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Abstract: This deliverable describes the evolution of BCI and BCI-related industry stakeholders towards 2020 focusing on task 3.3 related issues. We identify and classify current success stories and business cases, evaluate potential future exploitation avenues and provide general guidelines and recommendations derived from conclusive analyses of the selected use cases in the different BCI applications scenarios. These efforts intend to guide future opportunities for interfacing with BCI industry stakeholders, BCI collaborators, and policy makers.

Keywords: Brain-Computer Interface, BCI, Brain-Neural Computer Interaction, BNCI, Human-Computer Interaction, HCI, Roadmap, Future opportunities, Exploitation avenues, Guidelines, Recommendations

[1] Public
[2] Restricted to other program participants
[3] Restricted to a group specified by the consortium
[4] Confidential, only for members of the consortium

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1 Introduction and objectives

This deliverable provides practical guidelines and actionable recommendations derived from conclusive analyses of the selected use cases in the different BCI applications scenarios, i.e. replace, restore, improve, enhance, supplement and research (see D3.2; and Wolpaw and Wolpaw, 2012). Our main goal is to present functional means, mainly for SMEs and policy makers, to support and promote BCI industry innovation, and to encourage BCI transfer and exploitation.

Within the following sections, this deliverable intends to solve Task 3.3 demands bearing the final roadmap and our focus in mind. Section 3 identifies and classifies success stories from previous EU-funded projects and describes derived BCI products or prototypes (see also Annex 1). Section 4 provides means to develop future business plans and exploitation avenues in relation to the identified use cases in each application scenario (see also Annex 2). In section 5, we present a list of BCI requirements for SMEs and policy makers, which can be used as general guidelines for BCI exploitation and technology transfer. Section 6 concludes with recommendations and feedback mechanisms between industry and knowledge centres to foster market oriented R&D.

2 Methods

This deliverable corresponds to the final contribution to the roadmap and is driven by interactive and iterative activities across all work packages. Further, based on the Future BNCI roadmap, we first identified and analysed previous recommendations that may still be relevant at this point of time in relation to the BCI application scenarios and the corresponding selected use cases. We updated those highlighted recommendations and presented additional practical guidelines according to the latest industry and R&D knowledge. Future visions were assessed from the results of our driven surveys and questionnaires (see deliverables D3.1-D3.2), from visionary BCI stakeholders, who took part in the focus groups (see deliverable D4.4) and are based on the consortium's experiences in relation to their field. Part of the provided guidelines (see section 5) were also capitalized from previously established networking activities between i) the BNCI Horizon 2020 consortium, from which the majority of partners worked within national and EU research projects; ii) attendees to the Hallstatt retreat and BCI-related congresses; and, iii) the advisory board (external industry stakeholders).

In the previous deliverable D3.2, we provided qualitative estimations of the relative market growth and relative market value of a set of identified key BCI market applications by 2020[5]. This and its related market analysis is likely to guide future opportunities for interfacing with industry stakeholders from different synergy fields, specific target end users, potential competitors, collaborators, and some of their interrelations (see Annex 3)[5]. Overall, the presented guidelines and recommendations were discussed among research WP2 and end user WP4 work efforts to further confirm what may be technically and commercially feasible in a 5-10 years' timeframe, i.e. short-term and mid-term.

3 Success stories and business cases

Here we identify and classify some relevant success stories and derived business cases in relation to BCI systems that are currently on the market and are the result from previous and

[5] These estimations were validated by the aforementioned networking activities, including the whole BNCI Horizon 2020 consortium and attendees in the Hallstatt retreat.

current EU-funded R&D projects. The classification intends to be accord to the BCI application scenarios: replace, restore, improve, enhance, supplement and research (see deliverable D3.2; and Wolpaw and Wolpaw, 2012). Please refer to Annex 1 for the complete list of EU-funded projects.

3.1 Replace scenario

PRESENCCIA[6] (2006-2010) was an integrated FP6 EU-funded project. One of its work packages handled the development of novel BCI paradigms and BCI devices, to control the virtual body. Lessons learned in PRESENCCIA stimulated the development of the first worldwide commercially available BCI system, intendiX.

intendiX[7] is a BCI system for communication, designed to be installed and operated by caregivers or the patient's family at home. The system is based on visual evoked EEG potentials (VEP/P300) and enables the user to sequentially select characters from a keyboard-like matrix on the screen just by paying attention to the target for several seconds. This requires only a few minutes of training. Most subjects can use intendiX after only 10 minutes of training with reasonable performance, spelling five to ten characters per minute at their first trial. The intendiX BCI system is a relevant example of a successful product targeting the replace scenario, as it provides as new communication channel and therefore replaces other central nervous output that could be used for communication, such as talking or writing.

Additional features of intendiX, like the Screen Overlay Control Interface (SOCI), and intendiX Painting were further implemented and adapted to specific end users tasks and environments conjointly in other EU-funded projects like BRAINABLE[8], BACKHOME[9] and VERE [10] (see section 3.5). BRAINABLE[8] (2009-2012) and BACKHOME[9] (2012-2015) projects share in common the fact of develop new means to empower people with functional deficits to mitigate their own barriers of the everyday life, and to generally improve their quality of life (QoL) - by enabling autonomy and social inclusion.

IntendiX is a relevant example of an assistive technology BCI system for control and home-support services, where part of its research, design and validation has been supported by EU funds.

Nowadays intendiX is sold worldwide. However, the targeted market size, mainly in the replace scenario, is small (see section 4.1.1) and, generally, difficult to reach. New means and efforts are required to efficiently access those minorities who may profit best of this sort of BCI technology.

3.2 Restore scenario

TOBI[11] (2008-2013) was a large integrated FP7 EU-funded project. TOBI[11] aimed to develop BCI technology to generally improve QoL in people with functional deficits, and, to enhance the effectiveness of rehabilitation therapies (suitable for the improve scenario, see section 3.3). BCI applications were successfully developed and their proof of concept demonstrated - specifically, BCI controlled telepresence robots, hybrid BCIs, spelling devices, and, BCIs cursor control used for example for painting (suitable for the replace scenario, see section 3.1). A relevant demonstrated application in the restore scenario was a functional electric

[6] http://www.presenccia.org/
[7] http://www.intendix.com/
[8] http://www.brainable.org/
[9] http://www.backhome-fp7.eu/
[10] http://www.vereproject.eu/
[11] http://www.tobi-project.org/

stimulation (FES) hand orthosis for long-term use. The BCI controls the electrical stimulation which moves the according muscles of the upper limb, to perform grasping movements.

MUNDUS [12] (2010-2013) investigated multimodal neuroprosthesis for daily upper limb support. Several prototypes have been developed which enabled severely motor impaired people to improve arm reaching and hand function. Therefore, sensors, actuators and control solutions have been researched in order to enable the neuroprosthesis to adapt to the individual level motor control of the user.

WAY[13] (2011-2014) targeted at developing and evaluating non-invasive technologies that create bidirectional physiological links between a hand assistive device (like a hand prosthesis or other assistive devices) and the patient's volition. These links mainly aim at replacing (see section 3.1) but are also "restoring" a lost function, e.g. the ability to grasp is achieved by means of interfaces based on novel principles that combine multilevel biosignals and multimodal sensory feedback. Specifically in the restore scenario, WAY also developed a BCI system allowing for control of a hand-exoskeleton restoring the ability of a paralyzed hand to manipulate different objects in daily-life environments.

None of the TOBI[11], MUNDUS[12] and WAY[13] prototypes have directly been licensed as a market product or are commercialised at this point of time. However, their efforts are influencing R&D and technology transfer in several BCI application scenarios (here, we have highlighted relevant examples in the restore scenario).

Like in the replace scenario, new means and efforts are required to efficiently access those minorities who may profit best of this sort of BCI technology (see section 4.1.2).

3.3 Improve scenario

BCI based neurorehabilitation is likely to be one of the most promising BCI applications. Therefore, it is not surprising to find other FP7 EU-funded projects, apart from TOBI[11] and WAY[12], targeting directly at the improve scenario.

BETTER[14] (2010-2013) aimed at improving physical gait rehabilitation by introducing real time BCI feedback to the patient. With this approach, the level of assistance can be adjusted as needed. Due to the afferent feedback cues that are presented online, if the according motor regions in the brain are activated, brain plasticity could be elicited and thus rehabilitation could be optimized. DECODER [15] (2010-2013) targeted at cognitive assessment and rehabilitation. The consortium developed a BCI assessment battery that sup-ports an exact diagnosis of the state of consciousness by a variety of auditory, visual, tactile and mental stimulation paradigms. While the classification of the cognitive state of people with disorder of consciousness is nowadays done via behavioural tests, it was shown that this could easily lead to misclassification (Andrews et al., 1996). With BCI based assessment, even completely locked-in patients could be addressed and produce brain patterns showing their consciousness. In a second step, one could use the BCI also for communication and neurological rehabilitation of people who were classified to be at least in minimal conscious state.

In relation to BETTER[14] and DECODER[15], two exemplary BCI products can be already found on the market:

[12] http://www.mundus-project.eu/
[13] http://www.wayproject.eu/
[14] http://www.iai.csic.es/better/
[15] http://www.decoderproject.eu/

The mindBEAGLE [16] is designed for consciousness assessment and communication. It integrates four different BCI paradigms into one system. The product includes algorithms allowing to distinguish if a user is able to follow certain tasks, thus concluding that the patient is conscious during the test. Basic communication is also integrated into mindBEAGLE allowing to give simple YES/NO answers to questions.

The recoveriX [17] is designed for upper limb stroke neurorehabilitation. It provides visual feedback via an avatar, performing the intended movement on a computer screen and via FES. The FES stimulates the according muscles and assists in the movement task that is given to the user.

CONTRAST[18] (2011-2014) aimed at contributing to new medical and practical knowledge for guiding and improving intervention for daily life functioning after stroke. Specific goals were the development of (1) a new adaptive architecture allowing remote processing and shared decision making between experts and patients; (2) an individually tailored intervention for improvement of cognitive function guided by medical and neuropsychological assessment; (3) a Human-Computer Interface (HCI) neurofeedback based cognitive enhancement training including automated reward systems to maintain patient motivation; (4) a continuous onsite and remote monitoring of health parameters and evaluation;

COALA is an auto-adaptive tool for in-patient and home-based rehabilitation after stroke resulting from CONTRAST[18] efforts. To realize home-based training, an easy-to-use semi-dry EEG headset was developed allowing the patient autonomous and comfortable neurofeedback training. The included headset is already marketed by MindMedia B.V. (Herten, Netherlands)

> These "medical" products and prototypes, amongst others, are based on findings resulting from those aforementioned EU FP7-funded projects. Further research to confirm the clinical efficacy and the longer-term effects of BCI based neurorehabilitation is still required (see section 5).

WAY[13] (see in section 3.2) also demonstrates applications that aim at improving motor functions through daily life neurorehabilitation training. The idea is to increase the number of study participants and long-term observations by combining assistive and rehabilitative aspects of BCI systems that can be used in the daily life of patients with stroke and incomplete SCIs. First prototypes are currently tested in clinical environments.

> A major challenge in commercialization of such BCI based systems is to provide individually tailored effectors (e.g. hand-exoskeletons) and reliable BCI control systems requiring minimum maintenance (see section 5).

3.4 Enhance scenario

SENSATION[19] (2004-2008) explored a wide range of micro and nano sensor technologies, with the aim to achieve unobtrusive, cost-effective, real-time monitoring, detection and prediction of human physiological state in relation to wakefulness, fatigue and stress anytime, everywhere and for everybody. The project goal was not only to develop new sensors and related systems, but to design them in a way that they are accepted and, thus, used by the public. In order to do so, knowledge about the acceptance of sleepiness and stress measurements at workplaces was strongly required, as it was the fact that the user felt

[16] http://www.mindbeagle.com/
[17] http://www.recoverix.at/
[18] http://www.contrast-project.eu/
[19] http://www.sensation-eu.org/

comfortable in his or her typical environment. SENSATION inspired some of the first BCI neurofeedback licensed solutions in the enhance scenario that resulted in the current market product, Enobio.

Enobio[20] is now designed for a wider range of market applications, also targeting the improve scenario (see section 3.3), and provides a platform for their development away from the lab. Other projects that may have had an influence improving the design and development of the current Enobio are BEAMING[21], HC[2,22] and ASTERICS[23].

MINDSEE[24] (2013-2016) is a FP7-funded project that aims to develop an information seeking application which combines modern BCI technology with real-world HCI. The result will be a prototype for a cutting-edge information retrieval system that improves upon state-of-the-art tools with respect to performance of information seeking in realistic tasks.

More market research and user acceptability studies are required to be able to guarantee the success of this and other similar BCI related products (see section 5) in different market niches. This sort of products is mainly sold as a research tool, although their potential is large.

3.5 Supplement[25] scenario

Within the supplement scenario people can for example use a BCI to control a joystick, or a third arm. From all BCI application scenarios, the supplement scenario is the most futuristic and long-term application scenario.

VERE[26] (2010-2015), another FP7-funded integrated project, aims at dissolving the boundary between the human body and surrogate representations in immersive virtual reality and physical reality. Control of robots via fMRI and EEG based BCIs, were already successfully demonstrated within VERE. While in the fMRI demonstration, motor movements like move forward, left, right or back were encoded and transmitted to control a robot, in the EEG based demonstration, a hybrid BCI approach with P300 and SSVEP was used to select a command out of a list of presented high level commands. These lists of high level commands are generated based on the actual context. For example, if the system recognizes a bottle of water standing on the table in front of it, it will present the possibility to reach and grasp this bottle of water. The hybrid BCI control is presented in augmented reality that means the user can see what the robot sees, while the stimulations to control the BCI are overlaid over this vision. In fact, this approach in VERE did not control an additional third arm, but one or two of the arms of a humanoid robot. Nevertheless, it can be easily seen that the demonstration could be extended to control such a third arm or a joystick.

There are several sorts of prototypes being performed along VERE that can be useful for any person. Some of them may become products in the long-term. Market research is required to specify potential market niches in a sort of synergy fields.

[20] http://www.neuroelectrics.com/enobio
[21] http://beaming-eu.org/
[22] http://hcsquared.eu/
[23] http://www.asterics.eu/
[24] http://www.mindsee.eu
[25] Note that the Supplement scenario is analysed here but it has been dropped for the roadmap for being considered too futuristic
[26] http://www.vereproject.eu/

3.6 Research scenario

BRAIN[27] (2008-2011) aimed at developing BCIs into practical assistive and ICT tools to enhance social inclusion for a wide range of different users with functional deficits. BRAIN led to the development of a completely new, water-based EEG sensor. The goal was to make this EEG sensor easy to handle, fast to apply, comfortable to wear and yet maintain an excellent signal quality.

This gel-free wireless EEG system is now distributed by TMSI[28] and is used by a variety of research groups around the world, normally in combination with Mobita[29] amplifiers.

Brain mapping techniques are key important for some neurological research topics. The CSI[30] (2010-2013) project, funded by ENIAC[31], achieved substantial advances in state-of-the-art medical 3D-imaging platforms. It focused on the diagnosis and therapy of serious diseases of the central nervous system and brain, which could be used for several use cases within the research scenario.

cortiQ[32] is one licensed product that uses BCI technology for brain mapping research purposes. This allows personalized functional mapping of the cerebral cortex. With this mapping, one can find, for instance, the eloquent cortex of epileptic patients before doing a surgery. Findings from CSI and also VERE projects influenced the development of cortiQ and may lead to further improvements of the product.

Most SMEs in the BCI market target the research scenario, which in fact may cover all the aforementioned scenarios in a more preliminary stage - i.e. when the application is still not the focus, but exploring the brain instead.

4 Future exploitation avenues

In relation to the selected use cases (classified in Annex 2), this section provides a general analysis of the industry-related questions that we have been addressing and that may guide future exploration avenues and business plans for the European market. Annex 2 contains the answers to each particular use case in the different BCI application scenarios. We evaluated:

1-. the market size (according to each target group/niche)
2-. current treatment/options and their cost
3-. the payer - who pays?
4-. the incentive for industry - why should industry be interested?
5-. the time to market

4.1 The market size

We define the target group as a group of people (or niche) who could potentially benefit from a BCI product or market application. The **market size** is derived from the target group, and, here is characterized by the estimated number of European users per year that may benefit from the corresponding BCI solution in their market niche. We classify the market size for the European market as small, medium, large or very large:

- small (< 50.000 European users);
- medium (50.000 - 1 Million European users);
- large (1 - 10 Million European users), or;
- very large (> 10 Million European users).

[27] http://www.brain-project.org/
[28] http://www.tmsi.com/products/accessories/item/water-based-eeg-electrodes
[29] http://www.tmsi.com/products/item/mobita
[30] http://www.eniac-csi.org/CSI/
[31] European Nanoelectronics Initiative Advisory Council
[32] http://www.cortiq.eu

4.1.1 Market size in the replace scenario

Target groups from the different use cases in the replace scenario range from people in a completely locked-in state, to survivors of a spinal cord injury (SCI), or other potential users with severe motor impairments (e.g. amyotrophic lateral sclerosis (ALS), primary-progressive multiple sclerosis (PPMS), etc.). The **market size** considering each of these user groups can be classified as **small**. However, the expected impact of BCI technologies on the QoL of each individual within these niches is very high.

4.1.2 Market size in the restore scenario

According to Lee et al. (2011), the incident rate for SCI in Western Europe is 16/million, which results in about 8.200 people per year suffering a SCI within the EU. Detailed data about life expectancy does not exist, but the ten year mortality is about 10% to 20%. Based on these data, we can estimate the **market size** for BCI based neuroprosthesis and equivalent implanted technologies to be **small**. Again here the expected impact of BCI technologies on the QoL of each individual within these niches is very high.

There are other market niches that can benefit from BCIs in the restore scenario. Approximately, 70.000 individuals had received cochlear implants in the United States[33], and based on this figure we estimate about 110.000 people in the EU. Considering this specific population with hearing impairments and deafness, its **market size** could be defined as **medium**.

4.1.3 Market size in the improve scenario

According to the WHO estimates the number of stroke events in EU countries, Iceland, Norway and Switzerland is likely to increase from 1.1 million per year in 2000 to more than 1.5 million per year in 2025 solely because of the demographic changes (Truelsen et al., 2006). Further, 70% of stroke survivors have deficits in arm movement and 40% are unable to use one arm in the long term[34]. The **market size** for stroke rehab is potentially **large**, i.e. >1 million upper limb rehabs due to stroke. Additionally, as the population ages, the frequency of dementia is expected to double by 2030 and triple by 2050[35]. Recent epidemiological surveys report that "North America and Western Europe have at age 60, the highest prevalence of dementia (6.4% and 5.4% of the population at age 60)"[36]. The **market size** for BCI applications targeting neurorehab within this area is also **large** and progressively growing with the aging population.

Another different example in the improve scenario is the epilepsy niche. Two thirds of all epilepsy patients can be treated with drugs and around 8% with surgery. That leaves around one third of all cases to be potential candidates for stimulation treatment (i.e. vagal nerve stimulation, non-invasive stimulation, invasive stimulation), where BCI technologies may play a synergic role. The **market size** of the epilepsy population is also quite **large**.

4.1.4 Market size in the enhance scenario

In Europe, there are more than 100 million students. All of them could benefit from optimized BCI based learning environments. However, one cannot expect that everyone will use a BCI device (e.g. as a Neurotutor) to enhance his or her learning skills. Still we consider the **market size** in this area to be **large**.

In the years 2005 until 2014 Microsoft sold more than 80 million units of its Xbox 360 gaming console and more than 24 million of the Kinect, which is an additional motion sensing device used as additional input channel for gamers. Sony sold 8 million units of its

[33] http://www.asha.org/public/hearing/Cochlear-Implant-Frequently-Asked-Questions/
[34] www.stroke.org
[35] http://www.who.int/mental_health/publications/dementia_report_2012/en/
[36] http://www.who.int/medicines/areas/priority_medicines/BP6_11Alzheimer.pdf

PlayStation Move controller within the timeframe from September 2010 to April 2011. A BCI based gaming device that is supported by the manufacturer of the console and by some game developer could probably reach similar selling numbers as the Kinect or the PlayStation Move. The **market size** for BCI experiences in gaming applications is **very large**, the largest indeed. However, BCI technology should be affordable for each family to guarantee product success and mass penetration.

In Germany alone, the number of people older than 65 is about 16 million. The estimated potential **market size** for automatic emergency calls is therefore potentially **large**, which is another BCI application in the enhance scenario.

4.1.5 Market size in the supplement scenario

Generally, the supplement scenario can be regarded as the most futuristic and long-term application scenario. It targets healthy people willing to use BCI applications for specific purposes in different synergy fields. Currently, its market size is difficult to predict. We strongly believe that the **market size** may depend on the first acceptance of BCI technologies in the other shorter-term application scenarios, like the enhance and improve scenarios. If the BCI acceptance is high, the supplement scenario market size can be strongly relevant in the upcoming years (i.e. > 10 years), especially if we consider BCI solutions and applications complementing other commercially viable products like Google Glass for general communication purposes, gaming applications, or more skilled populations (e.g. surgeons). Note that because its market size current uncertainty as an isolated BCI device in this scenario, we did not provide further details of UCs in the supplement scenario in Annex 2.

4.1.6 Market size in the research scenario

In the UK there are 14 institutions who are granting degrees in cognitive neuroscience, in Austria, there are two of them, and in Spain there are three. An estimation for the whole European region could range from 50 to 120 institutions, which may result in a **small market size** targeting scientists in cognitive neuroscience (i.e. basic research). However, there are other knowledge and academic centres using BCIs for research purposes. Therefore, its market size may vary considerably from **small** to **medium**, since there exist multiple fields where a BCI can be used to further explore the brain. For instance, if we consider one specific use case, there are about 12.000 opticians and about 5.680 ophthalmologists only in Germany, who could progressively become customers of a derived BCI research prototype regarding optical examinations/tests.

4.2 Current treatment/options and their cost

In one specific use case regarding the replace scenario, there are no current options for communication with completely locked in patients. Other existing solutions cannot provide the same features and reliability as a BCI device could. In this sense, we cannot describe costs, because they are not comparable solutions. Specific examples of current treatments in the restore scenario could be a shoulder joystick if residual motor functions are available. Generally, the costs for alternative medical devices like arm orthoses and prostheses can be very high or too expensive if no insurance provides the financing. Overall, when considering medical devices mostly targeting neurorehab in the improve scenario, we should be careful when comparing different approaches by their "costs", since most of the alternatives are non-eligible as conventional treatment, and none of them is confirmed to be clinically effective. For this reason, BCI related products and applications in all medical related scenarios should keep cost/benefit (efficacy) and risk/benefit (safety) ratios in mind.

Some examples of current treatment/options and their approximate costs for specific UCs have been summarized in the corresponding column in Annex 2.

4.3 The payer - who pays?

When it comes to analysing the payer, we could generally differentiate between BCI medical and BCI non-medical devices. In Europe, it is expected that the public healthcare system or private (health) insurance companies will finance or co-finance BCI medical devices, as those derived from the replace, restore or improve scenarios. Charity entities could also be an option, if no legal claim exists. Overall, non-medical devices, like those in the enhance or supplement scenarios, will be paid by the user himself (or relatives), or by a private company, who may obtain some benefit by the use of the device. Research tools are expected to be paid by governmental entities or private companies that may profit from future derived market products. A classification for each UC could be found in the table provided in Annex 2 according to the following abbreviations:

Table 1 – Acronyms and definitions related to the payer (see Annex 2)

Acronym	Definition
HS	- healthcare system
PI	- private insurance (e.g. private health insurance, car insurance)
PC	- private company (e.g. employer, specific field company)
CH	- charity and non-profit entities
U	- the user or related (e.g. the user, the patient, family or relatives, friends)
G	- governmental entity

4.4 The incentive for industry - why should industry be interested?

For large and very large market sizes, numbers may speak by themselves. However, from the estimated small market size in the replace scenario, it cannot be expected that many companies target this market. The high expected price in those derived products though, and the corresponding reimbursement from private or public healthcare insurance companies may make it still interesting for SMEs or even for larger companies, if they manage to cover the whole market or a big portion of it. Similarly, the BCI solutions addressed in the restore scenario are not thought for large markets, although they could be adopted from a considerable number of users, if cost effectiveness is achieved. BCI controlled prostheses represent a cutting edge technology with high visibility and high social impact. Other analysis in relation to this question can directly be found in Annex 2 under the corresponding column per UC.

4.5 The time to market

We define the estimated time to market for the corresponding BCI solution in each UC as:
i) **short-term** (< 5 years); ii) **mid-term** (5-10 years); and **long-term** (>10 years).

Please refer to Annex 2 for this specific question in relation to each UC.

5 Guidelines for technology transfer

We provide here a list of BCI requirements intended to be used as general guidelines to support future actionable plans for BCI exploitation and technology transfer. Some of these guidelines are directly derived from the consortium's work on the specific UC analysis described in section 4. Additionally, this section highlights major milestones for industry stakeholders, the BCI community and policy makers towards BCI commercialization, product success and general acceptability.

5.1 For industry stakeholders

Type A: End-user, customer & commercialization requirements

A.1: Market research analysis

- **A.1.1**: competitors and SWOT[37] analysis to discover new opportunities
- **A.1.2**: identify how the customer perceives an improvement or novelty versus existing BCI solutions on the market (or in the research field)
- **A.1.3**: identify how the customer perceives novelty versus existing alternative competitors on the market (or in the research field)
- **A.1.4:** identify specific end-user and customer needs coming from different synergy fields (e.g. medical devices, robotics, gaming, ICT, marketing, safety...)
- **A.1.5:** plan and target at cost-effective solutions adapted to the specific field, use case and technology that is being addressed/used

A.2: Usability studies & testing

- **A.2.1:** early and continuous involvement of potential end-users, understanding of user/customer requirements and the whole user experience
- **A.2.2**: undergo usability studies addressed to the user, and his/her task and environment in each specific field (effectiveness, efficiency and user satisfaction)
- **A.2.3:** recognise different training needs (see section 6)
- **A.2.4:** conduct acceptability studies

A.3: Licensing & certification

- **A.3.1**: develop and use standards for BCI hard- and software
- **A.3.2:** obtain CE and (if required) medical certification
- **A.3.3:** (if required) conduct clinical trials (safety, feasibility and clinical efficacy)

A.4: Advertising

- **A.4.1:** improve knowledge of the access and availability of BCI systems for potential users (e.g. specific groups of people with functional deficits, their relatives, care-giving institutions and the general public)
- **A.4.2:** establish specific target campaigns for BCI solutions (e.g. targeting people with functional deficits, especially in the replace scenario where retailers/intermediaries may filter the access to end-users)
- **A.4.3:** extend dissemination mechanisms (see section 6)

Type B: Technology non-functional requirements *(product quality levels)*

B.1: Invasive BCI solutions

- **B.1.1:** very high resolution implantable sensor systems (e.g. ECoG grids or Utah arrays)
- **B.1.2**: fully-implantable multiple-channel amplifiers
- **B.1.3**: advanced real time signal processing techniques for high resolution data
- **B.1.4:** reliable sensory feedback mechanisms to the sensory cortex
- **B.1.5:** very low power consumption
- **B.1.6:** highly reliable wireless power techniques to charge micro-implants via near-field wave technology

[37] Evaluation of the strengths, weaknesses, opportunities and threats

- **B.1.7:** feasibility approval for long-term implant system durability (i.e. implants are required to provide long-term good signal quality and to last for > 10 years)
- **B.1.8:** safety approval for long-term implant systems (i.e guarantee safety and minimise related secondary adverse events).
- **B.1.9:** (derived from A.3.3) clinical studies (including risk-benefit and cost-benefit studies) to demonstrate clinical efficacy and gather the "standardised" required implant certification - (if required) learn from other implant fields (e.g. pacemakers, defibrillators, SC neurostimulators, DBS)

B.2: Non-invasive BCI solutions

- **B.2.1:** robust and reliable biosignals decoding and against interference
- **B.2.2:** robust continuous classification and adaptive learning algorithms, allowing data fusion of several streams
- **B.2.3:** user-friendly and comfortable BCI hardware (sensor technology and setup time) allowing long-term use at different settings (e.g home use, on the street - outside the lab)
- **B.2.4:** minimal or no calibration
- **B.2.5:** fast user-initiated action selection
- **B.2.6:** (for specific use cases) relieve BCI control platforms
- **B.2.7:** low-power and wireless solutions
- **B.2.8:** non-visible or aesthetically pleasing (e.g in-ear sensors or integrated in a cap)
- **B.2.9:** feasibility studies for system durability and especially system performance in home (outside lab) environment
- **B.2.10:** (if required; derived from A.3.3) clinical studies (including risk-benefit and cost-benefit studies) to demonstrate clinical efficacy and gather medical certification

5.2 For BCI community and policy-makers

Type C: Ethical & social requirements

- **C.1:** support initiatives in relation to ethical approval
- **C.2:** encourage proactive attitude towards BCI solutions, especially towards invasive BCI solutions
- **C.3:** strengthen the dialog between end-user groups and BCI research community (see section 6)
- **C.4:** establish feedback mechanisms from opinions leaders and decision makers to assure that appropriate guidelines are received (see section 6)

Type D: Finance & funding requirements

- **D.1:** increase research funding for BCI initiatives relevant to society and encourage feedback mechanisms from academia to industry and vice versa
- **D.2:** invest directly into SMEs that support BCI initiatives relevant to society
- **D.3:** support market research studies to analyse and promote commercialization of BCI-related products
- **D.4:** support standardisation bodies that promote commercialization of BCI-related products
- **D.5:** strengthen collaboration & private funding in identified synergy fields (e.g. robotics, HCI, medical devices, automotive, ICT)

- **D.6:** (if required) support proof-of-concept studies necessary to improve safety and standard technical specifications (e.g. sensitivity, power consumption, usability, robustness, reliability) getting towards a functional device
- **D.7:** (if required) support co-sponsorship of pre-clinical and clinical trials (safety, feasibility and clinical efficacy) in relevant fields for society
- **D.8**: (if required) support device approval and assist investors towards commercialization

6 Recommendations and feedback mechanisms

Here, we highlight and describe some recommendations and feedback mechanisms mentioned in the previous section.

6.1 Cooperation on assessment mechanisms

Consistent with the FBNCI roadmap, we recommend very strong support for engaging end users and end user groups. Some FP7 projects included end user representatives as partners and/or Advisory Board members. End user representatives are essential members of the BCI community and should not be ignored. It is also critical to seek information and help from persons who play a critical role in end user decisions such as doctors, friends, family and caretakers.

→ Recommendation on BCI assessment mechanisms:

We recommend changes to assessment mechanisms. BCI improvements could take many forms, such as improved interfaces, enhanced robustness in field settings or new output devices. Some common assessment mechanisms, such as ITR (bits per minute) are overrated or useless in some BCIs, such as asynchronous BCIs or systems focused on rehabilitation rather than communication. Therefore, there is no way to develop a single assessment approach and, in some cases, comparisons across different BCIs are not feasible.

→ Recommendation to policy makers:

Regarding industry cooperation, our initial view is that the EU is more supportive of SMEs and projects that include SMEs.

- We recommend continued support, since this is a key element of product development and distribution.
- We also recommend supporting industrial needs such as IP development, market research and packaging.

Some calls in Horizon 2020 explicitly encourage industry involvement, but do not support these activities.

6.2 Extend dissemination mechanisms

A related challenge is educating the public, including potential buyers and related decision makers, about the opportunities provided by BCIs. Most people in the general public do not know about BCIs, and/or have unrealistic expectations based on science fiction or other sources. This is also a concern for people who may influence buyers' decisions, such as doctors, nurses and assistive technology (AT) specialists. Even if BCIs can provide appealing options to some end users, these BCIs will not be adopted if they are not better known. This is a serious challenge. One major concern is the growth of 'toy' BCIs - very inexpensive systems that are often inaccurate and unreliable. Unfortunately, such systems have been

aggressively marketed as BCIs, thus providing the general public with unrealistic expectations followed by disappointment. The FBNCI roadmap listed this as a major concern, and we feel that this remains a problem today.

→ Recommendation on BCI dissemination:

We recommend continuing and extending dissemination mechanisms:
Workshop tours, webinars, peer reviewed publications, press releases, participation in exhibitions and conferences, Open House events and other mechanisms. These activities could be pursued through more CSA opportunities, and support of dissemination actions within other mechanisms.

6.3 Recognise training needs

Further, training needs vary tremendously across the different types of BCIs. Training may be subdivided into different categories. These include i) the time to train the user, ii) the time to train the classifier, and iii) the time to train staff as needed.

With some BCIs, training needs are minimal. For example, BCIs for communication and control based on the P300 or SSVEP require on the scale of a few minutes to train the user and classifier, with (almost) no further training needs. That is, an end user who is naive to BCIs could attain effective control within a few minutes; GTEC has demonstrated this with several hundred end users. BCIs that rely on motor imagery for control may take several minutes to a few hours to train the classifier and user, with ongoing research to reduce this time. These systems do not typically entail training medical staff or others.

On the other extreme, BCI applications focused on rehabilitation of cognitive or motor function may require dozens of sessions over the course of months to produce a positive result - such as a statistically significant improvement in cognitive or motor function. Similarly, staff at the user's hospital or rehabilitation centre may also require significant training to help identify the best training schedule, rehab parameters and other details for each user, and provide helpful support during rehabilitation.

Another example of a BCI direction that may require substantial support training is Smart Home control. Before helping users purchase, install and configure Smart Home tools that rely on BCIs, engineering staff may need substantial training and experience with sensors, actuators and other Smart Home systems. People with expertise in both Smart Homes and BCIs are still rare.

→ Recommendation on BCI training:

We recommend recognizing the very different training needs for different BCI systems.

- For BCIs that require little or no training, efforts to reduce training time are less important. Instead, effort should be focused on BCIs that require more training.
- Training time may be reduced by additional R&D, improved documentation and other educational mechanisms such as online support and on-site visits when needed.
- Devices for clinical use should be designed in a way that little training is necessary for medical staff. Consequently, the available options for them have to be reduced to a minimal setup that only requires minimal knowledge about BCI technology.

Acknowledgment

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D3.2 - Otal B, Ortner R. et al. (2014). BNCI Horizon 2020 - D3.2 Evolution of BNCI industry towards 2020 and transfer of technology

D4.4 - Real R, Schettini F. et al. (2015). BNCI Horizon 2020 - D4.4 Quality assessment guidelines

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Annex 1: Success stories (EU-funded projects)

Project	Scenario/Application	Product prototype	Paradigm	End User / Etiology
ABC: Augmented BNCI Communication (FP7-PEOPLE-2011-ITN - 2016 - 2016)	***Replace*** - communication ***Improve*** - rehab	ABC system (platform)	ERP, MI, SSVEP	cerebral-palsy
AsTeRICS: Assistive technology Rapid Integration & Construction Set (FP7-ICT-2010-2012)	***Replace*** Supplement	AsteRICS software (platform) improvements on Enobio (EEG headset)	ERP, MI, SSVEP	various groups
BackHome: Brain-neural computer interfaces on track to home (FP7-ICT-2012-2015)	***Replace*** - communication and control (AT)	improvements for intendiX (BCI speller)	ERP, SSVEP, MI	various groups
BETTER: Brain-Neural Computer Interaction for Evaluation and Testing of Physical Therapies in Stroke Rehabilitation of Gait Disorders (FP7-ICT-2010-2013)	***Improve*** - gait rehab	components of recoveriX (BCI for stroke reha)	SMR	Healthcare system / post-stroke
BRAIN: BCIs with Rapid Automated Interfaces for Nonexperts (FP7 ICT-2008-2011)	***Research***	Brain BCI (platform) water-based electrodes	ERP, SMR, SSVEP	various groups
BrainAble (FP7-ICT-2009-2012)	***Replace*** - Communication - Smart-home control - Inter-operability	ACTOR protocol (interfacing) improvements for intendiX (BCI speller)	SMR, ERP, SSVEP	people with motor disabilities Hospitals Universities
CONTRAST (FP7-ICT-2011-2014)	***Improve*** - post-stroke cognitive rehab - depression - motivation	COALA system (platform)	P300, SMR, neurofeedback	Healthcare system / post-stroke

Annex 1: Success stories (EU-funded projects)

Project	Scenario/Application	Product prototype	Paradigm	End User / Etiology
DECODER: BCI and Detection of Consciousness (FP7-ICT-2010-2013)	***Replace*** - communication ***Research*** - DOC assessment	components of mindBEAGLE (for DOC assessment and communication)	ERP	Healthcare system / DOC Nursing home Hospitals
MINDWALKER (FP7-ICT-2010-2013)	***Improve*** - gait rehab ***Replace*** - exoeskeleton for gait-control	Robotic exosceleton (under clinical evaluation)	SMR	SCI
MUNDUS: MUltimodal Neuroprosthesis for Daily Upper limb Support (FP7-ICT-2010-2013)	***Restore/Improve*** - neuroprosthesis - exoeskeleton rehab	MUNDUS system (platform)	SMR	severely motor impaired people
Presenccia (FP6-IST-2006-2009)	***Replace***	components of IntendiX (BCI speller)	P300, SMR	various groups
TOBI: Tools for Brain-Computer Interaction (FP7-ICT-2008-2013)	***Restore*** ***Improve*** ***Replace***	TOBI platform	SMR, ERP	various groups
TREMOR: An ambulatory BCI-driven tremor suppression system based on functional electrical stimulation (FP7-ICT-2008-2011)	***Improve***	Neuro-TREMOR (following project lasting until 2015)	SMR	Tremor
VERE: Virtual Embodiment and Robotic Re-embodiment (FP7-ICT-2010-2015)	***Supplement*** - Avatar control	improvements for intendiX (BCI speller)	ERP, SSVEP, SMR	various groups
WAY: Wearable interfaces for hAnd function recoverY (FP7-ICT-2011-2015)	***Improve*** - Upper limb rehab ***Replace*** - Hand Exoskeleton for ADLs	Hand Exoskeleton	SMR	SCI Stroke TBI

Annex 2: Use case industry analysis

		1	2	3	4	5
	Application scenario/ UC	**Market size**	**Current treatment/options & their cost**	**Who pays?**	**Incentive for industry, why would industry be interested**	**Time to market**
1	**REPLACE**					
1.1	**Unlocking the locked-in** *(invasive)*	small	If eye-movement is possible: - Eye tracker systems: €5.000-€17.000 - EMG-based switches & joysticks: >€2.000 otherwise, only for completely locked-in state: - EEG/NIRS-based systems: €5.000-€50.000	HS PI PC CH U	+ small number of companies having the whole market share + lincensed know-how of the product used in synergy fields (field patents&royalties) + high product price or govermental finantial support to guarantee return of investment (RoI) + acceptabiltiy by healthcare systems or insurance companies + cutting-edge technology with high visibility + increase of QoL in target end users that may lead to (partial) recovery + impact on society, high social value	mid-term
1.2	BCI-controlled robot assistant *(non-invasive)*	small	No existing solution for specific user-groups (e.g. ALS, PPMS with no motor/speech control). otherwise, - manual (e.g. with a joystick) or speech-controlled telepresence robots: €200-€20.000	HS PI PC CH U	Due to small market size, the incentive is the same as 1.1; and + potential to extend the product with healthy users and increase the market size	mid-term
1.3	Bionic hand with sensory feedback *(invasive)*	small	There is no real soultion for everybody and cost depends upon type of prosthesis chosen. - body-powered prosthesis (cable-controlled via other muscles in the body) - externally powered prosthesis: controlled by small switches that are manipulated by e.g. remaining digits or bony prominences.	HS PI PC CH U	Due to small market size, the incentive is the same as 1.1	long-term

Annex 2: Use case industry analysis

		1	2	3	4	5
	Application scenario/ UC	Market size	Current treatment/options & their cost	Who pays?	Incentive for industry, why would industry be interested	Time to market
2	RESTORE					
2.1	**BCI-controlled neuroprosthesis** *(non-invasive)*	small	- full-time caregiving: €8.000 per month; - neuroprosthesis: €2.000-€10.000 - shoullder joystick to control the prothesis: €2.000-€5.000	HS PI PC CH U	Due to small market size, the incentive is the same as 1.1; and + tendiatially increase the number of user, i.e. market size	mid-term
2.2	Cochlear implant (CI) adjustment *(invasive)*	medium	No option. Currently, CI have to be recalibrated on a regular basis in order to maintain an acceptable hearing quality.	HS PI PC CH U	+ small number of companies having the whole market share + increasing market size as an incentive of return of investment + increase of quality of life of target end users	mid-term
2.3	Spinal cord stimulation for reach and grasp *(invasive)*	small	SCI patients can gain some more motor function with FES systems, after rehab. - multichannel FES systems: >€1000(wihtout neurophrothsis)	HS PC U C	Due to small market size, the incentive is the same as 1.1; and + tendiatially increase the number of user, i.e. market size	long-term

Annex 2: Use case industry analysis

		1	2	3	4	5
	Application scenario/ UC	**Market size**	**Current treatment/options & their cost**	**Who pays?**	**Incentive for industry, why would industry be interested**	**Time to market**
3	**IMPROVE**					
3.1	**Hybrid BCI-driven FES for rehabilitation** *(non-invasive)*	large	ESO guidelines for motor rehabilitation include: FES/robotic assisted training, mechatronic rehabilitation; and constraint-induced movement therapy; Current cost of mechatronic rehabilitation devices for upper limb rehab (entire cost of clinical device, no therapist included): 1. MT Manus: €150.000 (aprox) 2. ReoGo: €60.000-€70.000 3. Amadeo: €40.000 (aprox)	HS PI PC CH U	+ small number of companies having the whole market share + lincensed know-how of the product used in synergy fields (field patents&royalties) + large market size that can guarantee profit beyond return of investment (RoI) + estimated market growth + acceptabiltiy by healthcar systems or insurance companies + cutting-edge technology with high visibility + increase of QoL in target end users that may lead to (partial) recovery + impact on society, high social value	mid-term
3.2	Seizure detection and suppression in epilepsy *(invasive)*	large	Epileptic patients can be currently treated with: - anticonvulsant medications (effective in about 2/3 of patients); - surgery (effective in about 8% of patients); - vagal nerve stimulation: aprox. €40.000 per person	HS PI PC CH U	Same as 3.1; and + invasive technolgoies are generally and sociall accepted	short-term
3.3	Cognitive stimulator *(non-invasive)*	large	There is no real working treatment to prevent or delay dementia symptoms. Cost highly varies. Currently, - Cognitive rehabilitation - FDA-approved drugs (Alzheimer's disease): donepezil, galantamine, memantine, rivastigmine, tacrine	HS PI PC CH U	Same as 3.1	mid-term

Annex 2: Use case industry analysis

		1	2	3	4	5
	Application scenario/ UC	Market size	Current treatment/options & their cost	Who pays?	Incentive for industry, why would industry be interested	Time to market
4	ENHANCE					
4.1	**Neurotutor** *(non-invasive)*	large	Comparable options would be private lessons. Estimations suggest that expenses for private households are >€0.7 billion per yearfor Germany alone.	PI PC CH U G	+ acceptability by end users that results in increasing sales + small number of companies having the whole market share + lincensed know-how of the product used in synergy fields (field patents&royalties) + large market size that can guarantee profit beyond return of investment (RoI) + estimated market growth + impact on society, high social value	mid-term
4.2	Enhanced user experience in computer games *(non-invasive)*	very large	Motion sensing devices (Kinect, Wii), virtual reality glasses (Occulus Rift), and smart game design in general. Aprox. costs: - Kinect: €150; Wii-mote €30, - PC home gain systems: €200-€700, - Control periperals (e.g. joysticks, mice, etc.): €10-€200.	PC CH U	+ estimated market growth that can guarantee profit beyond return of investment (RoI) + acceptability by end users that results in increasing sales + small number of companies having the whole market share	short-term
4.3	Automatic emergency calls *(non-invasive)*	large	Wearable medical alert system with fall detection Cost examples: - aprox €40 per month (wearable) - serivce of a company (e.g. Life Alert): >€1000 fee - telemonitoring platforms: variable	HS PI PC CH U	+ market size is large and tendencially growing + high product/service price to guarantee return of investment (RoI) + acceptabiltiy by healthcare systems or insurance companies + increase of QoL in target end users and relatives + impact on society, high social value	mid-term

Annex 2: Use case industry analysis

		1	2	3	4	5
	Application scenario/ UC	**Market size**	**Current treatment/options & their cost**	**Who pays?**	**Incentive for industry, why would industry be interested**	**Time to market**
6	**RESEARCH**					
6.1	**Research tool for cognitive neurosciences** *(non-invasive)*	small	Current technologies: EEG, fMRI, PET, NIR, MEG, ECoG etc Cost depends on provider	PC CH G	- joint R&D toghether with nonprofit organisations to validate company prototypes and perliminary prodcuts - real-time validated experiments and paradigms	short-term
6.2	Medical examinations *(non-invasive)*	medium	Active participation from the patient is required. - aprox. €13.000 for a refraction unit	PC CH G	- joint R&D toghether with nonprofit organisations to validate company prototypes and perliminary prodcuts - industry could share investment and profit from the solution if successful - if the product is acepted by insurance companies (e.g. because they can save money by reducing examination times)	short-term
6.3	Adaptive neurofeedback training app *(non-invasive)*	small	Normal BCI training without feedback.	PC CH G	- joint R&D toghether with nonprofit organisations to validate company prototypes and perliminary prodcuts - industry could share investment and profit from the solution if successful	mid-term

Annex 3: Market analysis validation process