**General comments and recommendation for the project LINARM++**

The LINARM++ project aimed at developing and validating a multisensory, multimodal and patient-oriented portable device for upper limb neuromuscular rehabilitation overcoming the limited set of functionalities of the currently available commercial devices. The robotic system is based on the evolution of the LINarm, previously developed by CNR, and includes a wearable FES system, a low-cost unobtrusive sensory system for measuring patient’s physical activity and physiological state, and a user interface based on a virtual environment.

The overall evaluation of the project is positive.

The project has been diligently implemented, most of the milestones have been achieved on time and reports of good quality have been timely delivered.

All the partners of the project have contributed in their respective roles, as planned. All the various subsystems feature state-of-the-art solutions, mainly deriving from previous research developments carried out by the same groups. Most of the novel research effort has been devoted to the design and development of the mechanical solution for the new therapeutic device, which makes use of an innovative variable stiffness actuator purposely conceived for such system. Commendable achievements have been made in the engineering of the smart wearable modules for recording physiological signals, which could have a great market potential per se for a variety of applications.

One modular prototype of the LINARM++ system has been fully designed and implemented, according to the main requirements and specifications as defined in the original project proposal, but with additional inputs derived from an initial survey on clinical end-users. A comprehensive demonstration of the prototype has been carried out during the final review meeting, with healthy human subjects belonging to the research team involved.

The participation of the Idrogenet company, a very active and competitive actor on the rehabilitation robotics market, provided a clear added-value for assessing the industrial and commercial viability of the project results and developing a preliminary business plan.

The review meeting run smoothly and effectively, giving the opportunity to the reviewers to have an in-depth knowledge of the status of the project and to pose questions to the coordinator and to all those other partner representatives who kindly attended (only one EPFL representative was missing, but their work has been reported by the project coordinator).

Some remarks about the project, shared unanimously by the reviewers and briefly communicated to the project team at the end of the review meeting, are reported below.

The development of a low-cost integrated FES\Robotic device for home rehabilitation with TRL7, as planned in the proposal, was definitely a very ambitious goal for this project. Extensive clinical research activities are actually still required to prove the efficacy and effectiveness of combining FES with robot-mediated therapy for upper limb neuromotor therapy. Strong evidence based on systematic reviews and meta-analyses of multiple double-blind, randomized, controlled clinical trials is not fully available to support the deployment to the home rehabilitation market of such a solution. The whole home rehabilitation market is in its infancy. With respect to the project proposal, the updated definition of LINARM++ requirements and specifications (D1.1) identified a twofold goal: the originally envisaged integrated LINARM++ solution, to be used for further clinical trials, thus targeting the hospital market; and a simplified solution for home use, to be identified at the end of the project. Based on the analysis of the deliverables and on the outcome of the review, such simplified solution has actually still to be defined in details in terms of expected performance, basic features and key modular components. The proposed variable stiffness actuation system is a very elegant, light and cost-effective solution, though it has significant limitations, which can put at risk its deployment to the market in its current design and implementation.

The minimum level of stiffness and residual inertia at the end-effector, the related isotropy and homogeneity along the linear workspace, reliability of the cable transmission system and the overall performance repeatability of the robotic device need to be significantly improved in order to comply with the actual requirements of the target application scenario. This would require some significant re-design and new iterations in the project lifecycle before delivering a system that could be extensively tested on human subjects.

A deviation to be noted from the original workplan is that a final activity of clinical validation of the prototype with some patients was not carried out because of the lack of an experimental protocol approved by an Ethics Committee and ad-hoc insurance coverage. Anyhow, the device has been tested in a rehabilitation centre with some physical therapists; the results obtained can be considered sufficient to highlight pros and cons of the system in the real operational scenario. A wide experimental validation was also carried out for the evaluation of the user’s state based on the sensory system and remarkable results have been presented for experiments carried out with healthy participants. Different strategies have been also presented and analyzed for the exploitation of the device, even if the role of the industrial partner involved in the project for future exploitation plans and the roadmap for the possible integration of its commercial robotic glove (Gloreha) with the proposed system has been not adequately detailed.

It is recommended to focus follow-up activities both on overcoming mechanical limitations of the robotic device and, subsequently, on performing extensive clinical trials involving end-users to provide evidence of the effectiveness of the integrated device in rehabilitation. Systematic review and meta-analyses on the use of combined FES and robot-mediated therapy for the upper limb should be retrieved and\or carried out in order to provide a strong evidence supporting the LINARM++ solution. The functional and technical specifications of two different product classes, one for hospital use and one for home use, should be identified in detail by exploiting the LINARM++ experience and further validating such specifications with end-users. Moreover, market analysis should be further developed and more rigorously performed focusing on the specific product(s) deriving from LINARM++. Proper strategies for IPR management, in particular for the novel mechanical and sensor solutions implemented, should be carefully analyzed in order to pave the way for attracting industrial interest and investments on this promising technology.