1. Publishable summary

This section should be of suitable quality to enable direct publication by the Commission. Please ensure that it is set out and formatted so that it can be printed as a stand-alone paper document not exceeding four pages. It shall also reflect the website of the project (if applicable).

Please include a summary description of the project objectives, a description of the work performed since the beginning of the project, a description of the main results achieved so far, the expected final results and their potential impact and use (including the socio-economic impact and the wider societal implications of the project so far). You should update this publishable summary at the end of each reporting period.

Please include also, as appropriate, diagrams or photographs illustrating and promoting the work of the project, the project logo and relevant contact details.

The address of the project public website should also be indicated, if applicable.

Cerebral vascular accident (CVA, Stroke) is a type of cardiovascular disease consisting on the interruption of blood flow through the arteries leading to and within the brain. It affects the arteries leading to and within the brain. The effects of a stroke depend on several factors including the location of the obstruction and how much brain tissue is affected. Impaired walking ability is a hallmark residual deficit that contributes to post-stroke walking disability. Walking incorrectly not only creates a stigma for these patients, but it also makes them more susceptible to injury and directly affects their quality of life.

BETTER designs BNCI prototypes that will provide active command and control inputs during physical therapy with existing (e.g. Lokomat) and emerging (exoskeleton-based ambulatory therapy) gait rehabilitation technologies and protocols. The BETTER consortium investigates on methods to acquire, process and analyse signals from the injured nervous system as sources of information to assess the current patient status, increase patient involvement and advance on the current knowledge of neural control and biomechanics of human walking.

On these foundations, the BETTER project proposes R&D into the following objectives:

OBJECTIVE O1. Foundations of robotic rehabilitation therapy based on BNCI technologies. Basis for clinical, functional and usability evaluations under the BETTER approach will be defined.

OBJECTIVE O2. Product requirements to develop the top-down approach for stroke rehabilitation. This includes generating the concept of the BETTER system in terms of the analysis of stroke groups and outlining the conceptual designs for development of the BNCI system and robot exoskeletons.

OBJECTIVE O3. Rehabilitation program with internal assessment and tuning for efficiency. The new BNCI information will enable the generation of new metrics that relate cortical planning and execution. BETTER will translate these performance measures for online feedback (e.g. suggestion of breaks) and long-term assessment (e.g. success rates along several weeks).

OBJECTIVE O4. Robot exoskeletons for gait rehabilitation compatible with BNCI technologies. The use of non-ambulatory rehabilitation robots in the clinical environment will promote earlier incorporation of patients (already at sub-acute phase). The use of the ambulatory rehabilitation robot will promote increased intensity and frequency of exercises and maintenance of the treatment during the chronic phase.

OBJECTIVE O5. BNCI system for gait rehabilitation robot exoskeletons. The BETTER robots need to provide different modes of operation and actuation modulated by a BNCI system. This system must provide BNCI-based measures of overall patient's performance (correlations of brain's motor activity, muscle recruitment and motion, indicators of compliance).

OBJECTIVE O6. BNCI interfaced robot for rehabilitation. The robot exoskeleton prototypes in BETTER will exerts physical stimulation -at the periphery- as a function of targeted neural activation patterns provided by the BNCI system developed in WP5.

OBJECTIVE O7. Scientific knowledge of physiological and neurological impact of rehabilitation. BETTER will explore the improvements in therapy outcome in clinical experimentations that incorporate the novel methodologies based on BNCI technologies. This objective provides a Proof-of-concept of BETTER based on clinical case studies.

The objectives and milestones as set forth in the Description of Work (Annex I to the Project Contract) have been fully met during the reporting period (Feb 2010 – January 2011). The work during this period has been mainly focused on setting the foundations of the BETTER rehabilitation approach, its own evaluation procedures, building the Technical Specification and on starting both the BNCI and ambulatory exoskeleton design. To this end, the following work packages have been active during this period:

WP1: Elicitation of user's needs and clinical protocol

WP2: Conceptual design

WP3: Development of new scales and standards to assess therapy and usability

WP4: Design and prototyping of new exoskeleton-based therapeutic technology

WP5: Development of BNCI system

WP6: System integration

WP7: Functional and clinical evaluation, proof of concept

As a result of the activities in these tasks, a number of deliverables have been issued in due time:

Deliverable D1.1 includes an analysis of user needs that encompasses two main aspects of an innovative therapeutic approach to gait rehabilitation based on BNCI-driven robotics: (i) neurological and functional aspects, and (ii) usability aspects.

Deliverable D1.2 provides a description of the rationale for selection of users involved along the project and selection of stroke groups and representative patient-end users (inclusion/exclusion criteria).

Deliverable D1.3 reports on the elicitation of user needs and clinical protocol. The report set the basis for the clinical and functional validation as well as the usability's analysis of BETTER that take place in WP7. Clinical scales are reviewed and selected in this report. The deliverable also includes a number of pilot studies that take place in BETTER concerning critical aspects for the elicitation of the users' needs and clinical protocol. The pilot studies in particular are 1) Electromechanical gait training (at FSL), 2) Brain areas involved in execution of active and passive movements (at EKUT), 3) passive BNCI for monitoring foot movement using a beta ERS brain switch in healthy users (at TU Graz). Finally, the deliverable provides information regarding the integration of measures for correlation of BNCI-based information with clinical and neurophysiological evidence.

Deliverable D2.1 reports on the analysis of information about the constraints in the design of the exoskeleton-based therapy as well as the requirements that the new and/or improved systems have to fulfil in order to be effective. The Deliverable analyses how rehabilitation robotics in stroke can be suited to improve the available evidences on the outcome of the rehabilitation process. This is done by incorporating the used needs in the

first set of specifications. The report also is supported by thoughtful complementary studies on: 1) risk analysis of the exoskeleton-based technology, b) analytical hierarchical process of the domain of needs and c) analysis of biomechanical requirements for the patient population.

Deliverable D3.1.1 is the first of three reports with the results coming from tasks WP3.1 and WP3.2. The Deliverable reports the review on clinical scales used for stroke patients assessment, and the protocol for the objective functional assessment of body function and structures. Thus, the report provides a description of the criteria followed to select the scales to be used for the patient trials and its classification according to the WHO ICF dimensions. Also, the report provides an analysis of the project's inclusion/exclusion criteria for patients selection, with respect to the measures for objective functional assessment of body function and structures.

Deliverable D5.1 describes the rapid prototyping environment for physiological analysis. This is a set of five prototypes accompanied by a document where we first describe the hardware consisting of the EEG cap, the active electrodes, the preamplifier g.GAMMAbox and the biosignal amplifier g.USBamp which is connected via USB interface to the laptop on which the rapid prototyping software environment is installed. The second part of this document describes the software issues. The main part of the software for the rapid prototyping environment is the SIMULINK driver which allows an easy data acquisition and data analysis using MATLAB/SIMULINK.

Deliverable D7.1 reports the updated clinical protocol in BETTER and summarizes the inclusion/exclusion criteria for the participant enrolment. The report provides the criteria to be used during the validation tests, the selection of sample of patient-end users are reported. The Deliverable provides the update of the clinical protocol in the light of the results obtained from the first pilot studies (reported in the Deliverable 1.3). Additionally, the preliminary results obtained from two different experimental setups that have been conducted for testing of a first monitoring tool (AFO-Monitoring Tool).

Towards MIII, work has also been done in the following work package:

WP8: Exploitation and Dissemination

In the framework of WP8.1 a number of dissemination activities have been performed related to the work done in WP1, WP2, WP3, WP4 and WP5.

As a result of the activities in WP8, a number of deliverables have been issued in due time:

Deliverable D8.1 is the BETTER project website. It can be reached at http://www.iai.csic.es/better/ and it is continuously maintained with updates on a weekly basis.

Deliverable D8.2 is a project presentation which can be easily accessed from the project website.

Deliverable D8.3 discusses the regulatory environment for medical devices, specially from the point of view of an active exoskeleton. Chapter 1 is a general introduction, chapter 2 describes the regulatory environment and chapter 3 gives a description of the BETTER exoskeleton as it is foreseen. In chapter 4 definitions from the Medical Device Directive (MDD) are introduced and how the BETTER exoskeleton fits in with them. Chapter 5 discusses the preliminary classification of such a device and mentions possible other project outcomes as well. Finally, in chapter 6, a short conclusion is given.

Deliverable D8.4 is prepared to serve as a guidance document for BETTER Consortium members when preparing dissemination of project results. The structure of the document is that chapters 2 and 3 give short introduction and background information and then Protection of Knowledge is discussed in chapter 4. Then the target groups and different dissemination routes are discussed in chapter 5 and a statement on exploitation is given in chapter 6. Finally, a short conclusion can be found in chapter 7.

Deliverable D8.6.1 is a first version of a DUP. The deliverable starts with a short introduction in chapter 1. Then dissemination activities are reported in chapter 2. In chapter 3 a setup for reporting on the different exploitable outcomes is introduced and some discussions on potential fields, where outcomes could be expected, are mentioned. Chapter 4 discusses market considerations for the BETTER device from different perspectives and also mentions current rehabilitation methods. Finally, a short conclusion is given in chapter 5.

The BETTER project logo is:

Figure 1. BETTER project logo

The project web site is periodically updated. A private area and a dropbox have been enabled to internally monitor reporting and dissemination activities.

Figure 2. *BETTER project web site*