E++ Booster Final Report

EXOTrainer – Marsi Bionics

1. Short Description of the overall status

The exoskeleton prototype developed within the Experiment, was already industrialized, leading to the commercial model, ATLAS 2020, for which Marsi Bionics is currently applying for CE marking. The certification process and development of a Europe-wide marketing strategy are being supported by an H2020 SME Instrument Phase 2 grant. The contribution of the Booster consists of facilitating penetration into the German market. A Marsi representative relocated to Munich for the program's duration. He will received guidance from NW-Medsales consulting on how to approach the German healthcare system, articulating a business plan around specificities of the German market, and help on how to approach German health insurances. The expected outcome is the introduction of ATLAS 2020 on the German market, which will act as a beachhead towards expansion to additional markets in Europe and beyond. In complement, NW-Medsales assisted Marsi Bionics in their effort to secure market access to support their expansion strategy.

2. Status before the beginning of experiments booster program

Marsi Bionics, the SME partner in EXOTrainer had already industrialized the prototype and developed a commercial model of the exoskeleton, ATLAS 2020. The next phases are to apply for CE marking as a medical device and enter into the European market. The European certification as a medical device and the European marketing strategy are currently the focus of the granted **H2020 SME Instrument Phase 2** activities. Both Echord++ EXOTrainer (on the development of the exoskeleton) and SME Instrument Phase 2 (on the European positioning towards its commercialization) programmes are aligned with Marsi Bionics final goal: To introduce disruptive technologies in Europe, facing the challenge of growing in robotic innovation, commercializing on a global scale. E++ Booster would help start executing the market access actions towards European commercialization after CE marking is obtained.

3. Things achieved during the period of the program

Relevant coaching activities have been conducted to understand in detail the German healthcare market, reimbursement system and stake holders. Coaching activities:

1. To understand the German health care market and system
2. To understand the German reimbursement system
3. Identification of important stakeholders like KOLs, medical associations
4. Approach strategy for stake holders
5. Communication strategy for stake holders and presentation
6. Work on a detailed marketing plan
7. Co travel to important stake holders and feedback

Important actions have been taken to build up a marketing and market access strategy, execution of the strategy and first steps in the German market:
Participation in MEDICA international fare with very important feedback from stakeholders.
The market strategy for the exoskeleton in the German Healthcare system has been developed based on the understanding of the reimbursement system. It is summarized as follows:

The DRG system is necessary to manage reimbursements. *For this reason, when faced with new diseases, new techniques or new treatment methods, there is a procedure through which the* ***creation of a new DRG code can be requested****. This procedure is called* ***NUB*** *(*Neue Untersuchungs und Behandlungsmöglichkeiten*, - New Methods of Diagnosis and Treatment-).*

Through this request a new DRG code is created, which enables to enter in the reimbursement process. For this reason, it is an opportunity for hospitals to get an additional reimbursement for a new medical device. It is important to know that each request is associated to a specific device, with a manufacturer and a hospital, request that has to be presented to INEK in the months of September and October, resolving the process with its approval or declination in January of the following year. It can be requested unlimited times. In addition, a hospital can and should request one, as if accepted, it would only be applicable to that hospital.

In order to apply for the NUB, a series of requirements are necessary:

1. *CE mark, which ensures usability and safety.*
2. *That it is a new device*
3. *First promising clinical data*
4. *That has clear benefits for the patient*
5. *Have clear economic benefits*
6. *That some German hospitals have conducted test cases and support the application*

Once the process has been positively completed, the hospital will be in a strong position to negotiate a budget with the health funds system for the following year.

Finally, the **G-BA** must decide on the authorization of new methods of examination and treatment of compulsory health insurance and identify the groups of medicines for which fixed amounts can be fixed. The entire NUB process is controlled by the G-BA.

A protocol of first contacting doctors and physiotherapists at reference centers in order to position ourselves in the market. Once this is done start contacting distributors to access the market. Associations of families and patients have been also contacted.
Lists of reference hospitals, distributors, associations of patients and competitors have been developed.

4. How the experiments booster program helped you with the exploitation of results

Marsi Bionics is initiating the European expansion from Germany as a key Country to spread across Europe. Marsi Bionics has benefited from the E++ Booster Programme by understanding the German Health Care system, which is complex to be approached without the coaching from the Programme, while Germany would be the first country in Europe (and the World) where ATLAS is commercialised. The E++ Booster Programme could also help find the investors needed for the next stage of the company once CE Marking and positioning has been achieved: stablishing a subsidiary in Germany and initiating industrial production for all European Countries. A new clinical trial is being prepared, taking place in a hospital in Germany. After all this the exploitation strategy will be ready to be executed in Germany.

5. General outcome, conclusion, and gains from the program

E++ Booster Programme has contributed to the implementation of the European expansion of Marsi Bionics ATLAS 2020 exoskeleton, by providing an instrument to penetrate into the German healthcare market.