeleton by by a clinical center (hospital, rehabilitation center, sociosanitary center, etc.). The main objective of this study is to validate the safety and performance of this new exoskeleton in domestic or community environments with at least 10 patients with paraplegia due to spinal cord injury. The study also aims to validate the usability and satisfaction of patients with the device, as well as demonstrate clinical benefits associated with its use (cardiovascular, respiratory, digestive, urinary, osteoporosis, spasticity, psychological, or quality of life improvement, among others).

(*) ABLE Daily is a bilateral lower-limb robotic exoskeleton for personal use manufactured by the Catalan company ABLE Human Motion, S.L. The device actively assists the hip and knee joints, helping to stand up, walk, turn, and sit down. It requires the use of a walker or crutches and supervision by a trained caregiver.

2. Activities and functions of participating bidders

The participating bidders must carry out the following tasks:

- Preparation of the Clinical Investigation Plan (CIP) for the study, including the protocol, complying with Good Clinical Practices (GCP), EN ISO 14155:2020, and MDR 2017/745 regulations.

- Submission of the CIP to the Ethics Committee (CEIm) of the center and the Competent Authority for medical devices in their country. Address any questions or modifications required for study approval.

- Patient recruitment: Recruit a minimum of 10 patients with spinal cord injury to participate in the study, according to the inclusion and exclusion criteria defined in the protocol.

- Clinical study: Conduct the clinical study with 10 patients in two phases. First, a training phase at the clinical center, where participants will learn to use the exoskeleton and perform complex skills (such as climbing stairs or ramps) under the supervision of a therapist from the clinical center. Once they have learned to use it with minimal assistance and passed the skill test, each participant will take the exoskeleton home. There, they can use it in the environments they decide, with the supervision of a companion, at least 2-3 times a week for a period of at least 10 weeks.

- Clinical data: Perform clinical assessments (e.g., osteoporosis, cardiorespiratory functions, quality of life, etc.) to evaluate the clinical advantages derived from the utilization of the exoskeleton.

- Systematic data collection to ensure traceable, complete, reliable results in compliance with EN ISO 14155:2020 and MDR 2017/745.

- Statistical analysis of results, preparation of reports, and scientific publications with the study results.

The tenders submitted by the participating entities must cover all the activities and functions mentioned in these technical specifications and in the special conditions for public contracts, all of which are compulsory for a tender to be admitted.

2.1 Objectives and milestones

The objectives to accomplish by the participating bidders are:

O1 Validate the safety and functionality of the ABLE Daily exoskeleton in domestic or community environments (indoors or outdoors) with at least 10 patients with paraplegia due to spinal cord injury.

O2 Validate the ease of use and satisfaction of spinal cord injury patients with the ABLE Daily exoskeleton.

O3 Demonstrate clinical benefits associated with the use of the exoskeleton for individuals with spinal cord injury (cardiovascular, respiratory, digestive, urinary, osteoporosis, spasticity, psychological, or quality of life improvement, among others).

To complete the aforementioned objectives, the participating bidders must accomplish the following milestones:

M1 Define and deliver a final protocol of the clinical study (September 2024).

M2 Study approved by the clinical center's Ethics Committee and the national Competent Authority (December 2024).

M3 Five patients recruited to participate in the clinical study (March 2025).

M4 Ten patients recruited to participate in the clinical study (June 2025).

M5 Obtain complete clinical data from the first five patients of the study, having completed a minimum of 30 exoskeleton sessions (July 2025).

M6 Obtain complete clinical data from ten patients, having completed a minimum of 30 exoskeleton sessions in the study (September 2025).

M7 Final report of the clinical study for domestic and community use, including statistical analysis of the collected data (October 2025).

M8 Draft of the scientific article presenting the results of the clinical study (December 2025).

2.2 Duration of the contract

The contractual agreement will begin the day after its formalization and will finish on december 31, 2025.

3. Value of the contract

This contract is funded by the Recovery, Transformation, and Resilience Plan – Funded by the European Union – NextGenerationEU, from the Call for Proposals: Public-Private Collaboration Projects 2021, State Plan for Scientific and Technical Research and Innovation 2021-2023. Project: CPP2021-008429 ABLE Daily Exo.

3.1 Base budget

Execution cost (VAT excluded)	Direct costs	114.591,29 €
	Indirect costs	11.459,13 €
Direct + Indirect costs		126.050,42 €
13% general expenses on this amount		16.386,55 €

6% corporate profit on this amount	7.563,03 €
Subtotal	150.000,00 €
21% VAT on the subtotal	31.500,00 €
Total amount (VAT included)	**181.500,00 €**

The estimation of salary costs has been calculated using the reference of the 3rd Collective Agreement of the Catalan Institute of Health (ICS) and the 2023 Salary Book for Statutory Personnel of the ICS published by the Government of Catalonia. This indication does not prejudice the agreement that may be applicable.

4. Compulsory requirements

Bidders must have sufficient technical, material, and qualitative means and human resources to carry out the tasks that are the subject of this contract.

The service regulated in these specifications must meet, at a minimum, the following requirements, without prejudice to the award criteria.

5. Monitoring and controlling the execution

The contractor must appoint a person who will be entrusted with managing the execution of the contract – i.e., the responsible for project execution (RPE) – who must guarantee the quality of the subject of the contract and deal directly with any issues related to the normal development of the tasks indicated herein with the interlocutor designated by the contracting authority.

The aforementioned persons must meet at least every two weeks to supervise, control, and deal with any aspect related to the development of the contract to ensure that it is being executed in accordance with the provisions of these specifications.

Moreover, the fulfilment of each of the milestones will be monitored and controlled in the following way:

M1: Every week the RPE will meet with the contracting authority to show and discuss the development of the protocol for the clinical study.

M2: The RPE will keep the contracting authority informed at all times about the process to obtain study approval from the Ethics Committee and Competent Authority.

M3: The RPE will notify the contracting authority when the 5th participant of the study is enrolled.

M4: The RPE will notify the contracting authority when the 10th participant of the study is enrolled.

M5: The RPE will notify the contracting authority when all the clinical data of the first 5 participants is obtained.

M6: The RPE will notify the contracting authority when all the clinical data of the total of the participants of the study is obtained.

M7: The RPE will meet regularly to discuss the progress of the final report of the clinical study.

M8: The RPE will meet regularly to discuss the progress of the scientific article presenting the results of the clinical study.

6. Technical documents required

The technical specifications proposed by the bidding company in its tender will become obligatory conditions that must be fulfilled during the execution of the contract if the bidding company is awarded the contract.

To certify the fulfilment of each technical specification, the successful bidder must provide the following documents:

- Send the final version of the protocol before be sent to the Ethical Committee and Competent Authorities (deadline: October 2024).
- Send a summary report of the first five participants, once all the data is recorded (deadline: July 2025).
- Send a summary report of the ten participants, once all the data is recorded (deadline: September 2025).
- Send the final report of the study (deadline: October 2025).
- Send the draft of the scientific article (deadline: December 2025).

Josep Maria Font Llagunes
Responsible of the contract

Barcelona, on the date of the signature