OECD Science, Technology and Industry Working Papers
2022/01

Brain-computer interfaces and the governance system: Upstream approaches

Laura Victoria García,

David E. Winickoff

https://dx.doi.org/10.1787/18d86753-en

OECD

OECD Science, Technology and Industry Working Papers

Note to Delegations:

This document is also available on O.N.E. under the reference code:

COM/GOV/RPC/DSTI/STP/BNCT(2020)2/FINAL

Brain-computer interfaces and the governance system: upstream approaches

Laura Victoria García (OECD) and David E. Winickoff (OECD)

Brain-computer interface (BCI) systems are in a period of rapid development and offer significant potential for the promotion of health and well-being. At the same time, they raise a range of unique ethical, legal, and policy questions, and few BCI-specific rules exist in a fragmented regulatory landscape. This report aims to help develop a responsible and anticipatory governance approach to promote innovation while shaping the trajectory of technology through a set of mechanisms, including (i) soft law, (ii) standardisation and ethics-by-design approaches, (iii) corporate self-governance, and (iv) participatory experiments for upstream governance.

Keywords: brain-computer interface, neurotechnology, responsible innovation, bioethics, regulation, standards, anticipatory governance, technology governance

Foreword

The OECD Council, on the proposal of the Committee for Scientific and Technological Policy (CSTP), adopted the *Recommendation of the OECD Council on Responsible Innovation in Neurotechnology* on 11 December 2019 (OECD, 2019a). This Recommendation is the first international instrument in its field. In the lead up to its adoption, the OECD led a series of multi-stakeholder workshops that explored strategies for the responsible development and use of innovative neurotechnologies. Building on this work, this current STI Working Paper seeks to inform a larger project in the 2020-21 Programme of Work and Budget of the Working Party on Biotechnology, Nanotechnology and Converging Technologies to work toward the instrument's implementation. It remains the work of the authors and not the OECD members.

This work began as a background paper for the *Recommendation for Agile Regulatory Governance to Harness Innovation* (OECD, 2021), adopted by the OECD Council at Ministerial Level on 6 October 2021, with the aim of helping governments "develop and implement agile and resilient regulatory approaches and facilitate institutional co-operation in response to and to further stimulate innovation". The report evolved from a joint project between the Directorate for Public Governance (GOV) and the Directorate for Science, Technology and Innovation (STI) related to "the Governance of Emerging Technologies in the era of Industry 4.0". In this context, the authors would like to thank Celine Kauffmann and Miguel Amaral (GOV) for their valuable comments and input to the final phase of the report. The report also benefitted greatly from a review by members of the OECD Directorate for Employment, Labour and Social Affairs (ELS). The authors would also like to thank Tatiana Legendre-Hyldig and Valérie Nowak for their valuable research assistance.

Table of Contents

Executive Summary

Neurotechnologies are in a period of rapid development and offer significant potential for the promotion of health and well-being. So-called brain-computer interface (BCI) systems are a leading example of the promise of neurotechnology for improving lives. At the same time, due to the unique functions and moral status of the brain, neurotechnologies – BCI technology in particular -- may raise a range of unique ethical, legal, and policy questions. These issues center on an array of human rights and interest, including human dignity, autonomy, privacy, human enhancement, safety and efficacy, digital security and dual-use. The widespread availability of enhanced computer system technologies (e.g. artificial intelligence algorithms), in conjunction with the vast amount of brain data generated by BCI technologies offers great promise, but also may introduce further uncertainties regarding the potential uses and misuses of brain data or its application in non-medical contexts.

The increasing convergence of BCI with enhanced computer system technologies makes this an opportune time to review current regulatory mechanisms as they engage novel issues posed by BCI devices. In some jurisdictions, traditional regulatory instruments may inadequately address long-term ethical and safety concerns, false or exaggerated claims from direct-to-consumer devices, and gaps in safety and liability rules. Stakeholders in the private sector are looking for guidance as regulatory uncertainty can be a barrier to innovation, impeding development and commercialisation of BCI devices. On the other hand, different countries and regions have taken a number of approaches for the oversight and regulation of BCI technologies. As an early step, agreement on the definition and categorisation of BCI systems is essential to create a solid but flexible regulatory framework, capable of stimulating technology while protecting the user and society from unintended consequences and intentional misuse.

Potential business models should address ethical challenges in order to maximise the benefit of BCI systems while minimising unintended consequences or technology misuse. The integration of norms and values with technical breakthroughs in BCIs may help address the unique ethical, legal and social implications (ELSI) raised by BCIs.

Enabling the development of BCI systems while addressing ELSI concerns is a challenge, but tools exist. Upstream and anticipatory governance approaches using a “Responsible Innovation” framework can help. These approaches try to enable innovation while shaping the trajectory of technology through a set of mechanisms:

1. **Soft law.** Soft law can be a useful component in a sound regulatory framework. As neurotechnology is an evolving field, a mix of soft and hard governance tools is arguably needed for tackling the different applications of BCIs. *Recommendation of the OECD Council on Responsible Innovation in Neurotechnology* aims to advance good governance through a set of principles, including: prioritise safety assessment; promote inclusivity; foster scientific collaboration; enable societal deliberation; enable capacity of oversight and advisory bodies; safeguard personal brain data and other information; promote cultures of stewardship and trust

across the public and private sector; and anticipate and monitor potential unintended use and/or misuse.

2. **Standardisation and ethics-by-design approaches**. Effective ethics-by-design approaches to governance can introduces norms, values, safeguards and goals during the design phase of a BCI product. Standards are currently emerging in the field of neurotechnology, around responsible design options, regulatory good practice and regulatory harmonisation.
3. **Corporate self-governance to advance responsible innovation in the private sector.** In the field of BCIs, effective governance must include governance tools boosting responsible innovation by the private sector, with measures such as, inter alia, appointing responsible innovation officers and boards, engaging in responsible technology transfer, investing in a socially responsible manner and diversifying hiring practices.
4. **Participatory regulatory experiments for upstream governance.** Companies, patient groups, and other stakeholders increasingly demand to participate in the co-development of governance and technology. Experiments such as test-beds, living laboratories or regulatory sandboxes are vehicles for such participation, which can help establish more robust social, ethical and technical conditions under which innovation occurs.

Introduction

Emerging technologies promise to spur economic development and human well-being. However, those benefits may come with potential disruptions to individual and collective social order, posing potential challenges to governance. Consequently, good governance often requires adopting a forward-looking approach. Such an approach aims not only to maximise the benefits and minimise risks, but also to ensure a just distribution of those benefits and risks.

Among emerging technologies, powerful new neurotechnologies are becoming a reality. Neurotechnology has been defined as "devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons" (OECD, 2019a). These emerging technologies are opening new ways to diagnose and treat brain disorders and improve health and well-being. Some estimates suggest that the global cost of those disorders will reach USD 6.0 trillion by 2030 (Insel et al., 2015). This societal need has triggered large public and private investments in neurosciences and neurotechnologies: current national-level brain research initiatives -- from Australia, Canada, People's Republic of China (hereafter 'China'), the EU, Japan, Korea, and the US -- invest a total of over USD 7 billion (Rommelfanger et al., 2018). Moreover, an overall worldwide market for neurotechnology products was forecast at USD 13.3 billion for 2022. (Royal Society, 2019; OECD, 2017a). As it has been pointed out, "if the technologies were affordable and available to all, then such technologies could support several of the UN Sustainable Development Goals" (Royal Society, 2019).

At the same time, developments in neuroscience and neurotechnology raise a wide range of ethical, legal and social issues (ELSI) that may call into question *inter alia* human dignity, personal autonomy, brain privacy, and social responsibility. In this context, the governance of emerging technology may help integrate social, scientific and technical aspects of neurotechnology breakthroughs. For these reasons, OECD countries recently enacted the *Recommendation of the OECD Council on Responsible Innovation in Neurotechnology* (OECD, 2019a).

The development of brain-computer interface (BCI) systems illustrates the potential impact of neurotechnology innovation on human beings, economy and society. This category of neurotechnology includes both invasive and non-invasive technologies capable of sensing and decoding brain activity, as well as recording and stimulating it. There are a number of current benefits of the use of this technology on recovering from a stroke and the treatment of Parkinson's disease or epilepsy; others are still in research, including the restoration of locomotion in paralysed individuals. It is important to clarify that the classification of BCIs (notably the distinction between invasive and non-invasive BCIs) will dictate different ELSI issues (and policy frameworks). The convergence of BCI systems with Artificial Intelligence promises even deeper technological change. For the purposes of this paper, an Artificial Intelligence system is defined as "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments" (OECD, 2019a). Furthermore, the US Defense Advanced Research Project's Agency (DARPA) is investing in the development of "cortical implants

that can stimulate 100 000 neurons and record from a million neurons" (Naufel and Klein, 2020). This opens up the way to the commercialisation of non-medical devices for training, commercial or military use, enabling hands-free device control (OECD, 2017a). Finding the appropriate regulatory mix for direct-to-consumer (DTC) devices faces additional challenges. As a result, depending of the categorisation of the BCI, the existing ELSI challenges could be more extensive, such as those related to privacy, cybersecurity, human enhancement, Algorithmic Application Bias and dual-use or "off-label" applications inherent to neuroscience (Baldwin et al., 2013; Ienca et al., 2018b).

Against this backdrop, science and society must work together in order to realise the full potential of BCI technology. Policy choices and flexible regulation can help drive innovation by generating public trust.

This analysis provides the groundwork for new ways of assessing the landscape of the governance of brain-computer interfaces. Chapter One reviews the key BCI technologies and their impact. Chapter Two presents certain key ELSI issues around BCI technology. Chapter Three examines the current regulatory and policy environment. Chapter Four analyses key BCI regulatory considerations. Chapter Five discusses the possible utility of responsible innovation frameworks and their associated tools.

The analysis reveals that governance frameworks in some jurisdictions may present gaps both in the treatment of risks and challenges posed by BCI, and in the way they are designed to face them. In received opinion, certain regulatory frameworks may not adequately address the complex ethical, legal and social questions in play, as they do not cover long-term concerns beyond questions of safety and effectiveness. Other potential gaps include false or exaggerated claims from DTC devices, the possibility of avoiding restrictive pre-market safety measures applied to medical devices, liability matters, and institutional and transboundary challenges. Moreover, regulatory uncertainty for the private sector could hinder innovation, presenting obstacles to development and commercialisation of BCI devices. Building a responsible and anticipatory governance approach would help promote the development of BCI technology/systems while addressing ethical, legal and social concerns.

1. Key technologies

Definition and categories

BCI systems are defined by their different forms of connection and data transfer as well as possible applications, and these classifications help determine which of the wide range of regulatory and governance frameworks might apply. Indeed, agreement on the definition and categorisation of BCI systems is essential to harmonise and create a solid but flexible regulatory framework, capable of stimulating technology in all its variants while protecting the user and society from unintended consequences.

In general terms, BCIs are "used to sense and decode neuronal activity patterns by external devices – linking thought commands to external devices" (OECD, 2016b). Thus, a basic BCI system includes a sensor to capture the brain signal, a computer (which converts the signal into an algorithm), and a computer element to control an external device. Nevertheless, some authors extend the BCI definition to devices connecting other parts of the neural system (neural interfaces) or to devices that (also) stimulate the brain (i.e. including a forth element of feedback stimulation) (UK, 2020).

Authors are using other terminology to refer to brain-computer interfaces, such as a neural interface (NI), mind-machine interface (MMI), direct neural interface (DNI), or brain-machine interface (BMI). This report considers a broader terminology to analyse all the possible challenges arising from these kinds of neurotechnology.

There are several BCI classifications that carry regulatory and governance consequences. The classification regards each component of the system (table 1).

Brain signal acquisition

BCI systems can use different ways to acquire the brain signal, from the least invasive to the most invasive techniques (tables 1 and 2) (Royal Society, 2019):

- Invasive: the implant requires surgical intervention with the risk that it entails possible subsequent complications for the user. However, it has a high-quality acquisition of brain signal. The best known in the world is the cochlear implant, used by more than 700 000 people who suffer hearing damage (NIH, 2021).
- Non-invasive: the sensors are located externally, using non-invasive techniques. They have no risks from surgery, but they get a weaker signal. The most widely used is electroencephalography (EEG). Other examples include magnetoencephalography (MEG) or functional electrical stimulation (FES).
- Partially invasive: the implant has a better acquisition of the brain signal than the non-invasive technique, but requires minimal surgery. An example is electrocorticography (ECoG).

Invasive BCI systems are particularly controversial as their future development could involve a number of far-reaching concerns and therefore are the focus of the challenges section of this report.

Table 1. BCI invasive technologies: description and classification

	Technology description	Applications	Functionality
Cochlear implants	Outside component fitted with microphones detects sounds, converting them to electrical signals that are sent to internal component that stimulates hearing cells in the cochlear nerve.	• To re-establish hearing lost	Stimulating
Cortical implant	Components inserted directly into the brain's cortex, transmit signals to a device located on the outside of the head that sends them on to external objects.	• On research: transmit brain signal, brain stimulation, restore sight or hearing, improve cognitive functions and restore paralysis.	Recording
DBS	Deep brain stimulation (DBS) entails inserting electrodes into deep regions of the brain. The electrodes are typically connected to a battery-powered implantable pulse generator (IPG) implanted elsewhere in the body.	• Treatment: drug-resistant epilepsy, depression and chronic pain, Parkinson's disease, dystonia and tremor. • Future use: Tourette's syndrome and obsessive-compulsive disorder	Stimulating
ECoG	Electrocorticography (ECoG) placed an array of electrodes directly on the exposed surface of the brain to record electrical activity from the cerebral cortex.	• Epilepsy pre-surgery • Treatment of severe epilepsy • Possible future long-term use as implant: stimulation	Recording
Neural lace	Arrays of tiny electrodes, placed on polymer wires or threads, which can be injected into the brain.	• Carrying electrodes into a brain rapidly avoiding blood vessels. Improvements on trial.	Recording
Retinal implants	Arrays of microelectrodes surgically attached on or beneath the surface of the retina. They transmit signals from incoming light that bypass damaged photoreceptors and stimulate the retina's remaining cells".	• Rehabilitation: *renitis pigmentosa* or macular degeneration	Stimulating
Stentrodes	Stents with electrodes inserted via catheters into blood vessels in the brain in an outpatient procedure.	• Treatment: neurological conditions • Wheelchair mind control	Recording
VNS	Vagus nerve stimulation devices (VNS) deliver electrical current around the vagus nerve that runs from the brainstem to the abdomen and are connected to an implantable pulse generator (IPG). Pulses activate neurons and release neurotransmitters that can change brain networks.	• Epilepsy surgery • Treatment: drug-resistant epilepsy, depression and substance abuse.	Stimulating
Vestibular implants	Electrodes placed near the vestibular nerve branches that transmit the signals to the brain.	• Rehabilitation: bilateral vestibular loss	Stimulating

Source: Information extracted from The Royal Society (2019), iHuman: blurring lines between mind and machine DES6094, ISBN: 978-1-78252-420-5, https://royalsociety.org/-/media/policy/projects/ihuman/report-neural-interfaces.pdf

Functionality

BCI signal can be unidirectional -- from the brain to the computer, detecting neural activity, or from the computer to the brain, administering stimulation without detection-- or bidirectional – i.e. in both directions, stimulating and registering.

Consequently, BCI systems can record, stimulate, or do both. Some examples of BCI technology are found in Table 1, listed according to functionality. An example of bidirectional BCI is neurofeedback EEG, a combination of EEG (recording) and FES (stimulant). Regardless of their functionality, BCIs can be implantable or not. A recent generation of neural prostheses are both bi-directional and implantable (Starr, 2018).

Purpose of use

A BCI system's target can be therapy or remediation (i.e. to repair impaired functions) or enhancement (i.e. to increase users' capabilities). Therapy and/or enhancement refers to cognitive as well as physical conditions. Enhancement is a controversial issue: the line between therapy and enhancement is sometimes not clear, but the distinction is crucial to determine the regulatory framework to apply (Palmerini, 2015). In its initial stages and still today, the majority of BCI systems develop in the clinical setting for therapy. Conversely, advances in neurotechnology are increasing the creation of devices for enhancement, inside and outside the medical environment.

BCI applications

At present, the majority of BCI systems develop in the clinical setting. For instance, there is currently a project to implant chips in human brains to treat neural disorders (Shen, 2022). However, advances in neurotechnology are driving research and development of devices for non-medical applications. The various devices marketed and under investigation fall into the categories below.

Medical applications

Most of the BCI systems are medical devices for a range of uses, e.g. brain imaging acquisition (e.g. EEG), control of assistive equipment for patients who have lost cognitive or physical function (e.g. FES), or neurostimulation to enhance the potential effectiveness of certain therapies (e.g. DBS) (UK, 2020) (Table 1). A governance issue related to medical devices is reimbursement as there is often a lack of clarity in rules in many jurisdictions. DBS devices tend to benefit from reimbursement while devices based on EEG neurofeedback do not.

Non-medical applications

BCI technology for non-medical applications is only recently entering the consumer market, and further growth is expected for a variety of areas, from entertainment (e.g. EEG gaming headsets) to training (e.g. EEG headsets to improve concentration) to neuromarketing (e.g. BCI to measure consumer reaction) (UK, 2020). Defense is another area in which different countries are increasing their investment, for example, to investigate the improvement of cognitive skills or aid in the decision-making of soldiers. Finally, law enforcement is another field of application, where BCIs are used for lie detection or law-enforcement, for instances (OECD 2017a; Garden et al., 2019).

Table 2. BCI non-invasive technologies: description and classification

	Technology description	Applications	Functionality
EEG	Electroencephalography (EEG) is electro-physiological monitoring method to record electrical activity of the brain. It entails the placement of multiple electrodes on the head, typically using a web or cap, which traces neural activity.	• Recording brain signal • Diagnose epilepsy, sleep disorders and coma. • Computer games On research: recovering from stroke	Recording and stimulating
FES	Functional electrical stimulation (FES) delivers electrical pulses to nerves to stimulate movement in muscles that have become paralysed or weakened.	• Treatment: movement disorders.	Stimulating
fMRI	Functional magnetic resonance imaging (fMRI) provides high resolution images by measuring changes in blood flow in the brain, requiring the patient to lie inside a large scanner. Technique depends on the fact that cerebral blood flow and neuronal activation are coupled.	• Research fields: memory, language, pain, learning and emotion • Lie detector • "Neuro-marketing"	Recording
fNIRS	Functional near-infrared spectroscopy (fNIS) detects neural activity by measuring blood flow patterns revealed by changes in near-infrared light.	• Diagnosing brain injury • Research of the brain functioning (in combination with fMRI).	Recording
MEG	Magnetoencephalography (MEG) records brain activity by monitoring magnetic fields produced by electric currents.	• Recording brain signal • (more precise than EEG)	Recording
MMG	Mechanomyography (MMG) traces muscle movement using sensors embedded in a wearable garment.	• Therapy: movement disorders. • Research: loss of function and the mechanisms of recovery	Recording
tDCS	Transcranial direct current stimulation (tDCS) delivers constant and direct low current impulses using electrodes placed on the head.	• Treatment: depression, pain and stimulate movement. • Future use outside medical field: cognitive processes and movement enhancement	Stimulating
TMS	Transcranial magnetic stimulation (TMS) employs a coil close to the scalp to produce a changing magnetic field.	• Research of brain areas activated and deactivated • Treatment: drug-resistant depression	Stimulating
TENS	Transcutaneous electrical nerve stimulation (TENS) deploys electrodes to stimulate nerves and reduce pain signals going to the spinal cord and brain".	• Reducing pain	Stimulating

Source: Information extracted from The Royal Society (2019): blurring lines between mind and machine DES6094, ISBN: 978-1-78252-420-5, https://royalsociety.org/-/media/policy/projects/ihuman/report-neural-interfaces.pdf

Convergence with Artificial Intelligence

In recent years the convergence of brain-computer interfaces and artificial intelligence have opened important new pathways of research and application (Zhang et al., 2020). BCIs and AI were historically developed and applied independently from each other. However, as neuroscience provides a rich source of inspiration for new types of algorithms as well as validation for AI techniques,

these fields of research have become more intertwined. Most of the BCIs, for example, use components of artificial intelligence (Ienca, 2018a). While the combination of both technologies has attracted interest and many stakeholders are dedicated to the development of the joint technology, the field remains specialised and mostly limited to the research-side rather than to that of product development, mainly in areas such as medical treatment. BCI-AI research applications range from cursor control to neuroprosthetics limb rehabilitation to auditory sensation; and speech synthesizers to optical prosthetics (Hassabis et al., 2017). Researchers are increasingly using AI algorithms to process information collected by micro-electrodes and send outputs back to the brain as feedback, allowing it to correct the investigated impairment (Zhang et al., 2020). This enhances capacity to move external devices and offers a powerful way to investigate brain function by providing direct knowledge and control over neurons controlling behavior. Both invasive and non-invasive BCI systems have been used to enable neural control of robotic limbs in human, where complex movements rely on the robot's AI software (Danziger et al., 2009; Orsborn et al., 2014; Zhang et al., 2020). In somatosensation, AI allows to efficiently explore the link between the pressure exerted on objects by the prosthesis (Muller-Putz et al., 2006; Zhang et al., 2020). Moreover, to find the best visual prosthesis, BCIs based on AI are indispensable (Zhang et al., 2020).

The convergence between BCI and AI technologies carries promise for the treatment of neurological disease, and has attracted both governmental and private sector interests both for therapeutic applications and for enhancing normal cognitive functioning (Zhang et al., 2020; Ienca, 2018a). With AI supported at high political levels, China has invested heavily in research in academia and industry, founding a number of dedicated BCI-AI research centres, including initiatives in three disciplinary areas: "brain-inspired" AI modelling aspects of human cognition; "connectomics" or brain mapping; and brain-computer interfaces that link the two "platforms". Specific laboratories such as the Tsinghua University BCI Lab (2014) or the CAS Institute of Automation, Research Center for Brain-inspired Intelligence (2015) have helped develop innovations such as "imaginative movement tasks" for better writing performance; a standard data set for electrical activity generated by the brain in response to visual stimulation; as well as "the fastest reported scalp-brain computer interface systems" which are hoped will promote the application of BCI in the daily life of healthy people (Dan et al., 2018). Thus, beyond therapeutic uses, BCI is seen as a potential direct link to AI, allowing the eradication of "middleware" and opening the door to cognitive enhancement (Hannas et al., 2020).

Moreover, the integration of brain-computer interfaces, artificial intelligence (AI) and nanotechnology holds great promise for neurotechnology. The recent convergence of BCI systems and nanotechnology is improving the precision and quality of the devices. Current research is focused on reducing the size of the components; biologically transforming them (reducing the implant reaction) or developing "injected floating nano-electrodes" (Athanasiou et al., 2016). Further complex engagements between AI and BCIs could emerge, with the development, for instances, of adaptive stimulation algorithms (Starr, 2018). A Human-AI integration through BCI may raise both ELSI issues, as well as potential benefits (e.g. "enhanced" decision-making) (Royal Society, 2019).

Laboratories beyond China are working in the BCI-AI research field. For instance, a team from Carnegie Mellon University in the US focuses on thought decoders, using machine learning (an AI subset) to discern numerical values from brain activation patterns (Damarla and Just, 2013). In the field of cursor control, there has been *inter alia* the development of a high-performance, invasive BCI used for communication that translates signals into point-and-click commands (Bacher et al., 2015). In Germany, the Max Planck Institute for Intelligent Systems works on neurophysiological causes of performance variations in BCI, using AI techniques for adapting BCIs to their users (Jayaram et al., 2016).

Regarding the private sector interest, Facebook has expanded activities towards the development of neurotechnology products with the acquisition of CTRL-Labs, a start-up building software to control digital software by thoughts, bypassing mouse and keyboards setups (Melcer et al., 2018, Naufel and Klein, 2020). Furthermore, Facebook announced their BCI program in 2017, where they advanced their long-term mission: silent speech communications, hoping to allow users to communicate at a speed of at least 100 words per minute (Facebook, 2017; Tech@facebook, 2020). Facebook-supported researchers at the University of California San Francisco (UCSF) demonstrated in 2019 that a BCI recording brain activity using implanted electrodes could be used to almost instantly decode speech in real-time (Moses et al., 2019; Makin et al., 2020). This promising, yet preliminary data, is a first in the field of combined AI/BCI-research and will primarily have important medical applications for people having speaking disabilities. Nonetheless, Facebook expects to use this technology for broader use, such as typing or Augmented and Virtual Reality programs, but has pledged to govern this research through an Ethics Board (Facebook, 2017).

In other high-profile private sector activities, Neuralink -- a neurotechnology company founded by Elon Musk -- has invested more than USD 150 million in neurotechnology research. Neuralink has addressed some of the issues hampering the next generation of invasive BCI development by introducing a novel integrated platform enabling a high-quality registration of thousands of channels (Pisarchik et al., 2019). This novel neurointerface could become a step forward to the next generation of BCI for both research and clinical applications. Finally, Kernel, a start-up created by Braintree co-founder Bryan Johnson in 2016, is also trying to enhance human cognition by trying "to read and write the underlying functions of the brain" (Vance, 2020).

2. Ethical, legal and social implications (ELSI)

BCI technology implicates human rights, interests and values, although these issues vary by the type of interventions being made. These emerging technologies – especially neurostimulation devices -- raise unique ethical, legal, and societal concerns that range from human identity, to autonomy, privacy, human enhancement, brain data privacy, regulation and marketing of direct-to-consumer devices, technology misuse or risks of inequalities (OECD, 2018; OECD, 2019a). It is crucial to analyse the connection between BCIs and these important considerations, as they provide the rationale for governance.

Human rights

First, certain BCI systems -- such as implantable deep brain stimulators or BCIs to control assistive devices – implicate interests and rights in individual autonomy, i.e. the freedom of person to make decisions (UNESCO, 2005). An alteration of autonomy may have implications for other key issues including cognitive liberty, informed consent, sense of agency and identity, manipulation, responsibility, human dignity and privacy (Burwell et al., 2017; Yuste et al., 2017; OECD, 2019a). Other implications may affect what have been called "neuro-rights", such as the right to personal identity, to free will, to mental privacy, to equitable access, to augmentation technologies and to bias protection and discrimination (O'Sullivan, 2019).

Second, and related to human interests in autonomy, are interests in cognitive liberty, or the related "right to mental self-determination" (OECD, 2019a). The degree to which neurostimulation systems interfere with such a notion of cognitive liberty is difficult to determine. Against this backdrop, scientists are currently investigating the metacognition in neurofeedback to determine whether BCI users could learn to recognise their brain activation (Stirner, 2022). Likewise informed consent -- the process warranting that the user has willfully permitted a procedure -- is difficult to calibrate when it comes to patients who have communication difficulties due to their illness (Burwell et al., 2017).

Third, BCI devices implicate the very understanding of the human being. On the one hand, some authors consider that human dignity may benefit from the increase of autonomy provided by medical BCI systems (Burwell et al., 2017). Similarly, BCI technology may help restore personhood in patients suffering from locked-in syndrome. On the other hand, the debate is ongoing about the unique and controversial relationship between human and machine. For some experts this relation is not new, while for others there are serious new concerns about the human condition. For their part, users may show reluctance to the idea of man-machine fusion (Burwell et al., 2017).

Fourth, with the commercialisation of BCI devices, driving innovation while protecting the privacy of personal brain data carries significant challenges (Holder et al., 2016 and Garden et al., 2019). Personal brain data might be defined as "data relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health, or mental states" (OECD, 2019a). To ensure data privacy, some experts

believe that users must give their express consent before data is shared (Yuste et al., 2017). Key challenges include, e.g. the gathering, protection and storage of the data obtained from BCI devices, how to avoid hacking and how to ensure respect for private life (Naufel and Klein, 2020). Furthermore, novel human rights concepts co-emerge with the technology, for instance around the notion of a right not to be measured.

Finally, decoding brain data or altering brain activity though neuroestimulation may result in an unauthorised manipulation of the user. Indeed, it is a matter of debate whether BCIs systems can be used to control and change people's behaviour in areas such as politics or marketing. For instance, collecting consumer data might lead to manipulation to sell unhealthy products to a certain vulnerable population (Garden et al., 2019).

Risk and safety of BCI devices

Depending on the particular technology (for instance whether it is invasive or non-invasive) and its potential uses and misuses, the use of BCIs may raise concerns for the physical and psychological well-being of their users. Risk also entails failures in maintenance of devices when a study ends for instance. Moreover, some authors point out that internet-connected devices multiply possibilities of technology misuse such as "neuro-hacking" (Yuste et al., 2017).

Human enhancement, social inequalities and dual-use

The line separating human enhancement from therapy is notoriously vague, especially since technologies are currently being developed for experimental treatments (Baldwin et al., 2013). In addition, the distinction of what is "normal" in terms of human capabilities is being actively debated, as well as the relation between BCI and stigma of disability (Burwell et al., 2017).

In this context, it is important to note that there are projects by government agencies, such as the US Defense Advanced Research Projects Agency (DARPA), which aim to increase the cognitive capacity of soldiers using BCI systems. This is an example of so-called dual use of neurotechnology (Yuste et al., 2017). From the dual use inherent in neuroscience, a series of risks and concerns arise regarding the misuse of technology by governmental or non-governmental actors, as well as question of autonomy, privacy and responsibility (Ienca et al., 2018b).

The potential for BCI devices to enhance users' capabilities may create social inequalities. Indeed, performance improvements through neurostimulation can discriminate against those who cannot afford the use of the technology (Garden et al., 2019). At the same time, algorithmic bias may exacerbate inequalities, as an algorithm reflecting absolute equity is very difficult.

Property rights

Using BCI systems raises ELSI questions about data ownership and intellectual property, not to mention ownership of the device. The amount of data generated and shared through BCI devices is greatly increasing thanks to the commercialisation of new devices connected to networks and digital platforms.

This has triggered an important discussion about BCI data ownership among multiple stakeholders including BCI researchers, policymakers, neuroethics experts, business as well as the public. BCI researchers are trying to lay a foundation for dealing with complex questions such as whether the data generated from medical devices can indeed be owned, or what exactly constitutes the patient's data ownership rights. It could be argued that patients have a right to personal data generated in the course of their treatment or research study (Naufel and Klein, 2020).

3. Current government/regulatory approaches

The regulation of BCI systems is more than ever at a critical juncture. Recent proposals for the inclusion of "neurorights" in both national and international regulations illustrate a dynamic landscape. Nevertheless, few BCI-specific rules exist in what amounts to a heterogeneous and fragmented regulatory landscape.

The regulatory environment for BCIs spans multiple regimes. The application of a governance regime depends on the BCI category considered (e.g. devices for medical use) and/or aspects to be regulated (e.g. data use). Since its development centres on research and medical applications, BCIs fall mainly into medical device regulation. That said, and because of the technology extension to other sectors, the importance of consumer rules and data governance, as a part of the BCI regulatory landscape, should not be overlooked. Furthermore, the regulatory regime applicable to a given BCI differs across jurisdictions and there are divergences in the type of norms governing the technology, from legal provisions to standards and guidance.

BCIs are considered medical devices in most jurisdictions, which implies a more rigorous safety and efficacy regulatory framework, establishing a premarket approval process for those devices, a post market surveillance and establishing barriers to the importation of unfit devices (Clément, 2019). In general, the regulation of medical devices contributes to better public health outcomes by "reducing potential health risks as much as possible and enabling patient access to high quality, safe and effective medical devices while restricting access to those products that are unsafe or ineffective" (WHO, 2017). In terms of international standards and nomenclature, ISO 14971[1] standard specifies terminology, principles and a process for risk management of medical devices (and other products not considered medical devices in some jurisdictions) in all phases of the life cycle of the device. This norm contains risk acceptability criteria but it does not specify risk levels, which are established pursuant to national legislation.

In order to speed up the medical use of implantable devices, the US Food and Drug Administration (FDA), has published a non-binding draft guidance (FDA, 2019) (Box 1). This constitutes a "leapfrog guidance", intended to serve as a mechanism by which the FDA can share initial thoughts regarding emerging technologies that are likely to be of public health importance early in product development. It is important to underline that this is a specific regulation on BCI. Taking a different approach, the EU Medical Devices Regulation (MDR) has recently tightened its regulation and extended it to non-medical devices operating in the same way, or with similar risks (EP, 2017) (Box 1).

Box 1. FDA guidance on Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations (2019)

Aimed at industry and FDA staff, the US Food and Drug Administration (FDA) draft guidance provides procedures for non-clinical testing and clinical trial phases in device development, to mitigate risks and ensure safety and efficacy. Testing of the device in non-clinical contexts can demonstrate a mitigation of potential risks before beginning a clinical study.

The draft guidance provides recommendations for a pre-submission process and for investigational device exemptions (IDE), including the provision of detailed information on:

- The device
- Software (including cybersecurity information)
- Determination of the biocompatibility of patient-contacting materials present in the device
- Sterility information: method, level and process
- Pyrogen specifications to avoid toxicity
- Shelf Life (to support the proposed expiration date) and packaging
- Testing of the Electrical Safety and Electromagnetic Compatibility (EMC)
- Testing of wireless technology transmission for the safe and effective use the BCI system
- Magnetic Resonance (MR) Compatibility
- Non-clinical bench testing, implementing risk analysis with examination of: potential hazard; testing electrodes, leads and connectors; checking implanted casing and electronics; measuring and checking the safety of the output stimulation; verifying the for a reliability of the programmers/control units performance; testing the Radiofrequency (RF) Transmitter and Receiver; system level testing
- Non-clinical animal testing to address factors that cannot be evaluated through bench tests or in a clinical study

Source: FDA, 2019.

Consumer protection laws

In certain jurisdictions, consumer protection laws provide protection, but these are typically less protective than medical device regulation. Indeed, consumer protection laws require lower levels of safety and quality for consumer devices to be commercialised and market monitored. The level of user protection is, therefore, lower for those devices falling only under the scope of consumer protection laws, such as electroencephalography (EEG) headsets used for gaming while, conversely, the requirements for their commercialisation are less onerous.

Consumer protection regimes intend mainly to safeguard consumers against unfair practices in the marketplace, but also covers a wide range of topics of relevance for the BCIs systems, including product liability, privacy, unfair business practices, fraud or misrepresentation.

The boundary drawn around a "medical" device versus a non-medical one is often determined by whether the device is intended for a health purpose or not. However, some jurisdictions have extended their medical device legislation to non-medical devices operating in the same way, or with similar risks (Box 2).

The general consumer protection measures comprise both national and international legislation, such as the Consumer Protection Act (CPA). However, it should be noted that not all the jurisdictions have a national policy on consumer protection, and the CPA has been criticised sometimes for not being adequately implemented (Consumer International, 2013).

Box 2. EU Medical Devices Regulation scope expansion

Since May 2020, the EU Medical Devices Regulation (MDR) scope expanded to non-medical devices performing similar work or carrying similar risks to medical devices. Therefore, pre-market tests on safety and quality -- and the subsequent post-market surveillance -- apply now to non-medical devices, such as certain non-invasive brain stimulation devices for cognitive enhancement. This change of legislation widens the scope of coverage to certain consumer device markets. However, it has been criticised that some recording BCIs are still outside the scope of this norm. The expansion may also present a barrier for manufacturers, who could instead try to obtain authorisation to commercialise their devices outside the EU market.

Sources: UK, 2020; Clément, 2019

Data protection regulation

The benefit of a rich and open data environment for the progress of science are well known, and are embodied in norms and calls for "open science" (Dai, Shin and Smith, 2018). Nevertheless, amidst concerns about privacy, data protection laws have proliferated in the last few years, in response to the increasing digitalisation of modern human life. These laws tend to cover the use and ownership of personal information derived from the use of BCI systems. For instance, Convention 108 of the Council of Europe[2] establishes principles for collection and automatic processing of personal data. Brain data obtained in clinical research or as a part of a treatment falls into current regimes such as the Health Insurance Portability and Accountability Act (HIPAA)[3] and the Common Rule in the US[4]. Regarding the commercial collection of data, the European Union's General Data Protection Regulation (GDPR), which entered into force on 2018, covers both personal data protection, including user's consent, and free movement of personal data[5] (EP, 2016; Van Est et al., 2017; Naufel and Klein, 2020).

The greater or lesser degree of protection depends on the context in which the data have been collected (Naufel and Klein, 2020):

- In a clinical context, collected data are considered medical data and their access is highly protected;
- In a commercial context, lower levels of protection apply.

While most BCI experts consider raw neural data as a kind of medical data, it has been critically observed that data protection laws are focused on the origin of the data more than on its nature or use data (Naufel and Klein, 2020). The origin refers both to the geographical and clinical (or non-clinical) context in which the data were generated. Firms, therefore, can collect personal data and distribute them to third parties. Furthermore, it should be noted that the commercialisation of BCI systems has generated an exponential increase in data. The generation of big data together with the lack of protection in the commercial environment, makes cybersecurity a key challenge not covered by the current regulatory systems (Ienca et al., 2018c).

Finally, explicit consent is generally a key safeguard before sharing brain data (UK, 2020). For example the EU general data protection regulation (GDPR) requires explicit consumer consent for data collected in a commercial context (EP, 2016).

Rules protecting Human Rights

In absence of specific regulatory mention, there is a set of international norms regulating Human Rights that would seem to apply to the BCI field, such as (Yuste et al., 2017):

- The Universal Declaration of Human Rights (1948)[6]: protecting generally Human Rights
- The Declaration of Helsinki (1964)[7]: establishing ethical principles for human medical research
- The Belmont Report (1979)[8]: for human protection Biomedical and Behavioural Research
- The Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention 1997),[9] establishing human rights in the biomedical field

International human rights legislation establish that Governments should "act in certain ways or to refrain from certain acts, in order to promote and protect human rights and fundamental freedoms of individuals or groups".[10]

In addition, several authors, institutions and governments are preparing important initiatives to develop neuro-rights in legal-binding instruments and therefore ensure that new neuro-technologies are "used for the benefit of humanity" (University of Navarra, 2019):

- A proposal from the so-called Morningside Group – a group of neuroscientists, neurotechnologists, clinicians, ethicists and machine-intelligence engineers – to include the so-called "neurorights" in the Universal Declaration of Human Rights and to create an international convention to list prohibitions related to neurotechnology (Yuste et al., 2017); those neuro-rights are: the right to personal identity, to free will, to

mental privacy, to equitable access to augmentation technologies and to bias protection and discrimination (O'Sullivan, 2019).

- Chile becomes first country to pass a law on neuro-rights. The amendment to the Chilean Constitution aims at protecting, especially, brain activity and information against advancements in neurosciences and AI[11].
- Spain has included the "neurorights" in the Charter of Digital Rights[12] and announced the promotion of a new innovation ecosystem, called SpainNeurotech[13], with a view - among other things - to minimise the ethical impact of neurotechnologies.
- The Council of Europe Bioethics Committee is also exploring the need to specify new human rights (COE, 2019).

4. Regulatory considerations

In parallel to this debate on whether or not certain uses of BCI technologies should be banned, there is also debate on the adequacy of existing regulatory mechanisms to regulate these devices or whether a reform is necessary (Baldwin et al., 2013). Establishing proper regulatory mechanisms is crucial to foster innovative BCI systems while addressing the potential risks. Finding the right mechanisms means facing problems that are not always new (Baldwin et al., 2013), including the unpredictable nature of the risks. However, the long-term concerns raised by BCI systems make the regulatory approaches governing this technology unique, leaving little space for the application by analogy of the rules that apply to other technologies (OECD, 2017a). In the context of a rapidly changing field, finding an appropriate yet flexible regulatory framework may present significant challenges. Those issues range from failure to address long-term concerns to questions of safety and efficacy, international cooperation, regulatory uncertainty or liability which are discussed here, but a full cross-country comparative regulatory review is beyond the scope of this report, which for the most part relies on secondary sources.

Addressing long-term concerns

Current governance and regulatory instruments should address concerns raised by BCI systems over privacy, autonomy, enhancement, inequality, and data access. The high level of uncertainty regarding the long-term impact -- whether at the economic, social or individual level -- of neuroscience research and innovation makes finding the right regulatory approach difficult. At the individual level, for instance, certain experimental interventions carry risk of irreversible damages (OECD, 2017a; Boucher et al., 2016).

With regard to data privacy, some experts think current regulatory frameworks are in general insufficient to address brain data privacy, although some countries and regions do contain robust cybersecurity protections for medical devices[14]. Procedural or criminal laws do not include risks derived from the exposure of data to the internet such as cyber-attacks to implanted devices. Moreover, in some countries, no privacy or security assessment is required before the devices are commercialised (Palmerini, 2015). Against this backdrop, they have pointed out different proposals (Naufel and Klein, 2020, Yuste et al., 2017, Palmerini, 2015), e.g.:

- A legal protection of privacy-by-design that precedes the commercialisation of the device;
- A strict regulation of the sale, transfer and use of brain data;
- A decentralisation of brain data processing.

With respect to an enhancement regulatory framework, some experts see a need for regulation in both a national and international context that respects cultural differences, while creating a necessary harmonisation in the protection of universal rights (Yuste et al., 2017 and Palmerini, 2015). Proposals call for banning or applying strict regulation to certain BCI devices or applications (Yuste et al., 2017).

Some authors have also proposed international moratoria for certain applications supervised by international commissions, together with an international public debate (Yuste et al., 2017).

As for agency and identity issues, some experts argue that national and international legally binding systems should expressly recognise them, in part because harmonisation is crucial in this context of human rights protection (Yuste et al., 2017).

Regarding inequalities, the commercialisation of non-medical devices for cognitive augmentation purposes may increase or create new inequalities to the detriment of citizens who cannot have access to them. Another example refers to cases of BCI devices replacing therapies reimbursed by the public health systems. Those cases could also exacerbate inequalities against people who cannot afford the alternative BCI treatments (Van Est et al., 2012).

Safety and effectiveness

There is a need to find appropriate regulatory means to avoid the potential risks of neurostimulation devices, guarantee real benefits and, consequently, breed public trust (OECD, 2017a). The current regulatory situation raises a wide spectrum of challenges.

In some jurisdictions, it is possible that manufacturers may avoid medical devices regulation regarding both body implants and non-invasive techniques (e.g. EEG neurofeedback) by indicating that the devices are not intended for medical use (Palmerini, 2015). In this case, consumer protection rules alone would be applied, and manufactures would not have to undergo certifications or efficacy and risk tests assigned to medical devices. The level of protection for those devices will be, therefore, lower in terms of product quality and user safety (Palmerini, 2015; Van Est et al., 2012). Furthermore, in some jurisdictions, the current informed consent procedures may not provide sufficient legal protection to the consumer with respect to the use and generation of data of a new technology that carries a potential security and effectiveness risk (Boucher et al., 2016).

Consequently, there could arise false or exaggerated claims from commercialised cognitive enhancement devices (Wexler et al., 2019). In fact, given that those devices usually do not fall into medical devices regulation, it becomes more difficult to verify and monitor both their claimed benefits and the potential negative effects on consumer health, i.e: “safety, quality assurance and market surveillance” as stated by the UK Parliament postnote, (Garden et al., 2016; OECD, 2017a; UK, 2020).

On the other hand, sometimes the status of the device is unclear, because it applies in both the medical and non-medical settings (e.g. EEG neurofeedback). Moreover, there are cases of off-label use of the devices, without fully demonstrated efficacy: for instance, some private clinics use Transcranial Magnetic Stimulation (TMS), designed for diagnosis and research, for the treatment of drug-resistant depression without clear proven efficacy (Van Est et al., 2012).

Lastly, there are serious health risks regarding the use of these non-implantable devices for cognitive enhancement or entertainment when devices are not used according to their labelling and whose safety and effectiveness could remain exclusively in the hands of the user (Garden et al., 2019).

Regulatory enforcement considerations: liability for manufacturers, operators and users

A full review of regulatory approaches is beyond the scope of this report. There is a robust debate regarding whether BCI technology requires regulatory change to address liability issues (e.g. Burwell et al., 2017). Concerning liability, the BCI discussion focuses both on product liability and on liability of the device user.

There are some views arguing for the adequacy of the current legal framework to respond in general to BCIs liability ambiguities. For some, the responsibility for involuntary acts derived from the use of the device should rest exclusively with the user, while others transfer the responsibility to the product manufacturer (Burwell et al., 2017). On the other hand, there is an opinion that the current system of legal liability is not suitable to BCI technology. For these authors, users may not be responsible for the actions derived from the capture of subconscious brain signals or third people's actions, for instances, in case of hacking (Burwell et al., 2017), or cases of devices not properly implanted, or the treatment not adequately applied.

Thus, whether BCI users can be held responsible for acts performed under their use is in question. For some authors, direct intervention in the brain of the user of a BCI device complicates assigning responsibility for side effects to manufacturers, operators and users, as it has been determined so far for other products (Holder et al., 2016). As some of them argue, BCI technology could alter the sense of agency and identity of the individuals and consequently the responsibility for the acts carried out (Yuste et al., 2017).

Institutional and transboundary challenges

There are concerns about the adequacy of certain BCI legal frameworks to respond fully to the potential threats at a transnational level (Boucher et al., 2016). Relatively strict regulation at the national or regional level can only reach so far. For example, the EU general data protection regulation (GDPR) is extra-territorial in scope, meaning that it applies to data collected by EU and non-EU companies collecting data inside the EU and it applies to EU companies collecting data outside the EU. However, it does not apply to non-EU companies collecting the data outside the territory of the European Union (EP, 2016; Naufel and Klein, 2020).

Finally, as human rights are rights inherent to all human beings, international harmonisation regarding BCI systems is also needed. The main problem is that outside of the Oviedo Convention, most of the current norms are not legally binding and they do not include specific neuro-rights or adapt the existing ones (Yuste et al., 2017). Against this backdrop, there are proposals to include neuro-rights – such as the right to cognitive liberty, the right to mental privacy, the right to mental integrity or the right to psychological continuity (Ienca and Adorno, 2017) -- in international legally-binding instruments (University of Navarra, 2019).

Regulatory uncertainty for the private sector: a barrier to innovation

Regulatory challenges may reduce innovation and the development of BCI technology (Palmerini, 2015). A frequent solution is to create a medical device first and then commercialise the non-medical device at a later stage (Clément, 2019). However, a problem is that medical devices have rigorous risk and efficacy pre-marketed controls. This evidence-based assessment may hinder the development of non-medical devices (Garden et al., 2016).

Another issue is that most BCI systems, in particular implanted devices, are still being tested, and are not yet ready to be offered to the public on a commercial basis until the safety and effectiveness of a medical device is demonstrated. Discussions are ongoing about whether the use of those devices should be considered as research or therapy (Baldwin et al., 2013). In any case, this experimental stage within the innovation process in certain cases falls under the general regime of medical devices, which oftentimes does not provide specific protocols. The existing alternative is the approval of this phase by hospitals' ethical committees and or institutional review boards (Palmerini, 2015). This regulatory gap creates uncertainty for both the user and the manufacturer.

Reliance on a standardisation system for implantable devices may also create concerns, as standards are non-binding private rules. The intervention of the regulator could be necessary, therefore, to drive the regulatory process of implantable BCI systems (Palmerini, 2015).

5. Moving governance upstream: the responsible innovation framework

As seen in the section above, the governance challenges of BCIs are significant. In the face of uncertain technological trajectories, traditional regulatory instruments – e.g. risk-based regulation, export controls and liability – tend to narrowly focus on immediate or readily quantifiable consequences and their management. But many of the issues raised by currently emerging technologies are more fundamental and long-term. For these reasons, in the field of brain-computer interfaces, traditional "end-of-pipe" regulation that focuses on a single final product and tries to fit that to an existing policy framework may be ill-suited to highly innovative and dynamic technologies, platforms, and systems (Perset et al., 2019).

These facts motivate an approach to governance that can address and shape different phases of the innovation pipeline, but here a famous dilemma in technology governance complicates the task of the policy maker. The so-called Collingridge dilemma holds that early in the innovation process — when interventions and course corrections might still prove easy and cheap — the full consequences of the technology — and hence the need for change — might not be fully apparent (Collingridge, 1980). When the need for intervention becomes apparent, in contrast, changing course may become expensive, difficult and time-consuming. Lock-ins are at the heart of many governance debates (Arthur 1989; David 2001) and continue to pose questions about "opening up" and "closing down" development trajectories (Stirling, 2008). A new, more anticipatory and upstream approach is needed, one that uses the multi-stakeholder model to collectively shape developments so that innovation is encouraged and productivity-boosting disruption enabled, but within a set of publicly defined policy objectives (OECD, 2018).

Responsible Innovation

The "Responsible Innovation" governance framework presents such an alternative in the field of brain-computer interfaces. It seeks to overcome the Collingridge dilemma by engaging concerns with technology governance in an upstream way. A major aim of responsible innovation is to enhance societal capacities to understand, communicate on, and shape technology through the course of development. This helps enable technology to advance under conditions of trust. Ultimately, technology will not be as useful unless it can be diffused and built into society in ways that are trusted and socially robust – resilient, trustworthy, accessible, socially acceptable. Core ideas of responsible innovation include an approach to technology governance that is more (i) anticipatory governance, (ii) inclusive innovation and (iii) alignment of technology with missions. This upstream approach to governance can arguably better enable converging technologies like brain-computer interfaces to achieve key societal goals.

Anticipatory governance

Predicting the path of new technologies is notoriously difficult, whether the context is government regulation, venture capital or academic research. Anticipation – e.g.

in the form of structured foresight, technology assessment and informed planning – is a key concern in many policy circles and boardrooms around the globe.

Recently, a range of anticipatory and upstream governance approaches have emerged that may help explore, deliberate and steer the consequences of innovation at an early stage. They allow for responding to public concerns or changing circumstances along the development trajectory. From an industry perspective, upstream approaches can incorporate public values and concerns, potentially mitigating potential public backlash against technology. In OECD countries, frameworks for upstream governance have entered policy debates, e.g. in the context of the "Anticipatory Governance" pillar within the U.S. Nanotechnology Initiative (OECD, 2012). Key mechanisms include structured public deliberation, engaging in multi-disciplinary research including the integration of ethics, and participatory technology policy agenda setting. Likewise, under the major EU research-funding programme, Horizon 2020, the Responsible Research and Innovation (RRI) pillar has attempted to mainstream this approach across all research activities, echoed by recent developments in the United States.

One important mechanism to enhance anticipatory governance is to engage in processes of societal technology assessment prior to formal regulatory process that raise fundamental questions about the distribution of the possible benefits and costs; the consequences of intellectual property in the field; whether there are particular pathways of greatest social benefit; and sources of uncertainty in assessing the technology. These processes must also consider the potential benefits of innovation.

Inclusion goes upstream in innovation

Recent OECD work has documented how, despite being an engine of productivity growth, innovation might be contributing to rising inequality and technological divides, necessitating a turn towards more "inclusive innovation" (OECD, 2017b). When talking about inclusivity, attention rightfully focuses on inclusive *outcomes*. This focus, however, should not be to the exclusion of the consideration of inclusive innovation *processes*.

Citizens have traditionally been assigned a passive role in the innovation process, i.e. as end-of-pipe consumers and with a view towards eliciting technology acceptance. This approach has been shown to backfire, e.g. in biotechnology (Irwin, 2001). The benefits of engaging citizens, publics, and systematically excluded actors in policy processes through well-designed exercises, deliberative hearings, panels and comment periods are well-known. Yet, in the domains of science and innovation policy – and particularly in the governance of emerging technologies – these benefits have received much less attention (Jasanoff, 2003; OECD, 2012).

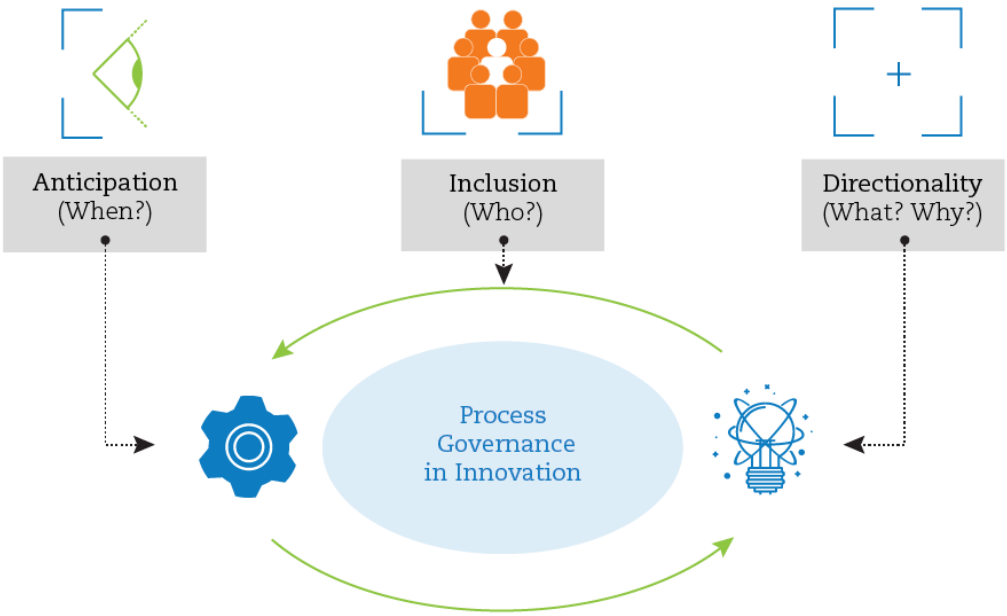
Greater emphasis on public engagement and process inclusivity can therefore help align science and technology with societal goals and needs, a major goal of the Responsible Research and Innovation (RRI) agenda in Europe and elsewhere (Stilgoe et al., 2013; Box 3). This emphasis goes beyond the widely acknowledged benefits (and biases) of open or user-led innovation, such as pooling external expert knowledge or collective creativity (Chesbrough, 2005). It adds an element of

democratic legitimacy to innovation while gauging public concerns and adjusting trajectories accordingly such as to avoid potential backlash (OECD, 2012).

Alignment of technology and missions

While often construed as a force of constraint on technology, governance can also enable technology and help steer innovation towards the greatest human needs. In this sense, governance is not just about controlling risk, but helping to determine benefits. In some OECD countries, directionality or "mission orientation" has returned to centre stage (Mazzucato, 2018; OECD, 2016a). The challenge of the misalignment between research, commercialisation and societal needs is not new (e.g. in the case of drugs for orphan diseases). However, present calls for "directed" and "purposive" transformative innovation display a new level of urgency to better connect innovation to "grand societal challenges" (e.g. the Sustainable Development Goals [SDGs]) (Carraz, 2012; Kuhlmann and Rip, 2014; Schot and Steinmueller, 2016) and respond to the particular needs of emerging economies (Kuhlmann and Ordóñez-Matamoros, 2017).

Figure 1. Schematic model for responsible innovation approach to technology governance



Source: (OECD, 2018)

Next the paper will cover some governance tools that could help implement a responsible innovation approach in the arena of brain-computer interfaces.

Soft Law: *OECD Recommendation on Responsible Innovation in Neurotechnology*

Soft law refers to policy instruments with moral or political force but without legal enforceability. Examples of soft law include private standards, general policies, guidelines, principles, codes of conduct, and forums for transnational dialogue.

Soft law measures, such as the Ethics Guidelines for a trustworthy AI, or the *OECD Recommendation of the Council on Artificial Intelligence* (OECD, 2019b), may not, and are not intended to replace the need for a sound regulatory framework. Such instruments, broader and more general in their assumptions, scope and conclusions, may instead be useful to shape a culture of responsible innovation. The various instruments of soft law might be well suited to the governance of emerging technologies where there is often a need to operate at the global scale and where a flexible approach might be appropriate given the uncertain trajectories.

In this context, the *OECD Recommendation for Agile Regulatory Governance to Harness Innovation* (OECD, 2021), provides a conceptual framework and guidance for policymakers to design agile regulations, which can address the regulatory challenges and opportunities arising from emerging technologies. So with this as the backdrop, new regulatory and governance structures could be considered to best govern and regulate innovation.

In the arena of neurotechnology, which encompasses brain-computer interface technologies, OECD countries recently adopted soft law instrument promoting responsible innovation. The Recommendation seeks to anticipate problems in the course of innovation and steer technology to best outcomes, and include many stakeholders in the innovation process (OECD, 2019a). The Recommendation is the first international instrument in the neurotechnology field. Over a period of over five years, the OECD led a series of multi-stakeholder workshops that explored strategies for the responsible development and use of innovative soft law, i.e. non legally-binding norms that are nevertheless enforced through moral suasion and regular monitoring across countries.

The Recommendation aims to help public and private actors address the ethical, legal and social challenges of neurotechnology while encouraging innovation. The Neurotechnology Recommendation is made up of nine principles (see Box 3 below), each principle being specified with more detailed recommendations that are not included here.

Box 3. ***OECD Recommendation on Responsible Innovation in Neurotechnology***

1. Promote responsible innovation
2. Prioritise safety assessment
3. Promote inclusivity
4. Foster scientific collaboration
5. Enable societal deliberation
6. Enable capacity of oversight and advisory bodies
7. Safeguard personal brain data and other information
8. Promote cultures of stewardship and trust across the public and private sector
9. Anticipate and monitor potential unintended use and/or misuse

Standardization and by-design governance

Standards "build in" certain norms, values, safeguards and goals into technologies and infrastructures (Bowker and Star, 2000; Busch, 2013; Timmermans and Epstein, 2010). In a trend that can be called ethics-by-design governance, the engineering phase of product development can optimize for key social values and standardize these features from the beginning. This approach is pursued for example by standard-setting bodies like the Institute of Electrical and Electronics Engineers (IEEE) as a means to codify what responsible design choices might entail in the fields of AI and neurotechnology[15]. In the area of brain-computer interfaces, the standard setting organisation IEEE has recently built a roadmap for the development of a suite of standards for regulatory good practice.[16] This is a good way to promote international dialogue and international harmonisation, where desirable.

Technology-based standards determine the specific characteristics (size, shape, design or functionality) of a product, process or production method. This form of governance can emanate from both the private sector (e.g. *de-facto* standards in the form of dominant designs) and the public sector (e.g. government regulated vehicle safety standards or mobile phone frequency bands). At the same time, careful consideration of product and process standards offers new inroads into the governance of emerging technologies. Recent efforts by technical and policy communities treat standardisation as a point of intervention to incorporate and make explicit certain ethical and political values into the material objects, networks and systems that they are designing (OECD, 2018).

Standards are critical for innovation: they define the conditions under which competition takes place, and act as a built-in infrastructure for technology uptake and use within supply chains, markets and society. From an economic perspective, they are desirable as vehicles of efficiency by ensuring interoperability, securing minimum safety and quality, reducing variety, and providing common information and measurement (OECD, 2011). On the other hand, they can also create barriers to entry, distort competition, and be prone to capture. They can serve as useful

vehicles of intellectual property rights (e.g. Blind, 2013), but they also carry the danger of reinforcing monopolistic power and incumbency (Swann, 2000; OECD, 2011).

Corporate self-governance

Traditional means of governing emerging technologies have typically relied on public sector pathways, for example through research ethics or product regulation. Traditional means of governing technology, whether through institutionalised research ethics, government regulation or market mechanisms, are increasingly ill-equipped to capture the pace and depth with which innovations are reshaping our societies and to provide adequate responses to social expectations, needs and concerns with regard to ground-breaking innovation. Yet, companies account for more than 70% of all R&D performed in OECD countries, and neurotechnology is no exception. What is more, mechanisms well-suited to public sector research don't easily translate into private sector settings. Effective governance must involve the private sector as a central actor early on, but requires a new set of perspectives and tools to do so.

Drawing from the field of Corporate Social Responsibility, a number of governance options may help advance responsible innovation in the context of brain-computer interfaces (Garden et al., 2019):

- Appoint responsible innovation officers and boards. Consistent attention to questions of responsibility requires human resources and organizational capacity.
- Engage in responsible technology transfer
- Socially responsible investment and certification
- Diversify hiring practices

Regulatory Experiments

Companies and innovation scholars are stressing the need to develop innovations in real-world settings that can anticipate and respond to the use, uptake, concerns, and potential regulatory issues. Novel instruments such as test-beds, living laboratories and regulatory sandboxes enable testing in spatially confined, experimental settings prior to broader rollout, frequently with some form of "co-creation": a form of innovation in which diverse kinds of actors and stakeholders participate in the development and roll-out of innovation (OECD, 2018).

These instruments can in fact be employed to co-develop appropriate rules and regulations in tandem with the technology, as currently seen in cases of autonomous driving and robotics. For neurotechnology, there are opportunities to investigate applications with selected populations (e.g. local mental health patients) together with the participation of public bodies to gauge regulatory needs.

A number of new co-creation instruments have recently emerged that are particularly promising for questions of technology governance. Prominent examples are test beds and living labs, designated spaces for innovation activity

and experimental technology implementation. They aim to test and demonstrate new sociotechnical arrangements in a model environment, under real-world conditions. The novelty is that the government purchases a solution that does not yet exist while simultaneously setting the social, ethical and regulatory conditions under which the innovation should operate. For example, in the European robotics consortium ECHORD++, public procurement of innovation was used to co-develop robotics technology involving firms, universities and municipalities to enhance sewer cleaning and hospital care (OECD, 2018).

Test beds are providing new opportunities to tackle governance issues in innovation. They offer a glimpse at new sociotechnical arrangements in an "as-if" mode of tentative roll-out, identifying not only glitches in the technology, but also societal responses and governance challenges (Engels, Wentland and Pfotenhauer 2019). Test beds can serve as an instrument to co-develop the very rules and regulations needed to cope with new technologies, and to gauge which existing regulations might be detrimental to adoption. For example, the European Energy Forum in Berlin has re-purposed a historical gas-storage facility into a private research campus that develops and tests new forms of energy, mobility and information technology solutions, blending technology creation-and-use environments (Canzler et al., 2017). Here, building, traffic and infrastructural regulations are being experimented alongside tested technologies, with a view towards scaling them across Berlin and beyond. While public policy has primarily focused on lowering local regulatory barriers in test-bed settings, or blurring boundaries between public and private interests, this experimental approach to governance also provides new opportunities to deliberate new rules and regulations in real time in order to direct innovation towards desirable outcomes.

6. References

Arthur, W.B. (1989), "Competing Technologies, Increasing Returns, and Lock-In by Historical Events", *The Economic Journal*, Vol. 99/394, pp. 116-131, Wiley, Hoboken, NJ, http://dx.doi.org/10.2307/2234208.

Athanasiou A., M.A. Klados, A. Astaras, N. Foroglou, I. Magras and P.D. Bamidis (2016), "State of the Art and Future Prospects of Nanotechnologies in the Field of Brain-Computer Interfaces", *In: Kyriacou E., Christofides S., Pattichis C. (eds) XIV Mediterranean Conference on Medical and Biological Engineering and Computing 2016. IFMBE Proceedings, vol 57. Springer*, Cham, https://link.springer.com/chapter/10.1007/978-3-319-32703-7_90

Baldwin, T., J. Cole, M. Fitzgerald, J. Kitzinger, G. Laurie, J. Price, N. Rose, S. Rose, I. Singh, V. Walsh and K. Warwick (2013), "Novel Neurotechnologies: Intervening in the Brain" *Nuffield Council on Bioethics, Nuffield Council on Bioethics*, ISBN: 978-1-904384-29-8, http://nuffieldbioethics.org/wp-content/uploads/2013/06/Novel_neurotechnologies_report_PDF_web_0.pdf

Bacher, D., Jarosiewicz, B., Masse, N. Y., Stavisky, S. D., Simeral, J. D., Newell, K., … Hochberg, L. R. (2015). Neural Point-and-Click Communication by a Person With Incomplete Locked-In Syndrome. *Neurorehabilitation and Neural Repair*, *29*(5), 462–471. https://doi.org/10.1177/1545968314554624

Blind, K. (2013), "The Impact of Standardization and Standards on Innovation", working paper, *Compendium of Evidence on Innovation Policy*, Manchester Institute of Innovation Research, Manchester, http://www.innovation-policy.org.uk/compendium/section/Default.aspx?topicid=30.

Bockbrader, M.A., G. Francisco, R. Lee, J. Olson, R. Solinsky and M.L. Boninger, (2018), "Brain Computer Interfaces in Rehabilitation Medicine", *PM&R,* 10: S233-S243. http://dx.doi.org/doi:10.1016/j.pmrj.2018.05.028

Boucher, P, M. Kritikos and L.Van Woensel, (2016), "What if others could read your mind?", Scientific Foresight Unit (STOA), April 2016 - PE 581.421, *European Parliament*, http://www.europarl.europa.eu/RegData/etudes/ATAG/2016/581421/EPRS_ATA(2016)581421_EN.pdf.

Bowker, G.C. and S.L. Star (2000), *Sorting Things Out: Classification and Its Consequences*, MIT Press, Cambridge, MA.

Burwell, S., M. Sample and E. Racine (2017), "Ethical aspects of brain computer interfaces: a scoping review", *BMC Medical Ethics*, Vol. 18/1, http://dx.doi.org/10.1186/s12910-017-0220-y

Busch, L. (2013), *Standards: Recipes for Reality*, reprint edition, MIT Press, Cambridge, MA.

Canzler, W. et al. (2017), "From "living lab" to strategic action field: Bringing together energy, mobility, and Information Technology in Germany", *Energy Research & Social Science*, Vol. 27, pp. 25-35, Elsevier, NY, https://doi.org/10.1016/j.erss.2017.02.00

Carraz, R. (2012), "Improving Science, Technology and Innovation Governance to Meet Global Challenges", in *Meeting Global Challenges through Better Governance: International Co-operation in Science, Technology, and Innovation*, pp. 173-205, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264178700-en

Chesbrough, H.W. (2005), *Open Innovation: The New Imperative for Creating And Profiting from Technology,* Harvard Business Review Press, Cambridge, MA.

Clément, C (2019), "Brain-Computer Interface Technologies - Accelerating Neuro-Technology for Human Benefit", *Springer Nature Switzerland AG,* https://doi.org/10.1007/978-3-030-27852-6

Collingridge, D. (1980), *The Social Control of Technology*, Open University Press, Milton Keynes.

Consumer International (2013), "The State of Consumer Protection Around the World", http://www.consumersinternational.org/media/154677/the-state-of-consumer-protection-around-the-world-full-report-en-revised-april-2013.pdf

Council of Europe (COE) (2019), Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025), https://rm.coe.int/strategic-action-plan-final-e/16809c3af1

Dai, Q., E. Shin and C. Smith (2018), "Open and inclusive collaboration in science: A framework", *OECD Science, Technology and Industry Working Papers*, No. 2018/07, OECD Publishing, Paris, https://doi.org/10.1787/2dbff737-en.

David, P.A. (2001), "Path dependence, its critics and the quest for 'historical economics'", in P. Garrouste and S. Ioannides (eds.), *Evolution and path dependence in economic ideas: Past and present*, p. 40, Edward Elgar Publishing, Cheltenham, United Kingdom and Northampton, MA.

Damarla, S. R., & Just, M. A. (2013). Decoding the representation of numerical values from brain activation patterns. *Human Brain Mapping*, *34*(10), 2624–2634. https://doi.org/10.1002/hbm.22087

Dan, Z., Jingjing, C., & Yijun, W. (2018). Looking Back on the Research and Development Hotspots of Brain-computer Interfaces in 2017. *Science and Technology Review*. Retrieved from https://www.programmersought.com/article/98383566757/

Danziger, Z., Fishbach, A., & Mussa-Ivaldi, F. A. (2009). Learning Algorithms for Human–Machine Interfaces. *IEEE Transactions on Biomedical Engineering*, *56*(5), 1502–1511. https://doi.org/10.1109/TBME.2009.2013822

Engels, F. Wentland and S.M. Pfotenhauer (2019), "Testing the future? Developing a framework for test beds as an emerging innovation policy instrument", Volume 48, Issue 9, 2019, 103826, ISSN 0048-7333, https://doi.org/10.1016/j.respol.2019.103826

European Parliament; Council of the European Union (2017), Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

European Parliament; Council of the European Union (2016), Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02016R0679-20160504&from=EN

Facebook. (2017, April). F8 2017: AI, Building 8 and More Technology Updtates from Day Two. *Facebook*. Retrieved from https://about.fb.com/news/2017/04/f8-2017-day-2/

FDA, U.S. Food and Drug Administration (2019). Proposed Regulatory Framework for Modifications to Artificial Intelligence / Machine Learning (AI / ML) -Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback. *U.S Food & Drug Administration*, 1–20. Retrieved from https://www.fda.gov/files/medical devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf

Garden, H., D.E. Winickoff, N.M. Frahm, S. Pfotenhauer. (2019), "Responsible innovation in neurotechnology enterprises", *OECD Science, Technology and Industry Working Papers*, No. 2019/05, OECD Publishing, Paris, https://doi.org/10.1787/9685e4fd-en.

Garden, H. and D. Winickoff (2018), "Issues in neurotechnology governance", *OECD Science, Technology and Industry Working Papers,* No. 2018/11, OECD Publishing, Paris, https://doi.org/10.1787/c3256cc6-en.

Garden, H., D.M. Bowman, S. Haesler, D.E. Winickoff, (2016), "Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science", *Neuron*, Vol. 92/3, pp. 642-646. Retrieved from http://dx.doi.org/10.1016/j.neuron.2016.10.053.

Giordano, J. (2012), "Neurotechnology: premises, potential, and problems", *CRC Press*, https://doi.org/10.1201/b11861.

Hannas, W., Chang, H.-M., Wang, J., Aiken, C., & Chou, D. (2020). *China AI-Brain Research*. Retrieved from https://cset.georgetown.edu/wp-content/uploads/CSET-China-AI-Brain-Research.pdf

Hassabis, D., Kumaran, D., Summerfield, C., & Botvinick, M. (2017). Neuroscience-Inspired Artificial Intelligence. *Neuron*, *95*(2), 245–258. Retrieved from https://doi.org/10.1016/j.neuron.2017.06.011

Holder, C. et al. (2016), "Robotics and law: Key legal and regulatory implications of the robotics age (part II of II)", *Computer Law & Security Review,* Vol. 32/4, pp. 557-576, http://dx.doi.org/10.1016/j.clsr.2016.05.011.

IEEE Standards Association (2020), Standards Roadmap: Neurotechnologies for Brain-Machine Interfacing, https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/presentations/ieee-neurotech-for-bmi-standards-roadmap.pdf

Ienca, M. (2018a), "Democratizing cognitive technology: a proactive approach", *Ethics and Information Technology*, Vol. 21/4, pp. 267-280, http://dx.doi.org/10.1007/s10676-018-9453-9.

Ienca, M., F. Jotterand and B. Elger (2018b), "From Healthcare to Warfare and Reverse: How Should We Regulate Dual-Use Neurotechnology?" *Neuron*, Vol. 97/2, pp. 269-274, http://dx.doi.org/10.1016/j.neuron.2017.12.017.

Ienca, M., P. Haselager and E. Emanuel, (2018c), "Brain leaks and consumer neurotechnology", *Nat Biotechnol* 36, 805–810 . https://doi.org/10.1038/nbt.4240.

Ienca, M. and R. Andorno, (2017), "Towards new human rights in the age of neuroscience and neurotechnology", *Life Sci Soc Policy* 13, 5, https://doi.org/10.1186/s40504-017-0050-1.

Insel, T., P. Collins and S. Hyman (2015), "Darkness Invisible: the hidden global costs of mental illness", *Foreign Affairs*, https://www.foreignaffairs.com/articles/africa/darknessinvisible

Irwin, A. (2001), "Constructing the Scientific Citizen: Science and Democracy in the Biosciences," *Public Understanding of Science*, Vol. 10/1, pp. 1–18, Sage Journals, Thousand Oaks, CA, DOI: https://doi.org/10.1088/0963-6625/10/1/301

Jasanoff, S. (2003), "Technologies of Humility: Citizen Participation in Governing Science," *Minerva*, Vol. 41/3, pp. 223–244, Dordrecht,. DOI: https://doi.org/10.1023/A:1025557512320

Jayaram, V., Alamgir, M., Altun, Y., Scholkopf, B., & Grosse-Wentrup, M. (2016). Transfer Learning in Brain-Computer Interfaces Abstract\uFFFDThe performance of brain-computer interfaces (BCIs) improves with the amount of avail. *IEEE Computational Intelligence Magazine*, *11*(1), 20–31. https://doi.org/10.1109/MCI.2015.2501545

Kuhlmann, S. and G. Ordóñez-Matamoros (2017), "Governance of Innovation in emerging countries: Understanding failures and exploring options", in Kuhlmann, S. and G. Ordoñez-Matamoros (eds.), *Research Handbook on Innovation Governance for Emerging Economies: Towards Better Models*, pp. 1-36, Edward Elgar Publishing, Northampton, MA.

Kuhlmann, S. and A. Rip (2014), "The challenge of addressing Grand Challenges... and what universities of technology can do"**,** University of Twente, Enschede, Netherlands, https://ris.utwente.nl/ws/files/13268719/2014_Kuhlmann.pdf.

Makin, J. G., Moses, D. A., & Chang, E. F. (2020). Machine translation of cortical activity to text with an encoder–decoder framework. *Nature Neuroscience*, *23*(4), 575–582. https://doi.org/10.1038/s41593-020-0608-8

Mazzucato, M. (2018), "Mission-Oriented Research & Innovation in the European Union: A problem-solving approach to fuel innovation-led growth*"*, European Commission, Brussels.

Melcer, E. F., Astolfi, M. T., Remaley, M., Berenzweig, A., & Giurgica-Tiron, T. (2018). CTRL-Labs. In *Extended Abstracts of the 2018 CHI Conference on Human Factors in Computing Systems* (pp. 1–4). New York, NY, USA: ACM. https://doi.org/10.1145/3170427.3186520

Moses, D. A., Leonard, M. K., Makin, J. G., & Chang, E. F. (2019). Real-time decoding of question-and-answer speech dialogue using human cortical activity. *Nature Communications*, *10*(1), 3096. https://doi.org/10.1038/s41467-019-10994-4

Muller-Putz, G. R., Scherer, R., Neuper, C., & Pfurtscheller, G. (2006). Steady-State Somatosensory Evoked Potentials: Suitable Brain Signals for Brain–Computer Interfaces? *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, *14*(1), 30–37. https://doi.org/10.1109/TNSRE.2005.863842

National Institutes of Health (NIH), "Cochlear Implants" Publication No. 00-4798 February 2016, Statistics updated March 2021. https://www.nidcd.nih.gov/sites/default/files/Documents/cochlear-implants.pdf

Naufel, S. and E. Klein, (2020), "Brain-computer interface (BCI) researcher perspectives on neural data ownership and privacy" *Journal of Neural Engineering,* https://iopscience.iop.org/article/10.1088/1741-2552/ab5b7f.

OECD (2021), Recommendation of the Council for Agile Regulatory Governance to Harness Innovation, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0464.

OECD (2019a), Recommendation of the Council on Responsible Innovation in Neurotechnology, OECD/LEGAL/0457, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457

OECD (2019b), Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449,

https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449.

OECD (2018), "OECD Science, Technology and Innovation Outlook 2018: Adapting to Technological and Societal Disruption", *OECD Publishing, Paris*, https://doi.org/10.1787/sti_in_outlook-2018-en.

OECD (2017a), "Neurotechnology and society: Strengthening responsible innovation in brain science", OECD Science, Technology and Industry Policy Papers, No. 46, *OECD Publishing, Paris*, https://doi.org/10.1787/f31e10ab-en.

OECD (2017b), *Making Innovation Benefit All: Policies for Inclusive Growth*, OECD, Paris, https://innovationpolicyplatform.org/content/making-innovation-benefit-all-policies-inclusive-growth

OECD (2016a), "Priorities, strategies and governance of innovation in Sweden", in *OECD Reviews of Innovation Policy: Sweden 2016*, OECD Publishing, Paris, https://doi.org/10.1787/9789264250000-9-en

OECD (2016b), "OECD Science, Technology and Innovation Outlook 2016", OECD Publishing, Paris, https://doi.org/10.1787/sti_in_outlook-2016-en.

OECD (2012), "Planning guide for public engagement and outreach in nanotechnology", OECD, Paris, http://www.oecd.org/sti/emerging-tech/49961768.pdf.

OECD (2011), *Demand-side Innovation Policies*, OECD Publishing, Paris, https://doi.org/10.1787/9789264098886-en

Orsborn, A. L., Moorman, H. G., Overduin, S. A., Shanechi, M. M., Dimitrov, D. F., & Carmena, J. M. (2014). Closed-Loop Decoder Adaptation Shapes Neural Plasticity for Skillful Neuroprosthetic Control. *Neuron*, *82*(6), 1380–1393. https://doi.org/10.1016/j.neuron.2014.04.048

O'Sullivan, S (2019), "Why we should ban the brain from being manipulated before it is possible", *Decrou,* https://www.decrou.com/why-we-should-ban-the-brain-from-being-manipulated-before-it-is-possible/

Palmerini, E. (2015), "A legal perspective on body implants for therapy and enhancement", *International Review of Law, Computers & Technology,* Vol. 29/2-3, pp. 226-244, http://dx.doi.org/10.1080/13600869.2015.1055664.

Perset, K., J. West, D. Winickoff and A. Wyckoff (2019). Moving "Upstream" on Global Platform Governance. Center for International Governance Working Paper. October 28, 2019. https://www.cigionline.org/articles/moving-upstream-global-platform-governance

Pisarchik, A. N., Maksimenko, V. A., & Hramov, A. E. (2019). From Novel Technology to Novel Applications: Comment on "An Integrated Brain-Machine Interface Platform With Thousands of Channels" by Elon Musk and Neuralink. *Journal of Medical Internet Research*, *21*(10), e16356. https://doi.org/10.2196/16356

Rommelfanger, K. et al. (2018), "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives", Neuron, Vol. 100/1, pp. 19-36, http://dx.doi.org/10.1016/j.neuron.2018.09.021.

Schot, J. and E. Steinmueller (2016), "Framing Innovation Policy for Transformative Change: Innovation Policy 3.0.", SPRU Science Policy Research Unit, University of Sussex, Brighton.

Shen, M. (2022), "Elon Musk's Neuralink plans to implant chips in human brains to treat neural disorders." USA Today Tech, January. 23, 2022, https://eu.usatoday.com/story/tech/2022/01/23/elon-musks-neuralink-implanting-chips/6629809001/

Starr, P.A. (2018), "Totally Implantable Bidirectional Neural Prostheses: A Flexible Platform for Innovation in Neuromodulation", *Frontiers in Neuroscience*, https://www.frontiersin.org/article/10.3389/fnins.2018.00619.

Stilgoe J, R. Owen and P. Macnaghten (2013), "Developing a Framework for Responsible Innovation," *Research Policy*, Vol. 42/9, pp. 1568–80, Elsevier, Amsterdam, DOI: https://doi.org/10.1016/j.respol.2013.05.008

Stirner, M., G. Gurevitch, N. Lubianiker, T. Hendler, C. Schmahl, and C. Paret (2022), "An Investigation of Awareness and Metacognition in Neurofeedback with the Amygdala Electrical Fingerprint", Consciousness and Cognition, 98, art. no. 103264, https://doi.org/10.1016/j.concog.2021.103264

Stirling, A (2008), "'Opening Up' and 'Closing Down': Power, Participation, and Pluralism in the Social Appraisal of Technology", *Science, Technology & Human Values*, Vol. 33/2, pp. 262-294, Sage Journals, Thousand Oaks, CA, https://doi.org/10.1177/0162243907311265

Swann, P.G.M. (2000), "The Economics of Standardisation", Final Report for Standards and Technical Regulations Directorate, Department of Trade and Industry, Manchester Business School, University of Manchester.

Tech@facebook. (2020). Imagining a new interface: Hands-free communication without saying a word. *Inside Facebook Reality Labs*. Retrieved from https://tech.fb.com/imagining-a-new-interface-hands-free-communication-without-saying-a-word/

The Royal Society (2019), "iHuman: blurring lines between mind and machine" DES6094, ISBN: 978-1-78252-420-5, https://royalsociety.org/-/media/policy/projects/ihuman/report-neural-interfaces.pdf.

Timmermans, S. and S. Epstein (2010), "A World of Standards but not a Standard World: Toward a Sociology of Standards and Standardization", *Annual Review of Sociology*, Vol. 36/1, pp. 69-89, Annual Reviews, Palo Alto, CA, https://doi.org/10.1146/annurev.soc.012809.102629

UK Parliament Postnote (2020), Number 614 (2020), https://researchbriefings.files.parliament.uk/documents/POST-PN-0614/POST-PN-0614.pdf.

UNESCO (2005), Universal Declaration on Bioethics and Human Rights, UNESCO, http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

University of Navarra (2019), "An initiator of the BRAIN Initiative speaks at the University about neuro-rights to ensure the proper use of neurotechnologies", https://www.unav.edu/en/web/vida-universitaria/detalle-noticia-pestana/2019/03/26/an-initiator-of-the-brain-initiative-speaks-at-the-university-about-neurorights-to-ensure-the-proper-use-of-neurotechnologies?articleId=21323397

Van Est, R. and J.B.A. Gerritsen, with the assistance of L. Kool, (2017) "Human rights in the robot age: Challenges rising from the use of robotics, artificial intelligence, and virtual and

augmented reality – Expert report written for the Committee on Culture, Science, Education and Media of the Parliamentary Assembly of the Council of Europe (PACE)", *The Hague: Rathenau Instituut,* https://www.rathenau.nl/en/digitale-samenleving/human-rights-robot-age.

Van Est, R, et al., (2012), European Governance Challenges in 21st Century Bio-engineering, STOA, European Parliament, https://www.europarl.europa.eu/stoa/en/document/IPOL-JOIN_ET(2012)471574

Vance, A. (2020). A Neuroscience Startup Uses Helmets to Measure Brain Activit. *Bloomberg*, pp. 1–5. Retrieved from https://www.bloomberg.com/news/articles/2020-05-05/brain-startup-wants-to-read-your-mind-with-a-helmet

Wexler, A. and P.B. Reiner, (2019). "Oversight of direct-to-consumer neurotechnologies" *Science,* 363(6424), 234-235, https://science.sciencemag.org/content/sci/363/6424/234.full.pdf.

World Health Organisation (WHO), (2017), "Global atlas of medical devices", *Geneva: World Health Organization*;. Licence: CC BY-NC-SA 3.0 IGO, http://apps.who.int/iris/bitstream/10665/255181/1/9789241512312-eng.pdf?ua=1

Yuste, R, et al., (2017), "Four ethical priorities for neurotechnologies and AI", Nature, vol. 551, no. 7679, pp. 159-163. https://doi.org/10.1038/551159a

Zhang, X., Z. Ma, H. Zheng, T. Li, K. Chen, X. Wang, C. Liu, L. Xu, X. Wu, D. Lin and H. Lin (2020). The combination of brain-computer interfaces and artificial intelligence: applications and challenges. *Annals of Translational Medicine*, *8*(11), 712–712. https://doi.org/10.21037/atm.2019.11.109.

Endnotes

[1] ISO 14971:2019 Medical devices – application of risk management to medical devices: https://www.iso.org/standard/72704.html

[2] https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/108

[3] https://www.cdc.gov/phlp/publications/topic/hipaa.html

[4]https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

[5] https://gdpr-info.eu

[6] https://www.un.org/en/universal-declaration-human-rights/

[7] https://www.who.int/bulletin/archives/79(4)373.pdf

[8]https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

[9] https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164

[10] https://www.un.org/en/sections/issues-depth/human-rights

[11] https://www.jurist.org/news/2021/10/chile-becomes-first-country-to-pass-neuro-rights-law/

[12] https://portal.mineco.gob.es/es-es/comunicacion/Paginas/210714_np_Carta-.aspx

[13] https://www.lamoncloa.gob.es/serviciosdeprensa/notasprensa/asuntos-economicos/Paginas/2021/271021-neurotecnologia.aspx

[14] E.g., Medical Device Cybersecurity: What you need to know (https://www.fda.gov/consumers/consumer-updates/medical-device-cybersecurity-what-you-need-know).

[15] The IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems. *IEEE* Available at: https://standards.ieee.org/industry-connections/ec/ead-v1.html.

[16] IEEE Standards Roadmap: Neurotechnologies for Brain-Computer Interfacing (2020). https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/presentations/ieee-neurotech-for-bmi-standards-roadmap.pdf