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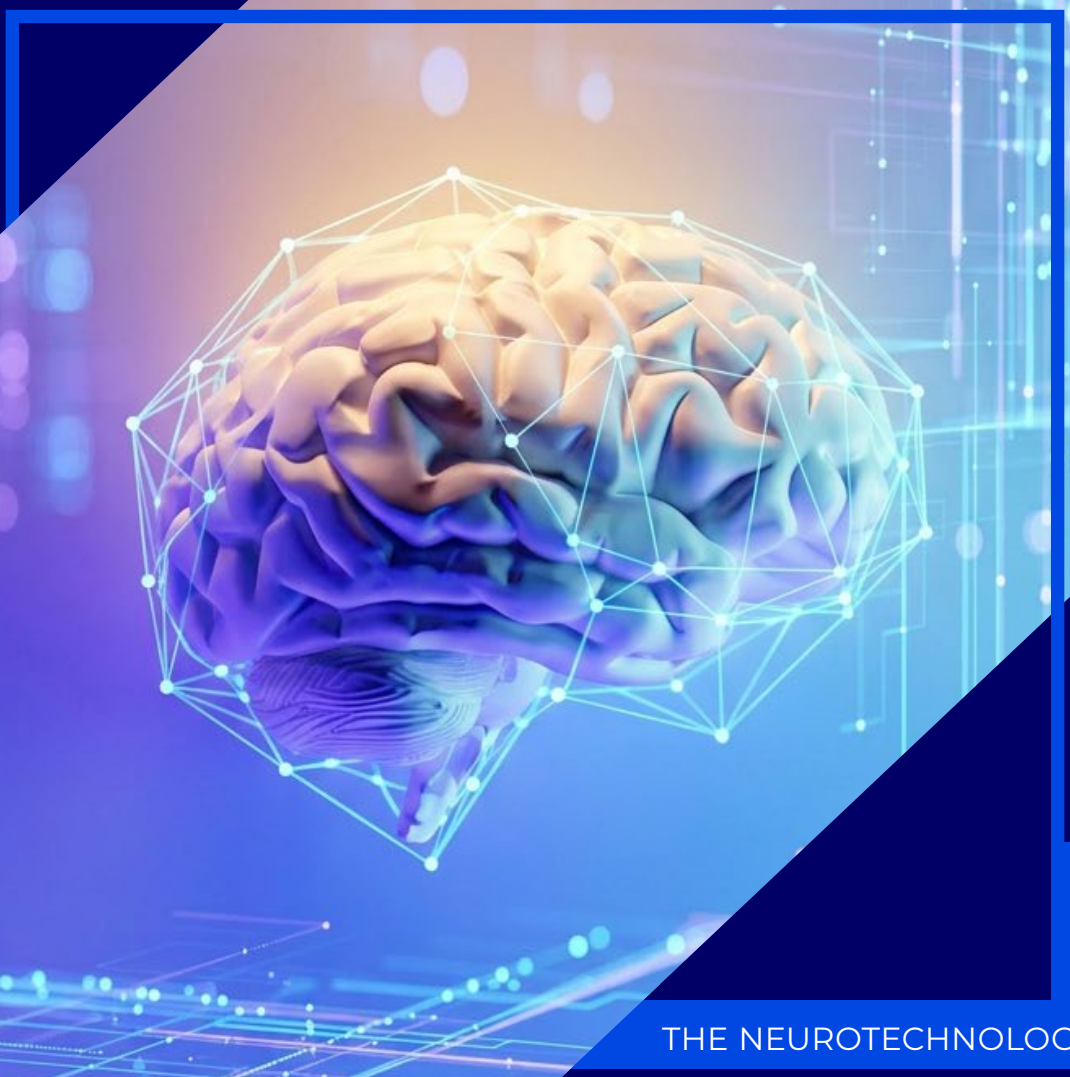

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THE NEUROTECHNOLOGY SHIFT

The Expanding Reach of Neurotechnology Beyond the Clinic:

Into Consumer Markets and the Workplace

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KEY FINDINGS

From Medical Devices to Digital Ecosystems

Brain-computer interfaces (BCIs) have entered wellness and workplace markets, not only as a new category of consumer devices, but as part of a broader convergence of neurotechnology, wearables, artificial intelligence, digital platforms, and data-driven business models. The governance challenge is not confined to the devices themselves but extends to the broader digital ecosystem through which neural data is collected, processed, stored, and monetized.

The Regulatory Grey Zone Between Wellness and Medicine

The United States and Europe host most consumer BCI companies, with wellness applications representing the largest and most governance-sensitive market segment. Many companies operate in a regulatory grey zone, making health-adjacent claims without demonstrating efficacy. This space between wellness and medicine often lacks scientific substantiation, leaving the actual capabilities of current devices unclear. Proportionate evidence requirements could help distinguish credible technologies from unsubstantiated promises, grounding the field in evidence—something that does not yet consistently occur.

Neural Data as a Strategic Asset

Neural data is increasingly central to BCI business models in wellness and workplace settings, not only as a byproduct of device use but as a strategic asset for personalization, model training, and licensing. Data governance questions nevertheless remain unresolved, leaving the protection of neural data ambiguous. Differing views on how it should be governed reflect disagreements about its nature, its capacity to reveal mental states and emotions, and the degree of uniqueness it confers to enable mental inferences. Grounding these debates in up-to-date scientific evidence could accelerate convergence as the market becomes increasingly data-driven. Privacy-preserving technical approaches, such as on-device (edge) processing, also warrant greater consideration in both policy and industry discussions.

Building Trust Through International Cooperation

International cooperation will be essential to the ethical development of the field. One area where meaningful consensus is achievable is the alignment of public narratives around the actual capabilities of these consumer technologies. Containing hype in consumer markets matters beyond its direct harms, as overstated claims risk eroding trust also in medical-grade BCIs, which represent a critical (and in some cases irreplaceable) intervention for patients with neurodegenerative, neurological, or psychiatric conditions, a population that is growing globally. International observatories and joint pre-competitive platforms represent further mechanisms through which cooperation could be institutionalized.

The Next Wave of Consumer Neurotechnology

In the near term, major technology companies are positioning themselves to integrate neural data into products already used by millions of people, bringing BCIs closer to becoming another layer of the digital ecosystem. This trajectory offers opportunities in healthcare and research while compounding existing risks around privacy, autonomy, and market concentration. Advances in artificial intelligence, sensing capabilities, and wearable form factors are likely to accelerate adoption at scale, expand workplace and human-machine interface applications, and further blur the boundary between wellness and medical uses. More powerful modalities not yet widely commercialized, such as focused ultrasound, may also enter consumer markets within the foreseeable future. Taken together, these trends make governance increasingly urgent.

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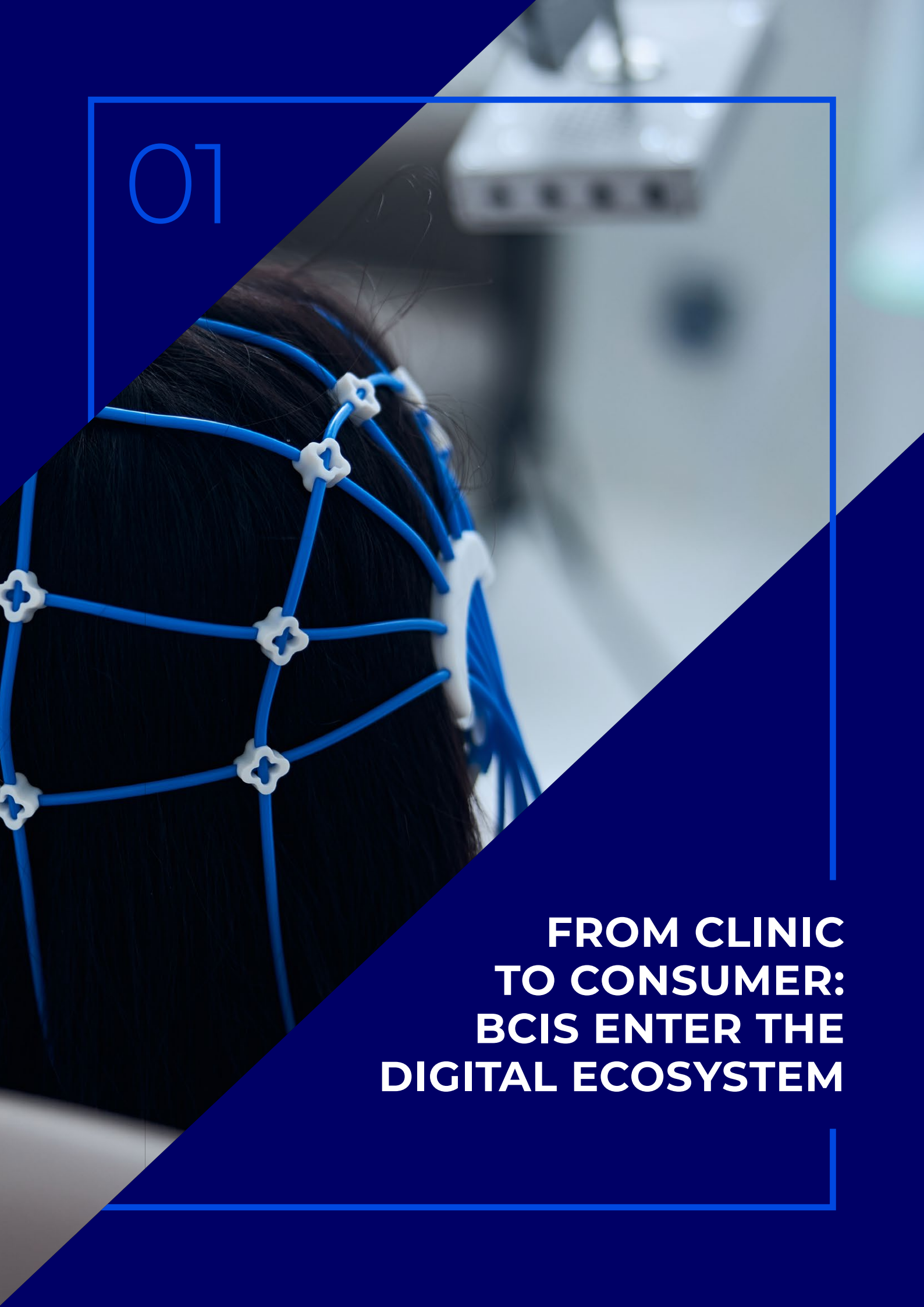


FROM CLINIC TO CONSUMER: BCIS ENTER THE DIGITAL ECOSYSTEM

1. FROM CLINIC TO CONSUMER: BCIS ENTER THE DIGITAL ECOSYSTEM

1.1. THE FIRST MASS-MARKET BCI WILL PROBABLY LOOK LIKE SOMETHING YOU ALREADY OWN

Despite its medical roots,the first widely adopted brain-computer interface (BCI) will probably not look like a medical device, but like something you already own. Headphones[1], earbuds[2], glasses[3], wristbands[4], and even caps[5] and beanies[6] now incorporate non-invasive neurotechnologies to measure and stimulate brain activity. Neurotechnology allows for these devices to perform their conventional functions while adapting and responding to the user's mental state: headphones with EEG sensors that adjust music to whether the listener is tired[7] or focused; a chatbot that modulates its language[8] to the cognitive load measured through a headband; a cap that detects fatigue[5] levels while operating complex machinery in the workplace; a headband that unlocks a banking app[9] when the user thinks of their passcode.

These BCI systems[10] read signals from the brain and translate them near-instantly into actions or outputs in the world, and in doing so, they change how the brain interacts with its environment without necessarily having a medical purpose.

The BCI products described above are either commercially available or nearing market deployment, making it increasingly plausible that some categories of consumer wearables will progressively incorporate neurotechnology or BCI-adjacent capabilities over the coming years. Hence, non-invasive BCIs, born in the clinic and carried forward by decades of technical advances[11] into consumer markets, may well find their most abundant market[12] not in healthcare but in everyday consumer settings, simply by virtue of the scale potential that lies beyond the more niche clinical segments they were originally designed for. This transition from medical to consumer markets sits at the heart of many of the governance challenges that neurotechnology faces today[13], as BCIs previously commercialized under medical standards and safeguards now enter the more permissive consumer market.

This shift of BCIs into consumer markets has **two important implications.**

1 **First**, it expands access to brain data, which may generate scientific and commercial value but also new opportunities for misuse or manipulation.

2 **Second**, and importantly, companies operating in consumer BCI markets are subject to considerably less stringent regulatory requirements[3] than those producing medical devices: provided they do not claim a medical purpose, they are not required to substantiate performance claims with evidence, even when the underlying technology closely resembles that used in clinical settings.

This distinction is particularly relevant, as real-world BCI performance outside the clinic remains constrained[14] by movement artifacts, environmental noise, and variability across users and contexts—constraints likely to be more pronounced in consumer devices, which are often built with fewer channels and simplified components in order to remain commercially viable at scale. In the absence of validation requirements, it is unclear whether, and under what conditions, consumer BCI devices deliver on their promises, and which opportunities for innovation are ethical and promising and which are not. In other words, the evidence gap in consumer markets complicates not only the identification of misleading or overstated claims, but also the recognition of valuable opportunities for innovation (e.g., fatigue detection for accident prevention or the discovery of data-derived early biomarkers of neurodegeneration). Because of all of these challenges, experts agree[15] that this transition of formerly medical BCI technologies into consumer markets is one of the most pressing topics[16] in neurotechnology governance, and particularly when capability claims touch upon wellness and health-adjacent topics such as improving sleep, helping with stress, or optimizing focus.

> Amidst governance challenges, data confirms the growth of the consumer market. Consumer neurotechnology firms accounted for roughly 60%[12] of the global neurotechnology landscape as of 2025, having outnumbered dedicated medical companies since 2018.

Since 2010, consumer neurotechnology firms have proliferated more than fourfold compared with the preceding twenty-five years, and at a faster rate than their medical counterparts. It is not only that the number of companies has increased, but also that investments in these companies have peaked, a testament to investor trust in companies' ability to deliver future returns. In fact, between 2014 and 2021 there has been a 700% increase in investments[17] in medical and consumer neurotechnology, totaling €29.20 billion. In the first quarter of 2026, BCI companies accounted for approximately 22% of total medtech funding[18] raised, a figure that includes medical applications but one in which non-invasive approaches with consumer potential tend to follow the investment trajectories set by more invasive predecessors.

In addition to company numbers and growing investments, **three adjacent developments** across the technological, sociological, and economic landscape point to ongoing growth in the consumer BCI market.

1 **First**, technological convergence is lowering many of the barriers that historically constrained commercial deployment. Miniaturization, dry electrodes, and AI-enabled signal processing, have all been central to consumer commercialization, independently of specific device capabilities. Equally important is the digital infrastructure[19] already embedded in everyday life, without which BCIs could not be deployed as consumer products. Consumer BCIs are increasingly dependent on smartphones, cloud connectivity, and app ecosystems, which provide the real-time processing, data storage, and user-interface layers needed to transform raw neural signals into consumer-facing products to be used outside clinical environments. It is this infrastructure, and not only the devices themselves, that enable the collection and analysis of large-scale neural datasets that can be used to train prediction models and to improve and personalize products much more rapidly. Over time, such datasets could generate defensible competitive advantages and support recurring revenue models[20] extending well beyond the initial BCI hardware sale. In other words, consumer BCIs have converged with the digital ecosystem of data, platforms, AI and cloud computing—and in doing so, with the business models that characterize the digital world.

2 **Second,** the expansion of consumer BCIs is taking place as global brain health worsens and gaps in access to care persist. The World Health Organization estimates that more than a billion people live with a mental disorder[21], yet public investment remains misaligned with this burden: governments devoted just 2.1% of health expenditure to mental health in 2021[22]. In addition, neurological conditions are the leading cause of ill health and disability[23], and affect over one in three people worldwide, while the prevalence of sleep disorders is equally relevant, with clinical insomnia alone estimated to affect 16.2% of the global population[24]. In Europe, nearly half of Europeans[25] report recent struggles with mental health, while access to care remains limited[26] and uneven[26] across socioeconomic groups. Where institutional healthcare systems fall short, individuals increasingly seek non-clinical alternatives, and it is precisely within the health-adjacent space that consumer BCIs have gained significant traction. Wellness is now the sector's largest consumer neurotechnology segment[12] and among the most heavily backed by venture capital[12] in both Europe and North America. This trajectory is unlikely to reverse[27], particularly as consumers turn toward non-clinical tools to support not only mental health and wellbeing, but also healthy aging, cognitive performance, and longevity. This trend extends beyond younger populations[27] to older adults, who represent a growing and economically significant consumer market[28].

3 **Third,** and perhaps most strategically significant, is the growing involvement of Big Tech companies in consumer neurotechnology[12]. Apple, Meta, Samsung, Amazon, and more[12], have all made strategic acquisitions[29] in neurotechnology, filed patents[30] related to neural interfaces or EEG-integrated wearables, or entered research partnerships[31] with neurotechnology firms. Neural data, encoding attention[32], intention[33], engagement[34], or emotions[35], is different from the behavioral and demographic data these companies already collect at scale. Contextualized within the ecosystems of location data, purchase history, search behavior, social interaction, and biometric measurement that these platforms already operate, neural data could become an additional tool for understanding and predicting consumer behavior, thereby amplifying existing concerns about privacy or profiling. In fact, neural data could potentially serve as ground truth for training algorithms to infer mental states from other types of collected data, even if future systems rely less on direct neural measurements at inference time. The commercial logic of Big Tech's convergence with neurotechnology may therefore not primarily be about selling BCI products (or even about directly collecting neural data in the future), but instead about enriching existing data ecosystems with the possibility to infer mental states using the same devices that millions of people use and trust—key to lower adoption barriers.

This convergence is strategically significant not only for industry but for policymakers: if neural data collection and, eventually, mental state inference become features of devices already embedded in everyday life, the governance window for establishing protective frameworks is narrowing.

Given these converging technological, commercial, and societal signals, the expansion of BCIs into non-medical markets deserves closer analysis from a multidisciplinary perspective. This paper focuses on Europe and the United States, the two largest consumer BCI markets[12], because they remain the primary sites where commercial models are developed and regulatory approaches are first operationalized. The analysis traces the shift of BCIs from medical to consumer applications, identifying emerging business models and use cases, and providing an overview of the regulatory asymmetries that are shaping innovation and governance across these jurisdictions. However, it is worth noting that this comparative focus does not assume the permanence of current trajectories. While Europe and the United States have historically led neurotechnology development, nowadays Asia-Pacific is the fastest-growing market for BCIs[36], and China has set a national strategy[37] to become a global leader in the field by 2030. If sustained, these trends could shift where key standards and governance frameworks are defined. The additional contribution of this paper is therefore to provide a baseline of the current transatlantic configuration against which these emerging shifts can be assessed.

1.2. SCOPE AND TERMINOLOGY

This paper is the opening contribution to a broader research agenda exploring *The Neurotechnology Shift*. Its scope is to introduce the topic by mapping and characterizing the technological and market dynamics driving the transition of neurotechnologies from medical to consumer applications. It serves as a preamble to a broader analysis of why these developments matter, and of the unresolved tensions they generate in both Europe and the United States, particularly with respect to emerging regulatory approaches. The paper is primarily descriptive and exploratory. It does not aim to provide an exhaustive legal analysis of the regulatory instruments discussed. References to specific frameworks (e.g., the EU Medical Device Regulation, the AI Act, the General Data Protection Regulation, and U.S. state privacy laws) are meant to illustrate their practical effects on the market and to flag open questions.

In addition, the paper aims to serve as a basis for further discussion and welcomes contributions from stakeholders across research, industry, policy, and civil society that can enrich the evidence base and advance understanding of the technological, commercial, regulatory, and societal dimensions of consumer BCIs.

The terminology used throughout the paper is defined on the following page. Not all definitions are intended to be comprehensive, given variation in the literature, but are provided to clarify the high-level distinctions adopted in this paper.

Table 1. Key terms and definitions used throughout this paper.

Neurotechnology	According to UNESCO[38], "Neurotechnology refers currently to devices, systems and procedures—encompassing both hardware and software—that directly measure, access, monitor, analyse, predict or modulate the nervous system to understand, influence, restore or anticipate its structure, activity and function. Neurotechnology combines elements of neuroscience, engineering, material science and computing, among others."
Brain-computer interface (BCI)	According to the definition of the BCI Society[10], a BCI is "a system that measures brain activity and converts it in (nearly) real-time into functionally useful outputs to replace, restore, enhance, supplement, and/or improve the natural outputs of the brain, thereby changing the ongoing interactions between the brain and its external or internal environments. It may additionally modify brain activity using targeted delivery of stimuli to create functionally useful inputs to the brain." A system that only stimulates without reading is not considered a BCI, a system that interacts with the peripheral nervous system and not with the brain is not a BCI, and a BCI is built using neurotechnologies.
NIBS (non-invasive brain stimulation) devices	Devices that deliver electrical currents or magnetic fields through the skull to modify neural activity, such as tDCS or transcranial magnetic stimulation, without surgical implantation. They are considered a BCI if they stimulate the brain in response to recorded activity.
Neurotech wearable	A consumer portable device worn on the body (headphone, earbud, headband, cap, wristband, glasses, etc) that incorporates neurotechnology. A neurotechnology wearable can be a BCI if it satisfies the BCI definition, independently of its form factor.
Neural interface	Any point of interaction between the nervous system and an external device. For instance, devices that read peripheral neural or motor signals (for example, a wristband translating motor-neuron activity) as well as brain activity. Neural interfaces that interact with the peripheral nervous system are not BCIs.
Neural data	According to UNESCO[38], "neural data include qualitative and quantitative data about the structure, activity and function of the nervous system gathered through neurotechnology as defined above. These are the most direct measurements or observations of nervous system states, many of which are correlated with mental states. They encompass data relating to a nervous system's activity, including both direct measurements of neuronal structure, activity and/or function (e.g. neuronal firing or averaged bioelectric signals from EEG) and indirect functional indicators (e.g. blood flow in fMRI and fNIRS)." Brain data is neural data, but not all neural data is brain data.
Mental inference	The generation of information that interprets or predicts an individual's cognitive, affective, or conative states. Such generation may be drawn from neural data, as defined above, or from non-neural data, sometimes referred to as cognitive biometric data[39]). Cognitive biometric data is not derived from neurotechnology but nonetheless permits such inferences. Technologies that enable cognitive biometric data collection include eye tracking, voice analysis, typing dynamics, gait analysis, skin conductance, heart rate variability, facial emotion recognition, and potentially others.
EU / Europe	"EU" refers to European Union member states and the body of EU law (MDR, GDPR, the AI Act). "Europe" is used more broadly to include non-EU European countries (e.g. the United Kingdom, Iceland, or Serbia), in line with the market analysis in Section 2.

02

MARKET LANDSCAPE: WELLNESS LEADS A DIVERSIFYING, DATA-CENTRIC BCI SECTOR

2. MARKET LANDSCAPE: WELLNESS LEADS A DIVERSIFYING, DATA-CENTRIC BCI SECTOR.

2.1. TWO MARKETS, TWO SPECIALIZATIONS: U.S. WELLNESS VS. EUROPEAN R&D

A recent report[12] by the Centre for Future Generations (CFG) mapped the neurotechnology market and compiled a database of 278 dedicated neurotechnology companies worldwide, out of which 60% were dedicated to consumer applications and the remaining 40% had medical certification or were in active pursuit of it. Since 2010, the number of these consumer neurotechnology firms has grown more than fourfold compared with the previous 25 years (Figure 1).

Among the 153 consumer neurotechnology companies identified globally in this report, 60 are headquartered in Europe and 59 in the U.S., with the remaining 33 distributed across Canada (12), China (6), Israel (6), India (5), and other markets. It is worth noting that data from the Asian market may be underrepresented given language and transparency barriers in accessing company information. Within Europe[1], the five countries with the highest number of consumer neurotechnology companies as of 2025 were the United Kingdom (13), Germany (7), France (5), Poland (5), and Spain (4).

Here, we narrow CFG's analysis to focus only on BCIs, which represent a large portion of the neurotechnology market. According to its definition[10], a device that only stimulates the nervous system without previous recording of neural activity is not considered a BCI.

Excluding the companies whose sole activity is neural stimulation, regardless of the stimulation modality (electrical, magnetic, optical, etc), 52 European consumer companies and 43 U.S. consumer companies qualify as BCI companies, developing devices or products that are part of the BCI tech stack. Out of the 52 European and 43 U.S. BCI companies, 19 European companies (36%) already have products available on the market, compared to 27 U.S. companies (62%) (Figure 2a).

Interestingly, the industry composition of consumer BCI companies differs markedly between the U.S. and Europe (Figure 2b), in line with the broader consumer neurotechnology market.

> In the U.S., the sector is dominated by companies developing products for wellness (21 out of 43, or 49%). This includes companies developing BCI wearables to track and optimize sleep[40], help with meditation[41], improve focus[42] and productivity[1], support sport performance[43], or provide cognitive, age-related, and longevity biometrics[44].

1 For the purposes of the analysis, Europe was defined broadly to include both European Union member states and non-EU European countries, specifically the United Kingdom, Norway, Switzerland, Iceland, and Serbia.

They are often presented to consumers in the shape of headbands, headphones, or earbuds, and are marketed often under slogans such as "FitBit for your brain" or "democratizing brain health", appealing to the health-minded consumer who is already familiarized with other health trackers. In Europe, however, the landscape is more research-oriented: companies developing tools for Research and Development (R&D). constitute the largest segment (18 out of 52, or 33%), followed by wellness applications. Companies developing R&D tools focus on the development of highly accurate devices[45] that are portable enough to be used in research settings, but that do not have the general consumer as their main customer.

All in all, data shows that the consumer BCI market has grown each year since the 2010s, and that wellness is the largest market segment in the U.S. and the second largest in Europe. At the same time, wellness is the segment that presents the greatest regulatory and governance challenges[13], and arguably, it is also where the most consequential consumer-facing developments are taking place, as devices in this space may offer great potential for meaningful societal impact[46]. The wellness market, therefore, deserves the most careful attention, both for the scale of its opportunities and for the risks that come along with them, which are examined in the next section.

Figure 1.
Cumulative number of neurotechnology companies founded worldwide (1987–2024). The upper lines track all consumer (n=153) and medical (n=118) neurotechnology companies globally. Consumer firms overtook medical ones around 2018 and have grown faster since. The lower lines show the BCI subset, both BCIs headquartered in Europe (n=52) and the U.S. (n=43). Both BCI lines were nearly flat before 2010, with virtually all growth occurring in the last 15 years.

Adapted from "Neurotech Market Atlas", 2025.

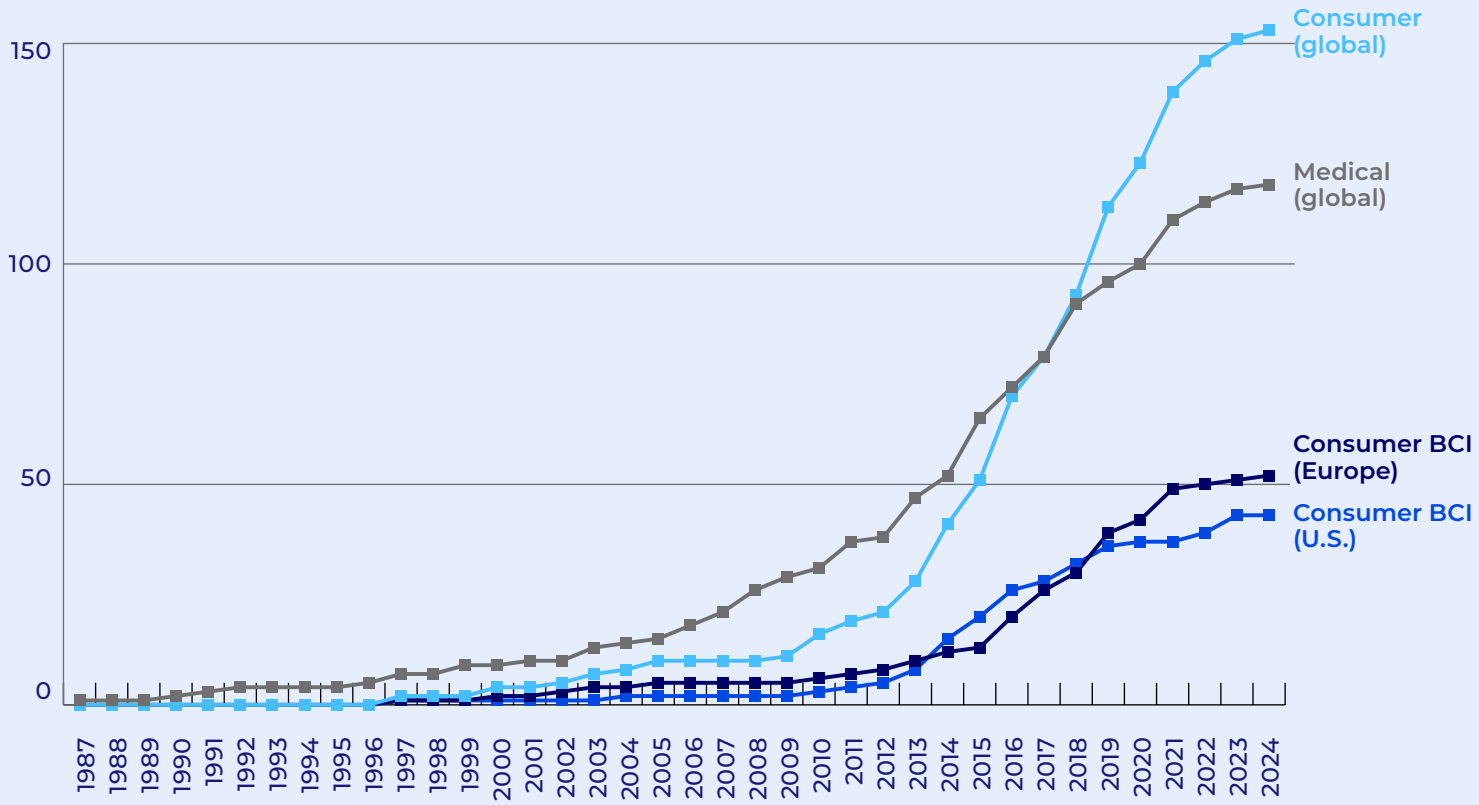
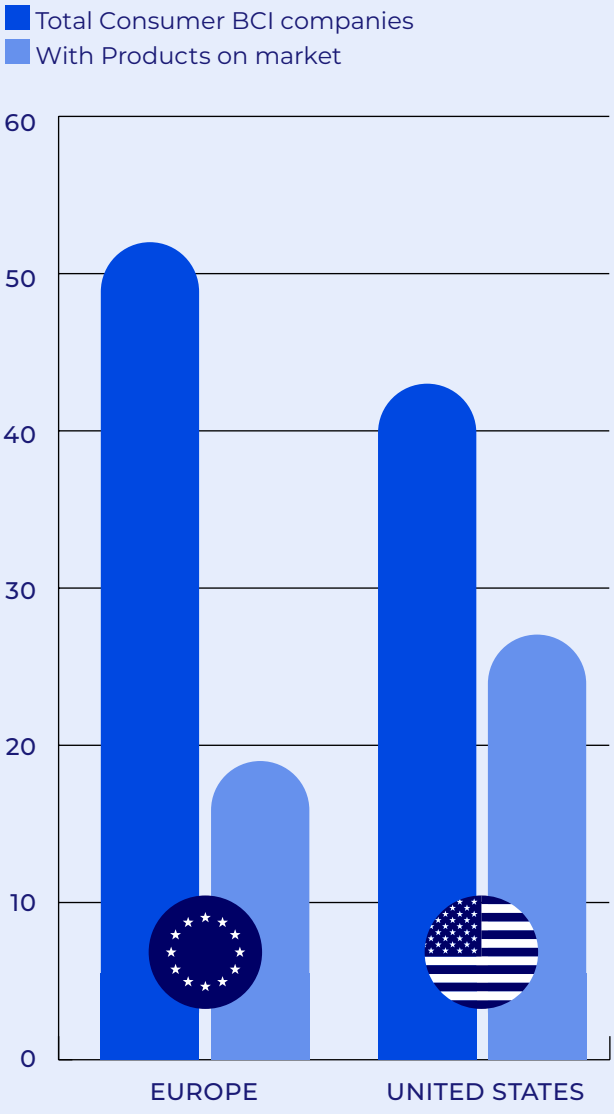


Figure 2.
Evolution of neurotechnology company foundings, as well as BCI company foundings in Europe and in the U.S.

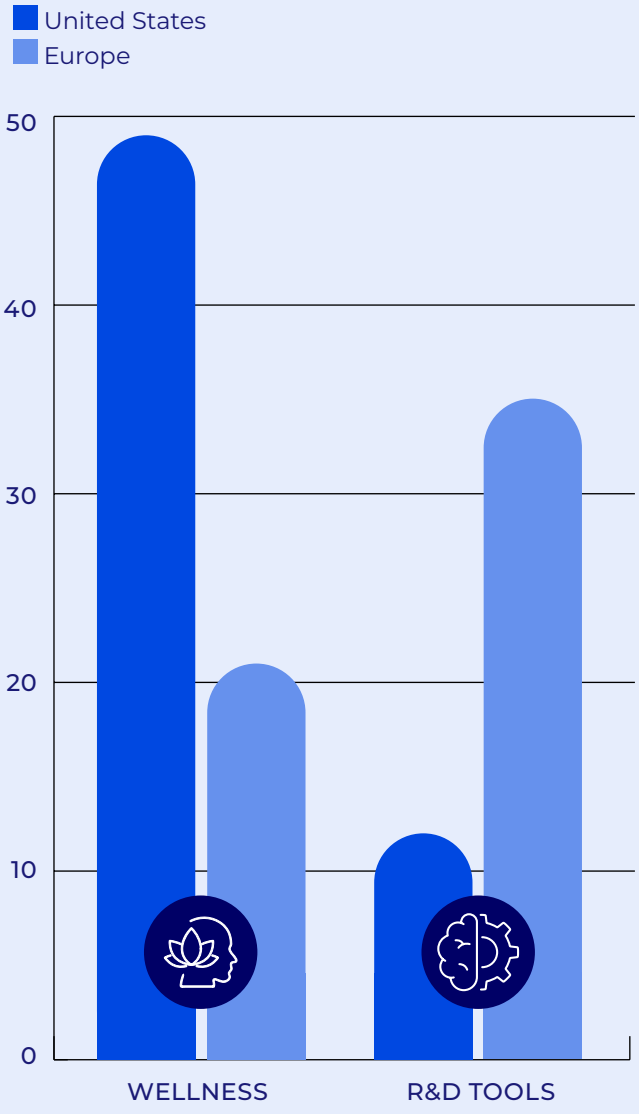
Adapted from "Neurotech Market Atlas", 2025.

2a. **Europe Leads in BCI Company count**
The U.S. leads ins the market readiness



Total number of BCI companies in Europe and in the U.S., and number of companies with products on the market. Proportionally, more BCI consumer companies in the U.S. have commercialized their products.

2b. **Wellness dominates in the U.S.**
R&D toold lead in Europe



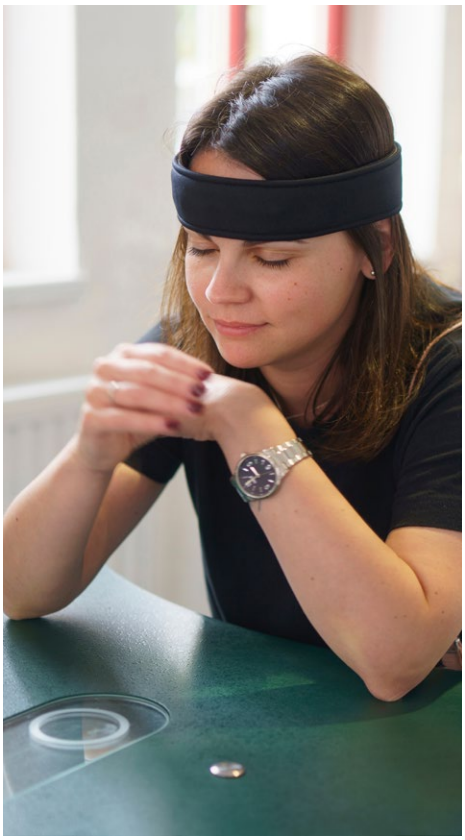
In the U.S., nearly half of consumer BCI companies (49%, n=21) target the wellness market, including sleep, focus, meditation, or cognitive performance. In Europe, the landscape is more research-oriented: R&D tools constitute the largest single segment (35%, n=18), with wellness second (21%, n=11). The remaining companies in both geographies span consumer electronics, software, information technology, and other sectors. Figure data adapted from the "Neurotech Consumer Market Atlas".[12]

2.2. OPPORTUNITIES AND CHALLENGES IN THE WELLNESS BCI MARKET

Wellness represents the largest and most commercially mature segment of the non-invasive BCI market, spanning products for sleep, focus, relaxation, and stress management, among others. Yet measuring brain activity to obtain information about these states, and particularly by means of non-invasive BCIs, has traditionally been difficult because the skull protects the brain and attenuates neural signals. It is only recently that these limitations are beginning to be overcome, with more powerful electrodes and algorithms[47] that are capable of extracting information from non-invasively recorded signals and through consumer form factors, even for applications with clinical relevance[48]. Extracting health-adjacent insights from recorded data, storing data for future analysis, and applying it for product personalization drives the wellness sector, particularly as increasing scientific evidence proves that some mental states including sleep[49], attention[50], engagement[51], drowsiness[52], or fatigue[53] (and even the reconstruction of seen images[54]), can be, to a certain extent, reliably decoded from the data collected through these devices.

At the same time, healthy skepticism is needed when discussing the decoding of emotions[55], intent[33], words[56] or speech[57], which can be decoded with more complex equipment and in laboratory settings, but that may be difficult or turn impossible to detect with devices that have fewer recording channels[58] or in real-world environments where subjects move and signals are inherently noisier. Avoiding hype[59] concerning what these devices are capable of doing today is critical to maintaining a healthy field, but it is also reasonable to acknowledge that the simpler decodable states such as attention, sleep, and fatigue (increasingly decodable with consumer devices) are enough to support a business model and create both opportunities and risks in the wellness market.

In addition, wearable sensor technology may improve and data collected today could be reanalyzed with more powerful tools tomorrow.



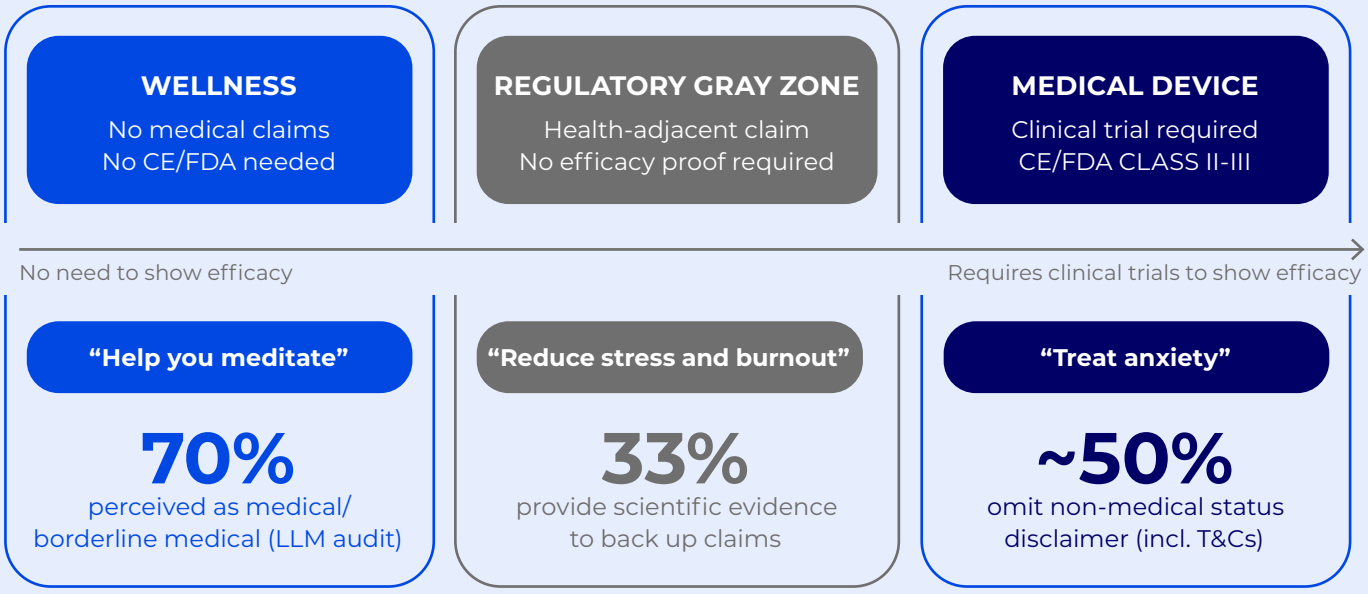
This makes the wellness BCI market not merely a hardware market but a data-driven one that projects into the future with the data of today.

In a context of increasing capabilities, many companies developing BCI products for wellness claim that consumer BCIs are democratizing access to brain health, but what brain health means and how these devices can meaningfully contribute to it remains unclear. Most BCIs can be commercialized in consumer markets[60] without having to prove efficacy, as long as their intended purpose is not medical, like any other consumer good. This can become very tricky[61] and potentially misleading[62] when products target health-adjacent applications[46] such as sleep, stress, productivity, or burnout. Claims such as "Reduce stress in four minutes", "Forget fatigue", "Mental health care for everyone" are technically acceptable in consumer markets because they avoid the medical language of "diagnose" or "treat", but are sufficiently ambiguous to risk consumer misperception, medical substitution, or reputational damage[59] to the neurotechnology field as a whole if companies do not deliver on their promises. Naturally, these tensions are not unique to neurotechnology but are characteristic of the wellness industry more broadly. However, they are particularly pronounced in this field due to the inherently subjective nature of mental experiences, where states such as stress and anxiety, poor sleep and insomnia, or temporal inability to focus and ADHD, among others, can overlap and resist clear separation.

This ambiguous space between wellness and medicine is what has been referred to as a regulatory gray zone[13]. The key regulatory aspect here is that, with few exceptions[63], what determines whether medical regulation applies is not the technology itself, but the claims made about its intended use[63] or purpose[64] 2: for instance,"treats anxiety" is medical and requires clinical trials, while "helps with stress" can reach the market without evidence of efficacy.

Figure 3.
The regulatory gray zone in practice is characterized by a continuum of ambiguous claims between wellness and medicine. Statistics concerning the percentage of companies perceived as medical, the percentage of companies providing solid scientific evidence to back up their claims, and the percentage of companies omitting transparency disclaimers around non-medical status are adapted from "Between wellness and medicine, 2026"[13].

Source: Bernáez Timón L and Mahieu V, 'Promise and Peril in Wellness Neurotech' (Centre for Future Generations, 1 April 2026)



2 As long as devices are considered low-risk. An implantable, for instance, would be considered a medical device regardless of its intended purpose.

Wellness startups can legally leverage health-adjacent claims while enjoying the less regulated consumer market without the burden of clinical trials. Conversely, it is also possible that some companies deliberately downplay their capabilities to operate in consumer markets, where it is possible to reach more users and collect more data with fewer safeguards, in order to study the feasibility of a medical case in the future.

> In fact, based on the marketing claims on their website, a CFG study[46] found that 70% of consumer companies are perceived as medical or borderline medical in an LLM model analysis of scrapped web text.

The same study also reported that, despite their claims, only one third of companies provide scientific evidence to back up the claims, and almost half fail to disclose, not even in their Terms and Conditions, that their product is not medically certified. Many of them display testimonials from users referencing clinical conditions without proper scientific back up (e.g. users reporting how a consumer device helped with anxiety, ADHD, or PTSD) or use medical visual aesthetics on their website, potentially to imply clinical credibility. In the absence of evidence standards and requirements, virtually anything is utilized as evidence.

Beyond the risk of consumer misperception and inappropriate medical substitution, a further a concern relates to the governance of data collected in wellness markets[65], particularly as such devices often operate alongside companion apps that collect additional user data, incorporate chatbots, allow users to log diary entries, or interact with large language models for explanatory purposes. When brain data is collected without adequate safeguards and subsequently contextualized through this user-input data, it becomes unclear how meaningful consent can be ensured[17]. Such data may eventually permit inferences[66] about individual preferences or markers of neurodegeneration, raising questions about whether consent obtained at the point of collection can meaningfully anticipate future applications, as flagged by UNESCO[38].

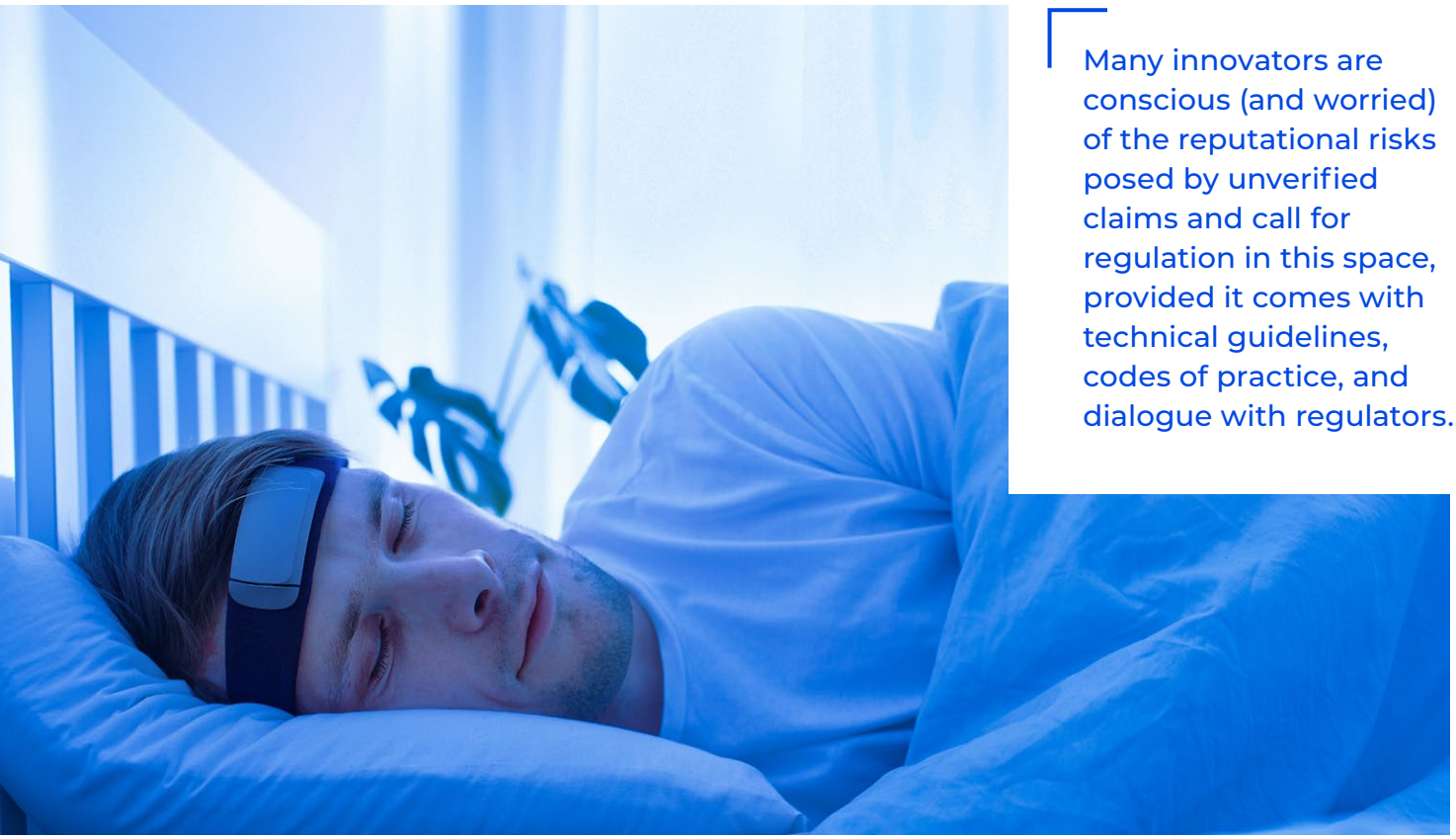
The risks are tangible, but at the same time, so are the opportunities—similarly to other wearables[67]. Balancing these competing considerations presents a significant governance challenge. Wellness BCIs offer at least three advantages in wellness and health-adjacent contexts.

1 **First**, continuous[68] and remote monitoring outside the clinic[69], which is not possible with clinical devices today, and particularly valuable for conditions like sleep disorders, where replicating the trigger in a hospital setting is difficult.

2 **Second**, data at scale, which could help establish biomarkers[70], detect early signs of neurological[71] conditions, improve treatment matching, and establish causal links between lifestyle factors, such as smartphone use, and mental health outcomes.

3 **Third**, everyday wellness value: much like going to the gym or a mindfulness class, these devices could expand the toolkit people use to feel better, as long as claims remain proportionate.

The regulatory gray zone between wellness and medicine is therefore an ambiguous space, in which identifying which applications offer value and which ones carry risk (such as misleading claims or medical substitution) is genuinely difficult. Part of the difficulty comes from a lack of robust efficacy evidence for what these devices



Many innovators are conscious (and worried) of the reputational risks posed by unverified claims and call for regulation in this space, provided it comes with technical guidelines, codes of practice, and dialogue with regulators.

can actually detect, in a domain that is often inherently subjective. For instance, the line between stress and anxiety is blurry, and marketing claims can exploit that ambiguity.

For applications that neither claim to diagnose nor treat conditions, demanding the same rigorous efficacy standards as medical devices may be disproportionate, but demanding no standards at all may be equally so. Accordingly, different voices, including UNESCO[38], have raised the importance of defining evidence standards proportional to the actual nature and risk profile of wellness neurotechnology products. This could mean basic safety and usability evidence for general wellbeing claims, more robust and transparent substantiation for claims relating to sleep, stress, attention, or fatigue, and stricter evidence and scrutiny where products approach clinically relevant outcomes. This is not without precedent: cosmetics[72] and food supplements[73] are already governed by frameworks that impose clear safety, labelling, and claims[74] requirements without subjecting products to full medical device regulation. CFG, for instance, has proposed a dedicated EU governance category for health-adjacent wellness technologies[75] along these lines, requiring proportionate safety assessment and labelling, binding standards on marketing claims, and promoting interoperability with the healthcare sector. At a minimum, companies should be expected to provide disclosures when their products are not medically certified. Such a scheme could build on the EU-funded Label2Enable project[76] or the European Brain Council's Seal of Responsible Neurotechnologies[77], an ethical label that operationalizes the European Charter for the Responsible Development of Neurotechnologies[78].

Industry appetite[79] for such a framework may be greater than the policy discourse currently acknowledges. Notably, some founders report that navigating the patchwork of consumer market regulation (GDPR, the AI Act, and others) can be harder and less structured than pursuing medical certification, where clinical needs and validation pathways are longer and resource intensive but well-defined. In addition, many innovators are conscious (and worried) of the reputational risks posed by unverified claims and call for regulation in this space, provided it comes with technical guidelines, codes of practice, and dialogue with regulators.

2.3. CO-EVOLVING CONSUMER AND MEDICAL BCIS FOR USABILITY AND CLINICAL RIGOR

The governance challenges described above are in part a consequence of how closely consumer and medical BCIs have traditionally grown together, despite operating under very different regulations today, and of how technology is blurring the line between wellness and medicine. That blurred line is not only creating risk and ambiguity, but also opening up opportunities for the co-evolution of both markets.

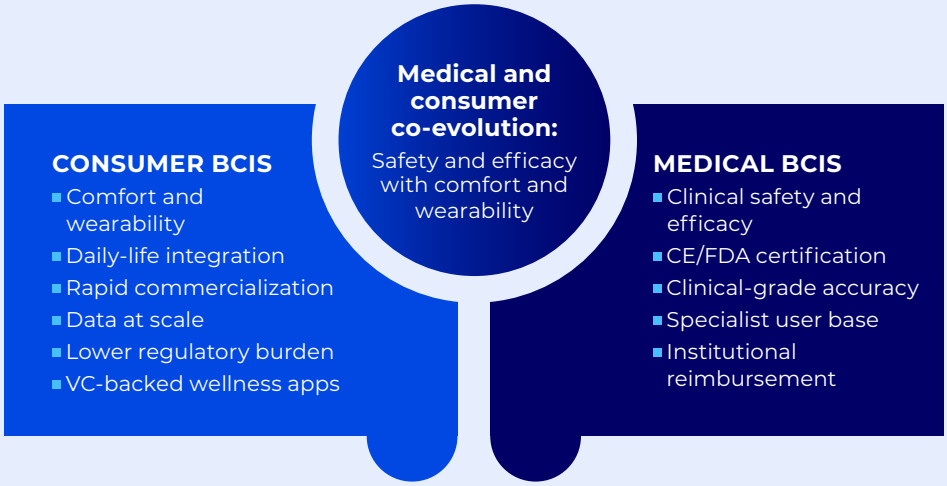
In addition to regulatory differences, consumer and medical BCIs serve different customers, and therefore reflect different design priorities. Consumer devices optimize for comfort, wearability, and integration into daily routines, while medical devices are built around safety and clinical efficacy without necessarily prioritizing user-friendly designs. These different priorities push the two ecosystems to innovate in different directions, but at the same time, medical and consumer markets often draw on the same underlying technologies (e.g. electroenchephalography, or EEG, is used by 63% of consumer companies[12]), and are beginning to influence each other's development in consequential ways. Merging the best of both worlds could produce devices that combine genuine capability with the usability characteristics of a consumer product. This trajectory is already visible in a number of medical-grade wearable devices that have emerged partly from consumer ecosystems, or have crossed into consumer markets after obtaining medical regulatory clearance (for example, some medically-certified wearables for at-home treatment of depression[80], chronic insomnia[81], or PTSD[82]).

Such devices could reduce the need for hospital visits, enable remote and continuous monitoring[69], improve patient comfort and adherence[67], and alleviate pressure on healthcare systems by reducing demands on clinical infrastructure and trained personnel. At the same time, the co-evolution of consumer and medical BCIs risks further blurring the boundary between wellness and healthcare without yet an adequate framework for evidence requirements, as we discussed. Given the potential to unlock significant benefits for patients and healthcare systems from this convergence, addressing this blurred boundary is particularly important.

The migration of additional medical neurotechnologies into consumer markets is equally plausible. For instance, focused ultrasound[83] or even invasive neural implants[84], could eventually be repurposed for consumer use with no medical claim attached, much as cosmetic procedures have already normalized bringing invasive clinical techniques into an elective, non-medical market. If this occurs, the same regulatory gray zone described above would have to contend with considerably more powerful, and in some cases more invasive technology.

Figure 4.
Despite different regulatory regimes and design priorities, consumer and medical BCIs share core technologies, creating an opportunity to develop devices that combine clinical rigour with everyday usability. Certified at-home wearables for depression, insomnia, and PTSD are early examples.

Source: Author's elaboration



2.4. BEYOND WELLNESS: BCIS AT WORK AND MACHINE CONTROL

While wellness is the application that most consumer BCIs target today, other markets are showing meaningful growth and deserve attention. Among these, the workplace[85] represents a commercial opportunity for many BCI developers.

The clearest case is safety monitoring in high-risk industrial environments. Companies[5] already deploy EEG-embedded caps and helmets to track fatigue levels in sectors such as mining, transport, and manufacturing, where operators must sustain attention over long periods of repetitive work. Systems that detect fatigue and alert workers or supervisors before an accident occurs represent a potential application of BCI technology with a legible safety rationale and an employer risk-management incentive that is likely to sustain commercial demand.

A second and more contested category concerns the optimization of cognitive performance[86] in professional environments[87]. This includes headphones[88] that track focus levels and adapt audio output to help the user concentrate; neuroadaptive environments such as booths[89] that adjust lighting, noise cancellation, and task recommendations in response to a user's measured cognitive state; and more experimental applications such as adapting the pacing and language of LLM responses[8] to the user's real-time stress or focus levels. Better management of cognitive load and early detection of burnout could reduce mental health-related leave[90], which is an outcome that in principle benefits both workers and employers. However, the ethical[91] and governance questions here are different from the safety case. When the purpose shifts from preventing accidents to optimizing output, the interests of employer and employee are no longer clearly aligned, and the use of neural monitoring through BCIs becomes also a question of power, consent, and labor rights. It is unclear how employers would be required to manage individual-level cognitive data, whether it could inform hiring or performance evaluation decisions, and what recourse workers would have against inferences drawn from their brain activity.

A third category involves active and passive neural control[92] of external machines, such as robots, drones, or manufacturing equipment, via BCI commands that bypass conventional input devices such as keyboards or control panels. The recently released neural wristband by Meta[5], which translates peripheral motor neuron activity into handwritten text, illustrates the proximity of this use case to commercial deployment even at the level of a consumer wearable. Applications based on direct brain activity recording[93] rather than peripheral muscle signals may be feasible in workplace contexts in the near term, enabling faster and more seamless interaction with complex systems in environments where hands-free operation is advantageous.

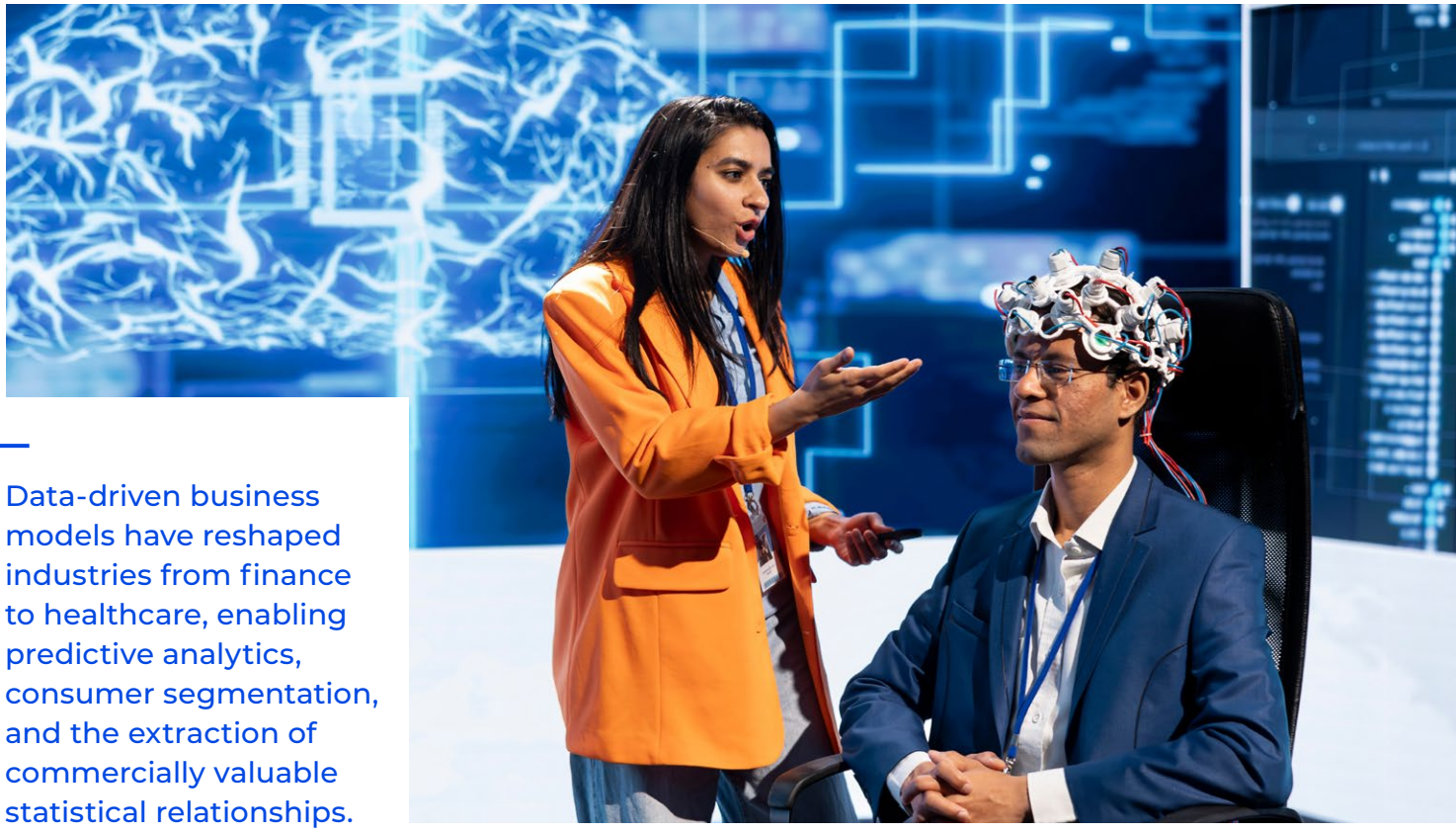
From a regulatory perspective, the AI Act[94], the EU law for AI systems, may treat the three cases above very differently. As we will discuss below in more depth, the Act prohibits AI emotion recognition systems in occupational settings, but exempts the detection of fatigue, which is considered a physical state, and permits emotion recognition where safety is the primary justification. This plausibly shelters the industrial fatigue-monitoring case from regulatory scrutiny but exposes some cognitive optimization applications.

2.5. THE DIVERSIFYING BUSINESS MODELS OF BCI COMPANIES

Regardless of application, the revenue models available to BCI companies have diversified substantially over the past decade (Table 2). This diversification is inseparable from the growing centrality of data[95]. Data-driven business models have reshaped industries from finance to healthcare, enabling predictive analytics, consumer segmentation, and the extraction of commercially valuable statistical relationships. BCIs extend this logic to the brain.

A decade ago, most BCI companies developed vertically integrated products, handling everything from hardware to software within a single stack and relying primarily on device sales. Today, the sector is increasingly specialized and data-centric. Some firms focus on materials and sensing hardware for neural signal acquisition; others develop signal-processing and machine-learning systems that convert neural activity into interpretable outputs; others provide APIs, software infrastructure, or cognitive-state inference services that can be integrated into third-party products.

Direct-to-consumer models increasingly combine hardware sales with subscription platforms, where profitability depends less on the device itself than on subscription retention and data monetization. EEG-enabled headbands linked to sleep, focus, or meditation applications illustrate this shift, particularly in the premium wellness market. In enterprise settings, BCIs are being deployed for fatigue monitoring and safety management in high-risk environments, with BCI companies typically selling devices and aggregated workforce insights. Another increasingly important model is platform or component licensing: firms specializing in proprietary algorithms for signal processing or hardware license these capabilities to larger companies integrating BCIs into mainstream wearables such as headphones. For smaller firms[79], founders say that this model offers scalability, lowers distribution costs, and may position them better for acquisition by larger technology companies. Some companies are also beginning to monetize access to proprietary neural datasets for researchers as an additional revenue stream.



Data-driven business models have reshaped industries from finance to healthcare, enabling predictive analytics, consumer segmentation, and the extraction of commercially valuable statistical relationships.

The diversification of business models is, in principle, positive for innovation and the market's long-term development. More revenue paths create more viable company structures and broaden investment opportunities. However, the same fragmentation that creates commercial opportunity also creates governance risk[96]. As neural data moves across an increasingly complex digital ecosystem[97], ensuring adequate safeguards becomes more difficult. The architecture of the market itself can diffuse accountability and make meaningful consent verification increasingly impractical. Plus, transparency around data sharing (or selling) practices[98] has been contested. Developing governance frameworks capable of addressing these risks is likely to become an important challenge for policymakers in both Europe and the U.S., as UNESCO[38] flags in its 2025 Recommendation on the Ethics of Neurotechnology, and particularly if Big Tech enters the space more prominently.

Table 2. Overview of key BCI business models by application area (type of use case), primary customers (who buys the product), revenue model (how the company makes money), data flow (how neural data moves through the ecosystem), innovation opportunities (potential benefits enabled), and governance concerns (key risks and regulatory challenges).

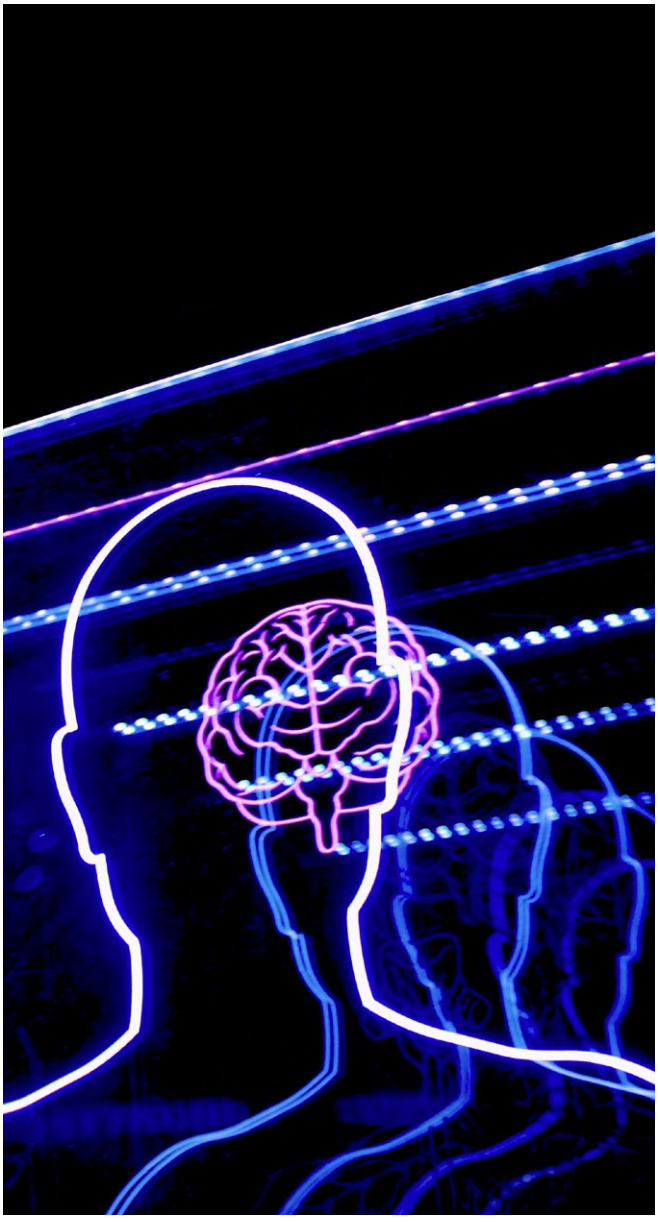
Application area	Consumer BCI (e.g. wellness)
	Workplace safety monitoring or cognitive optimization
	Component and IP licensing
	Proprietary neural datasets sales
Primary customer(s)	Individual users, premium health-conscious users
	Employers and enterprises
	Other BCI and wearable manufacturers, large tech companies
	Other BCI and wearable manufacturers, marketing firms, researchers, governments
Revenue model	Neural signals captured using the device are processed and stored in the cloud via app ecosystems
	Neural data aggregated from workers shared with employers
	Proprietary algorithms or hardware layers integrated into third-party products, neural data processed within partner ecosystems
	Anonymous neural recordings shared with buyers
Innovation opportunities	Personalized wellness tools, biomarker discovery, integration with broader health ecosystems
	Accident prevention, reduced burn-out and mental-health leave, productivity gains
	Scalability for smaller firms, lower distribution costs, and positioning for acquisition
	Accelerated research and model training, biomarker discovery, enabling third-party innovation without full vertical integration
Governance concerns	Unverified health-adjacent claims, future reuse of data beyond original consent, data privacy across digital environment
	Worker consent and autonomy, scope of data shared with employers, potential for surveillance, hiring or firing decisions, worker re-identification
	Diffused accountability across the stack, harder consent verification as data moves between actors
	Re-identification risk, absence of ongoing consent mechanisms, potential misuse by commercial or government actors.

03

HOW REGULATORY DIFFERENCES BETWEEN THE EU AND THE U.S. AFFECT INNOVATION

3. HOW REGULATORY DIFFERENCES BETWEEN THE EU AND THE U.S. AFFECT INNOVATION

The main regulatory differences between Europe and the U.S. concern, mainly, three points: the classification of non-invasive devices that stimulate the brain, the regulation of the use of AI, and the regulation of neural data. This section focuses on how these differences impact the market.



3.1. BRAIN STIMULATION DEVICES: MEDICAL IN THE EU, CONSUMER IN THE U.S.

One of the most consequential regulatory divergences between Europe and the U.S. concerns the legal classification of non-invasive brain stimulation (NIBS) devices, those that deliver electrical currents or magnetic fields through the skull to modify neural activity, when these devices are marketed for non-medical purposes. This is relevant for BCIs that record and stimulate the brain.

The EU's Medical Device Regulation (MDR, Regulation 2017/745)[99], through Section 6 Annex XVI, extended the medical device regulatory framework to certain products that do not have an intended medical purpose. While the MDR usually classifies devices as medical or non-medical based on their intended purpose, Annex XVI treats NIBS differently, as their classification depends only on the device's technical characteristics, regardless of what they are used for[60]. This means that consumer-facing NIBS devices that "apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neural activity" are treated as medical devices under EU law even when their manufacturers do not have an intended medical purpose.

In addition, non-medical NIBS devices are classified as Class III medical devices under this framework. This is the highest risk tier in EU medical device law, otherwise reserved for implantable neurosurgical interventions such as deep-brain stimulators. Therefore, Class III status entails the most demanding compliance pathway in the EU: manufacturers must obtain certification from a Notified Body, conduct clinical investigations demonstrating safety and efficacy, and produce extensive technical documentation. The application of

his classification to non-invasive BCIs without a medical intended purpose has attracted criticism[100]. Some argue that scientific evidence does not back up the classification[101], others point out the potential detrimental effects on research, innovation, and eventually on translational applications[102]. They have argued that this classification may slow or prevent patients from accessing non-invasive research tools and novel applications. At the same time, Annex VXI has also been described as a forward-looking extension of EU medical device law[60], that only includes those consumer BCIs that currently pose severe health-related risks, and that addresses the practice of BCIs being falsely under-qualified as wellness tools by manufacturers.

The U.S. Food and Drug Administration takes a different approach. Consumer NIBS devices that do not make medical claims are generally not subject to FDA medical device regulation, with their marketing claims instead addressed in general wellness guidance[103]. This means that products such as transcranial direct current stimulation (tDCS) headsets marketed for sleep enhancement or transcranial stimulation patches framed as focus aids, among others, can reach U.S. consumers without premarket authorization, clinical trial data, or FDA involvement. Some researchers claim that oversight[104] in this market is minimal. This more permissive environment has recently intersected with broader U.S. policy trends: the Trump Administration's "Make America Healthy Again" agenda[105] has promoted the mass adoption of health-tracking wearables and launched a data-sharing initiative between the federal government and large technology companies. This move could empower preventative care, but has already raised concerns[106] about health data privacy and the potential for sensitive biometric data to be accessed for purposes beyond healthcare.

Independently of the rationale behind these regulatory asymmetries, consequences for the market are tangible. For instance, the same device may be lawfully sold as a consumer wellness product in the U.S.[107] and simultaneously as a CE-marked medical device in the EU[108].

> This dynamic also shapes innovation trajectories. Companies in the EU that want to operate in consumer markets have to focus on recording products and avoid neurostimulation applications entirely, unless they pursue medical certification. Consequently, the market for NIBS in wellness is exclusive to the U.S..

3.2. BCIS AND AI: THE EU AI ACT VERSUS THE U.S. PATCHWORK

Artificial Intelligence is one of the key enablers of consumer neurotechnology. Consequently, most consumer BCI companies use AI in one way or another, which raises the question of whether they fall under scope of the AI Act[109], the European law regulating the use of AI systems.

> The use of AI in consumer BCIs is diverse. For some companies, AI is the core technology behind their business model[12], for others it underpins signal processing and de-noising.

In the EU, AI systems for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data fall within the scope of the AI Act (Regulation EU 2024/1689)[94] where they qualify as AI systems and are placed on the EU market, regardless of where the provider is based. The U.S. has no equivalent horizontal federal regime, though companies may still be subject to FTC enforcement, FDA oversight (for medical applications), and emerging state-level rules.

The AI Act takes a risk-based approach[110]. For BCIs, two provisions are particularly relevant. Article 5(1)(a) prohibits AI systems that deploy subliminal techniques to materially distort or manipulate behavior in ways that cause or are likely to cause harm; recitals explicitly identify brain-computer interfaces as a potential vector[111]. Article 5(1)(f) prohibits AI systems intended to be used to detect the emotional state of individuals based on their biometric data and related to the workplace and education, except where the use of the AI system is intended to be put in place or into the market for medical or safety reasons. The prohibition has applied since 2 February 2025 and carries the Act's top penalty tier, up to €35 million or 7% of worldwide annual turnover (Article 99[112]).

Beyond outright prohibitions, emotion recognition systems are also classified as high-risk under the Act, when deployed beyond workplace and educational settings and for reasons other than safety or medical. The European Commission has drafted guidelines[113] to support providers, developers, and market surveillance authorities in assessing if an AI system should be classified as high risk. High-risk cases trigger requirements around transparency, human oversight, and third-party assessment (Article 50[114]), obligations that are not trivial for many start ups. The legal application of these requirements for high-risk AI systems, originally planned for August 2026, may be delayed until December 2027[115] pending the outcome of the Digital Omnibus.

It is unclear if and how the AI Act will affect the market for wellness and workplace BCIs, which mainly use AI in applications for sleep, stress, focus, productivity, concentration, or fatigue. The AI Act illustrates the notion of "emotion" with examples including happiness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction and amusement, but it does not define emotion itself[109], making the classification of certain inferences using BCIs that use AI systems potentially difficult. In addition, the AI Act considers pain or fatigue as physical states, which fall outside the prohibited practices and high-risk categories. This means that BCI companies developing tools for fatigue detection at the workplace (or beyond) do not fall under the scope of the AI Act. In practice, however, emotions and these physical states can be intertwined. For instance, a fatigued person may also lack amusement, and inferring one will inevitably mean inferring the other, even when not intended. Therefore, it remains to be seen how these nuances will materialize in the market, and particularly for wellness BCIs, whose inferences closely relate to some of the emotions described.

As the BCI market grows and neural data becomes increasingly central to business models on both sides of the Atlantic, differences in regulatory frameworks become a governance challenge, particularly in light of the GDPR's rules on international data transfer and special category data.

3.3. THE ONGOING DEBATES AROUND NEURAL DATA

The governance of neural data is one of the most complex debates in neurotechnology, and as such, it has been extensively examined in the literature[96]. Approaches to neural data governance range from rights-based frameworks that propose new human rights or "neurorights"[116] to protect mental privacy, to adaptations of existing data protection law, particularly the GDPR[117], to cover the sensitivity of neural data. Some scholars also argue that any adequate framework must extend beyond neural data[39] and encompass the broader class of non-neural signals capable of inferring emotions[118].

In Europe, neural data sits within GDPR's architecture. Depending on how it is collected and used[119], it may qualify as health data, biometric data, or personal data, each of which attracts a different level of protection. This classification has been considered unclear and ambiguous, and has recently motivated a plea to make neural data a special category in the GDPR[117], including concerns about data handling in consumer markets under its current protections.

Industry executives report[79] that the burden of an unclear classification falls on technical teams, who often struggle with compliance infrastructure design without sufficient guidance from regulators. In addition, they claim that data ambiguities and the uncertainty about how it will be regulated in the near future can discourage long-term investment in data-centric BCI companies, particularly those whose business models depend on neural datasets as a recurring asset.

In the U.S., there is no federal privacy law that specifically addresses neural data, and no general data protection framework comparable to GDPR. What has emerged instead is a growing patchwork of state-level legislation: California, Colorado, Connecticut, and Montana have all amended their consumer privacy laws to treat neural data as a particularly sensitive category, though with meaningfully different definitions and scope. The MIND Act[120], introduced in September 2025, is a bill that would direct the Federal Trade Commission to investigate legislation to protect neural data at the Federal level.

As the BCI market grows and neural data becomes increasingly central to business models on both sides of the Atlantic, differences in regulatory frameworks become a governance challenge, particularly in light of the GDPR's rules on international data transfer[121] and special category data. These differences may pose an obstacle to the kind of transatlantic data flows that many BCI companies, particularly those operating in both markets, depend on. For instance, joint R&D, training AI models, establishing licensing agreements, or inspiring investor confidence across the Atlantic are common industrial practices that can turn difficult to BCI companies. This is one of the most concrete but challenging areas where transatlantic dialogue could yield practical benefits, and one where Europe's more developed regulatory starting point gives it a potential role in shaping emerging global norms. Well-calibrated governance could serve as a competitive advantage, signaling trustworthiness to consumers, investors, and international partners alike.

04

HOW CAN INTERNATIONAL COLLABORATION FOSTER INNOVATION, DEVELOPMENT, AND COMPETITIVENESS

4. HOW CAN INTERNATIONAL COLLABORATION FOSTER INNOVATION, DEVELOPMENT, AND COMPETITIVENESS

Collaboration between European and other BCI markets can offer a credible pathway to foster ethical innovation, accelerate the development of beneficial applications, and enhance mutual competitiveness in an emerging BCI ecosystem that increasingly relies on international data flows. From a European Union perspective, this also requires aligning on shared opportunities, safeguarding rights and sovereignty, and jointly mitigating systemic risks, something that is inherently complex but particularly challenging within the current geopolitical climate. Nevertheless, there are concrete domains where complementarities, in particular between the U.S. and Europe, the two largest markets, can create a pragmatic basis for cooperation.

For instance, on the technical side, joint pre-competitive research platforms could be a promising mechanism to exploit innovation strengths across geographies, allowing stakeholders to collaborate on technical challenges such as testing methodologies or establishing common benchmarks, while preserving space for downstream competition regardless of political agreement or disagreement. A precedent of this strategy happened in AI, with technical networks advancing evaluations and standards, despite the UK and U.S. not signing the Paris international AI declaration in 2025[122].

Standard-setting is another interesting avenue for technical cooperation. The relative youth of the consumer BCI field comes with a lack of standards around performance or evidence of efficacy in consumer markets. As discussed above, the lack of evidence standards has already generated regulatory frictions[13], particularly at the boundary between wellness and medical applications. A coordinated approach to defining standards in wellness markets could be built upon existing architecture, such as IEEE P2731[123], that is developing a unified BCI terminology, or ISO/IEC JTC 1/SC 43, the first international standards committee dedicated to BCIs. These are convenings where stakeholders from multiple geographies, including the EU and the U.S. already sit together, and represent an ideal setting to cover areas such as signal quality, data interoperability, and validation protocols for decoding and inference of mental states in wellness markets[3]. Existing normative instruments, including the OECD Recommendation on Responsible Innovation in Neurotechnology[124] and UNESCO's 2025 Recommendation on the Ethics of Neurotechnology[38], provide the high-level foundation on which this operational work can be built.

Communicating expectations proportionately and ensuring evidence-based engagement with the public is another critical priority for the EU, particularly in an interconnected world where unvalidated narratives about technology spread easily through social media. The field of neurotechnology has previously been affected by cycles of hype[125], ranging from exaggerated claims of "mind control" or "mind reading" attributed to current consumer devices, to discourses that publicly assert the imminent possibility of merging human brains and consciousness with machines and AI. Such narratives, when not grounded[126] in solid science, can fuel both public skepticism and fear. Reputational volatility poses risks not only to consumer markets but also to clinical innovation, particularly for BCI technologies that represent the only available solution for patients with certain neurodegenerative and psychiatric disorders—an unmet clinical need critical

3 A prerequisite for all of this is that neural data be understood and defined consistently across jurisdictions.

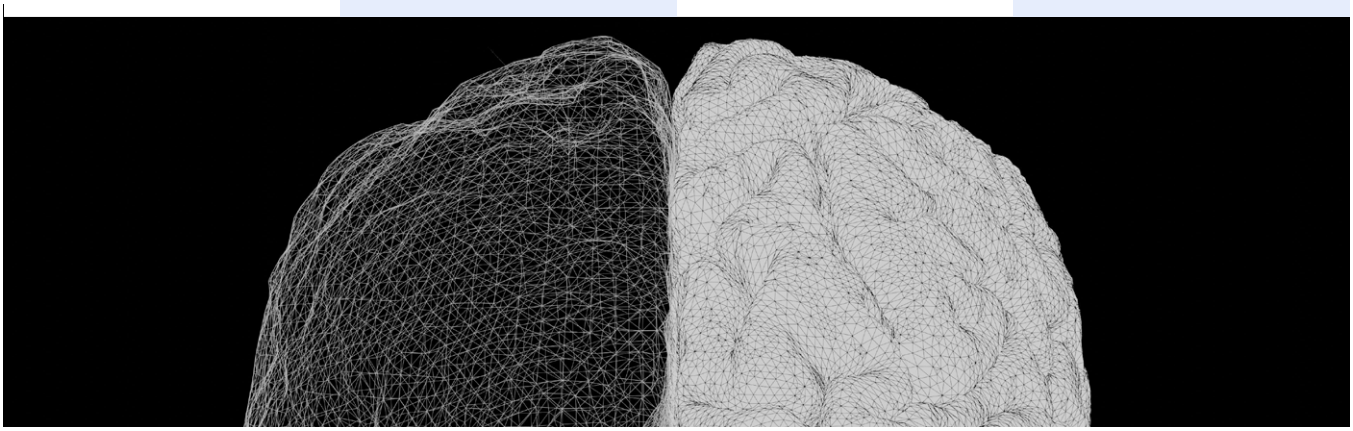
for the EU. Europe possesses strong scientific and industry communities capable of anchoring the field in evidence-based communication and coordinated efforts to promote realistic narratives.

Ultimately, effective collaboration depends on sustained coordination across disciplines and stakeholder groups. Neurotechnology sits at the intersection of engineering, neuroscience, ethics, law, and human rights, and involves a wide range of actors, from researchers and innovators to clinicians, patients, and policymakers. Concrete outputs resulting from international collaboration could be regularly updated market maps, evidence tiers, validation benchmarks, model clauses for neural data governance, public communication guidelines, or interoperability recommendations. Many of these outputs intersect with open scientific and conceptual debates that remain unsettled: whether neural data is "unique", and in which sense, or categorically distinct from other biometric or inferred data, in which cases is neural data superior in providing information about mental states and in which cases it is not (or not necessary) , how meaningfully it can be anonymized and de-anonymized according to signal quality, or what should even count as a "thought" or a "mental state" for governance purposes and why it matters. Because the answers carry direct policy implications, they should be worked out through sustained dialogue with neuroscientists and other researchers, so that the boundaries of these questions are framed in step with the current state of the science, avoiding both hype about what these devices can do and the risk of overlooking emerging capabilities.

Neurotechnology sits at the intersection of engineering, neuroscience, ethics, law, and human rights, and involves a wide range of actors, from researchers and innovators to clinicians, patients, and policymakers.

Table 2. Proposed mechanisms for international cooperation in consumer neurotechnology, with key advantages and challenges.

Mechanism	Description	Key opportunities	Key challenges
International consumer neurotechnology observatory	Joint monitoring of market evolution, company claims, investment trends, and regulatory frictions	Early identification of emerging risks and gaps, shared intelligence across jurisdictions	Requires sustained institutional commitment and cross-agency coordination
Joint pre-competitive testing platforms	Shared infrastructure for signal quality, usability, reliability, and validation of neural inferences	Reduces duplicated R&D costs, builds common evidentiary baselines without constraining downstream competition	Governance of shared platforms across different legal and funding systems
Shared evidence tiers for BCI claims	Harmonized framework distinguishing wellness from health-adjacent claims	Reduces regulatory friction at the wellness/medical boundary, supports consumer protection and lowers ambiguity for developers	Requires alignment on what constitutes sufficient evidence and risk
Coordination through existing standards bodies	Engagement via IEEE, ISO/IEC JTC 1/SC 43, OECD, and UNESCO instruments	Builds on established multilateral architecture, international stakeholders already participate	Standards processes are slow, risk of lowest-common-denominator outcomes in geopolitically fraught contexts
Public-facing communication guidelines	Shared principles for evidence-based, proportionate communication about consumer neurotechnologies	Counters hype cycles and unfounded fears, builds public trust across markets	Coordinating messaging across diverse media ecosystems and languages is operationally complex
Joint scientific-policy working groups	Recurring dialogue between neuroscientists, technologists, and policymakers to characterize unsettled conceptual questions with policy relevance	Grounds neural data governance and technology capabilities in current scientific evidence. Keeping definitions responsive to emerging device capabilities	Scientific consensus may itself be unsettled or contested. Research can be slow in resolving open conceptual questions



05

WHAT TECHNOLOGICAL AND MARKET EVOLUTION TRAJECTORIES ARE MOST LIKELY OVER A FIVE-YEAR HORIZON

5. WHAT TECHNOLOGICAL AND MARKET EVOLUTION TRAJECTORIES ARE MOST LIKELY OVER A FIVE-YEAR HORIZON

Over the next five years, technological capabilities will likely continue to increase, and there is no reason to think at the moment that they will reach a ceiling within this time frame. Even if AI development plateaued today, data collected by BCI companies will likely keep growing, enabling better models and more personalized products.

New form factors such as earbuds, glasses, or headphones will become more widespread and established. A plausible technological disruption that also bears on data privacy is the deployment of edge computing for BCI consumer technology, which would allow for in-device processing of collected data instead of processing and storing it in the cloud. Advances here could open new avenues for data protection, and it would be worth promoting innovation in this field and studying the feasibility of this approach. The BCI field may also move toward passive control and interaction with devices[127], including interfaces with AI and chatbots, smart homes, neuroadaptive environments, and perhaps even robots. A highlight in this field in Europe is the Neuroadaptivity for Autonomous Systems (NAFAS) project[128], a 30 million euro contract signed in 2023 between the German Cyberagentur and the company Zander Labs to develop BCI prototypes for human-machine interaction.

At the market level, wellness will likely continue to be the largest application segment, driven by sustained public interest in health optimization[27], particularly in the U.S. As technological capabilities expand and increasingly blur the line with medical applications, the regulatory grey zone[13] may grow. This could trigger regulatory discussions and potentially lead to the development of new standards and evidence requirements for wellness devices, which could open the door to their use in health-adjacent applications in certain cases. In the EU, data integration with the healthcare system[75] could happen through the European Health Data Space[129], which could provide a starting point for the introduction of consumer wearable data into health records, and from there, research and analysis could give rise to new medical applications.

In the U.S., Big Tech companies may enter the space [130] in the next five years. Various companies have been placing bets[12] through patents, research partnerships, and investments, and this activity may materialize in the first mainstream product by a Big Tech company that includes neurotechnology. The neural wristband already released by Meta suggests that earbuds or glasses could follow. This could change the landscape significantly: if BCIs are embedded in products that many people already use and trust, the ecosystem shifts from the specialist consumer actively seeking neurotech to something closer to a default option, representing a move from opt-in to opt-out. The questions around data become considerably more pressing in that scenario, though it remains to be seen whether Big Tech will commit to that path, given regulatory uncertainty in consumer markets[131] and the likelihood that consumers will be considerably more demanding about neural data privacy than they have been about smartwatch data.

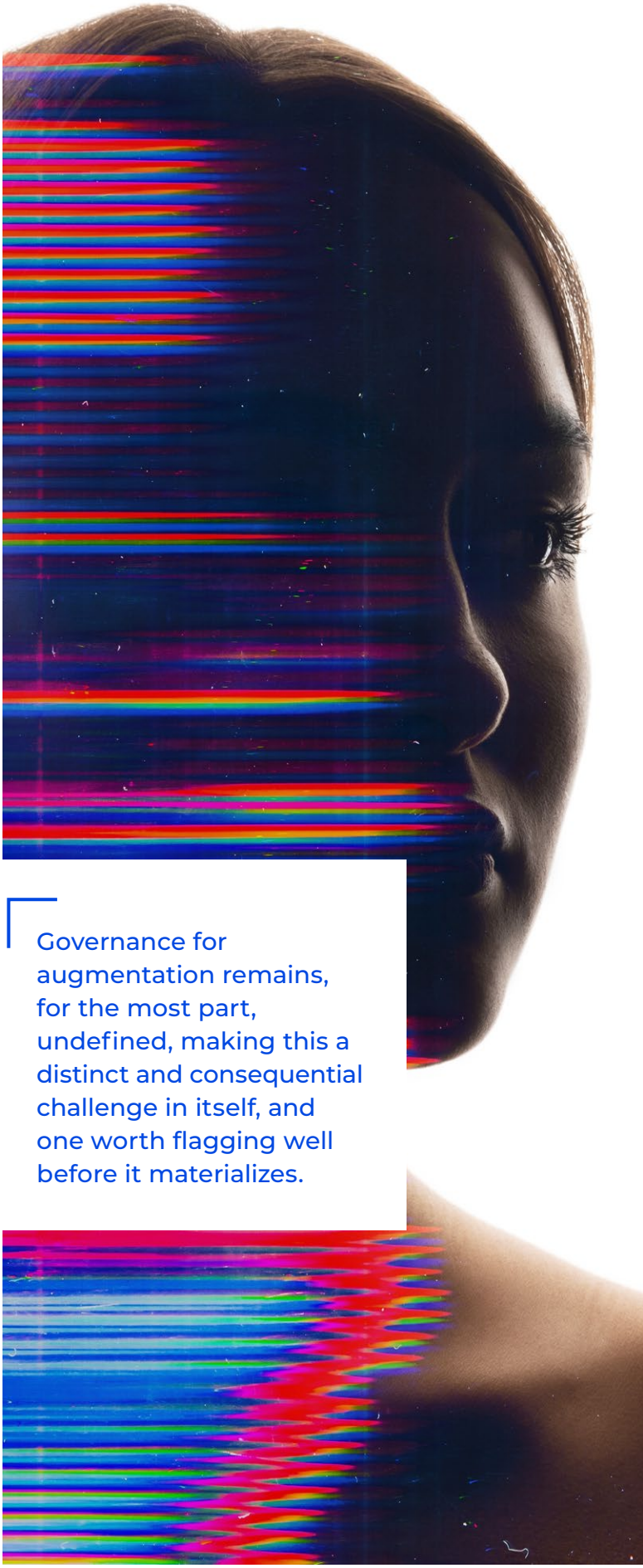
> China could also reshape the market, as it has articulated a strategy[37] to advance its neurotechnology industry and become a global leader by 2030.

Its BCI market is growing rapidly, and China was the first (and so far only) country to bring a brain chip to

market[132]. Its well-developed robotics industry also points toward applications in which BCIs either serve to connect workers with robots, or to train robots using data from workers. If this proves to offer a competitive advantage, other regions may face pressure to adopt solutions before adequate governance is in place, in order not to lose ground.

On the workplace front, where much still depends on how frameworks such as the EU AI Act are implemented, the coming years may see the first real-world deployments of BCIs in occupational settings, with some industries introducing BCIs as a compulsory safety measure that workers must accept as a condition of employment, with a corresponding legal basis. In the U.S., productivity and prevention tools in workplace settings also seem plausible, though this appears considerably more complicated in the EU given existing regulation.

Finally, and likely beyond the five-year horizon for most of these developments, BCIs may find applications in military contexts, particularly in cognitive warfare[133] in civilian settings if BCIs become widespread. If attention data can be intercepted, it could be exploited for commercial purposes or by malicious actors seeking to spread misinformation. The coming years may also see one or more implantable BCI companies announce the development of devices, whether implantable or otherwise[134], for human augmentation[135], a use case for which regulation is not yet in place. This trajectory could be accelerated by the same medical-to-consumer migration discussed in this paper: technologies such as focused ultrasound and neural implants (whether in their conventional invasive form or in newer, minimally invasive variants designed to be safer and potentially reversible) are already substantially more powerful than anything currently available in consumer markets. If these technologies migrate into consumer use without a medical purpose, they could give rise to the first forms of human augmentation, triggering public, policy, and scientific debates about the ethics of augmentation and how to distinguish it from other uses such as restoration or optimization. Governance for augmentation remains, for the most part, undefined, making this a distinct and consequential challenge in itself, and one worth flagging well before it materializes.



Governance for augmentation remains, for the most part, undefined, making this a distinct and consequential challenge in itself, and one worth flagging well before it materializes.

6. RECOMMENDATIONS

Drawing on the analysis presented across this paper, the following recommendations are proposed for the consideration of policymakers, regulators, and industry stakeholders. Although the analysis includes a comparative perspective with the United States, the recommendations are focused on the European context in line with the geographical scope of this study:

Develop proportionate evidence standards for wellness BCIs, and an EU-wide labelling scheme to make those standards legible to consumers.

The regulatory grey zone between wellness and medicine is one of the most pressing governance gaps in the consumer BCI space. While there are no evidence requirements today, evidence requirements should be scaled to the nature of the claim—from basic substantiation for general wellbeing applications to stricter scrutiny where products approach clinically relevant outcomes—without imposing the full burden of medical device certification. A harmonised labelling scheme grounded in these standards, building on existing initiatives such as the European Brain Council's Seal of Responsible Neurotechnologies, would provide consumers with information on important considerations including safety, efficacy, and data security of the device.

Foster structured, continuous, and evidence-based dialogue to resolve the open scientific and governance questions surrounding neural data.

Neural data governance is one of the most extensively debated areas in neurotechnology, with a variety of proposed approaches that reflect the unsettled nature of the underlying questions and the philosophical and social traditions that shape how they are framed. As neural data becomes increasingly central to BCI business models, and increasingly available through consumer and digital markets, key questions require ongoing grounding in the evolving state of the science: whether neural data is categorically distinct or unique, what can and cannot be reliably decoded from consumer-grade devices, how meaningfully neural data can be anonymised or de-anonymised, why or why not neural data protection would suffice for protecting privacy or integrity, or what makes consumer neurotechnologies fundamentally different from other technologies with which we also share information about emotions or thoughts. These questions should be worked out through sustained, inclusive dialogue involving neuroscientists, legal scholars, ethicists, and industry representatives. This dialogue is particularly pressing in light of the prospective entry of major technology companies into consumer BCI markets, which would substantially expand the scale of neural data collection and amplify the consequences of any unresolved ambiguity for consumers and innovators.

Invest in privacy-preserving technologies.

Edge computing, federated learning, and data-minimization architectures offer promising avenues for data protection as governance debates continue. Public investment and international collaboration on these technologies could address some of the most acute concerns around neural data derived from its inclusion in digital ecosystems.

Establish, within the EU, a dedicated international observatory for consumer neurotechnology.

This observatory would monitor market evolution, identify technologies with potential to migrate to consumer markets, potential convergences with other technologies such as AI or robotics, identify enabling developments in adjacent technologies, analyse company claims, investment trends, and track scientific and regulatory developments across jurisdictions. Its focus would be specific on the consumer market. Its concrete outputs could include regularly updated market maps, investment data, scientific summaries and innovation reports, public perception surveys—providing the shared intelligence base that proactive governance of this rapidly evolving field currently lacks.

Support evidence-based public communication about consumer neurotechnologies.

Public narratives in this field have at times outpaced the known capabilities of devices, and, when insufficiently grounded in science, they risk eroding public trust, amplifying unfounded concerns, and affecting responsible innovators. Reputational consequences of this kind may extend beyond consumer markets, potentially affecting a field that, in its clinical form, represents in many cases the only available therapeutic pathway for patients with certain neurodegenerative and psychiatric conditions, as the prevalence of these conditions continues to rise. Europe's scientific and industry communities are well-placed to contribute to a more measured and realistic public discourse, including among regulators and governments.

7. CONCLUSION: A WINDOW FOR PROACTIVE GOVERNANCE

BCIs have moved beyond clinical and research settings into consumer markets and digital ecosystems. Technologies originally developed to restore lost function are now being integrated into products such as headphones, earbuds or glasses marketed for sleep monitoring, stress management, cognitive performance, or workplace safety.

This transition creates remarkable and new opportunities to interact with external devices, expand access to brain wellness and health tools, generate large-scale physiological datasets, and accelerate the development of devices that combine clinical relevance with usability. At the same time, it raises important questions about the nature, collection, use, and commercialization of neural data, about what evidence standards are reasonable in wellness markets, or even about what constitutes thought or emotion versus other physiological states. As neurotechnology increasingly becomes embedded in everyday products that operate through digital ecosystems, decisions about data governance, evidence standards, user protection, and responsible ethical innovation are also becoming increasingly intertwined with digital policy.

The coming years are likely to be a critical period for the development of consumer BCIs, given the pace of technological developments, the growth of the industrial and investment ecosystem, and the interest demonstrated by large technology companies in the field. Many of the standards, evidence requirements, and data protection frameworks that will shape this promising sector are still under development. Therefore, there remains a significant opportunity to influence in an anticipatory, inclusive, and evidence-based manner, how consumer BCIs evolve and how its benefits and risks are distributed across society—and given the breadth of those potential benefits, there is every reason to ensure that it is they, not the risks, that prevail.

REFERENCES

1 'The Mind. Unlocked.: Work Smarter, Not Longer' (Neurable), www.neurable.com, accessed 11 June 2026.

2 'Advanced Brain Data & Wireless EEG Solutions' (Emotiv), www.emotiv.com, accessed 11 June 2026.

3 (AAVAA glasses), aavaa.com/products/glasses, accessed 11 June 2026.

4 'EMG Wristbands and Technology' (Meta), www.meta.com/en-gb/emerging-tech/emg-wearable-technology, accessed 11 June 2026.

5 'Mining Fleet: Safety: Safer Operations: Fleet Management Systems (FMS)—WENCO Mining Systems' (Mining Fleet | Safety | Safer Operations | Fleet Management Systems (FMS)—Wenco Mining Systems), www.wencomine.com/our-solutions/safety, accessed 11 June 2026.

6 'Sabi—Just Think' (—Just Think), https://sabi.com, accessed 11 June 2026.

7 'BrainBit Headphones' (BrainBit), https://store.brainbit.com/products/brainbit-headphones, accessed 11 June 2026.

8 'Project Overview ' Neurochat' (MIT Media Lab), www.media.mit.edu/projects/neurochat-ai-bci/overview, accessed 11 June 2026.

9 'Yneuro: The Startup behind Neuro ID®' (YNEURO 2024), www.yneuro.com, accessed 11 June 2026.

10 'BCI Definition' (bcisociety.org, 7 January 2025), https://bcisociety.org/bci-definition, accessed 11 June 2026.

11 Caiado F and Ukolov A, 'The History, Current State and Future Possibilities of the Non-Invasive Brain Computer Interfaces' (2025) 25 Medicine in Novel Technology and Devices 100353.

12 Bernáez Timón L and Mahieu V, 'Neurotech Consumer Market Atlas—How the Sector Is Making Moves into the Mainstream' (Centre for Future Generations, 2026).

13 Bernáez Timón L and Mahieu V, 'Introducing "Neurotech between Wellness and Medicine"' (Centre for Future Generations, 23 April 2026).

14 Vincenzo R and others, 'Beyond the Lab: Real-World Benchmarking of Wearable EEGs for Passive Brain-Computer Interfaces' (2025) 13 Brain Informatics.

15 European Commission, Joint Research Centre, 'Emerging Applications of Neurotechnology and Their Implications for EU Governance: A Technology Foresight Study' (EU Policy Lab 2025).

16 OECD, 'Issues in Neurotechnology Governance' (OECD Publishing, May 2018).

17 UNESCO, 'Ethics of Neurotechnology' (UNESCO), www.unesco.org/en/ethics-neurotech, accessed 22 June 2026.

18 Life Science Intelligence, 'BCI Market: Following the Capital Into Neurotechnology's Next Frontier' (2026), www.lifesciencemarketresearch.com/insights/bci-market-following-the-capital-into-neurotechnologys-next-frontier, accessed 11 June 2026.

19 Consumer BCI: Are We Ready for Mass-Market Brain-Controlled Gadgets? Medium), https://medium.com/@lanceharvieruntime/consumer-bcis-are-we-ready-for-mass-market-brain-controlled-gadgets-b21fdfe59f77, accessed 11 June 2026.

20 Rao N, 'Models to Markets: BCI, Neural Data, and Business Innovation in the AI Era' (NEUROTECH FUTURES, 28 March 2026), https://neurotechnology.substack.com/p/representations1, accessed 11 June 2026.

21 'Over a Billion People Living with Mental Health Conditions—Services Require Urgent Scale-Up' (World Health Organization), www.who.int/news/item/02-09-2025-over-a-billion-people-living-with-mental-health-conditions-services-require-urgent-scale-up, accessed 11 June 2026.

22 'Mental Health Atlas 2024' (World Health Organization), www.who.int/publications/i/item/9789240114487, accessed 11 June 2026.

23 World Health Organization, Global Status Report on Neurology (WHO 2025) ISBN 978-92-4-011613-9, www.who.int/publications/i/item/9789240116139, accessed 22 June 2026.

24 Benjafield AV and others, 'Estimation of the Global Prevalence and Burden of Insomnia: A Systematic Literature Review-Based Analysis' (2025) 82 Sleep Medicine Reviews 102121.

25 European Commission, 'Flash Eurobarometer 530: Mental Health' (October 2023), https://europa.eu/eurobarometer/surveys/detail/3032, accessed 11 June 2026.

26 European Psychiatric Association, 'Socioeconomic Inequalities Drive Significant Gaps in Access to Mental Health Care Across the European Union' (Press Release, 7 April 2025), www.europsy.net/app/uploads/2025/04/Socioeconomic-Inequalities-Drive-Significant-Gaps-in-Access-to-Mental-Health-Care-Across-the-EU.pdf, accessed 11 June 2026.

27 'The Future of Wellness Trends Survey 2025' (Mckinsey), www.mckinsey.com/industries/consumer-packaged-goods/our-insights/future-of-wellness-trends, accessed 11 June 2026.

28 Wolfgang Fengler, Juan Caballero and Vijeth Iyengar, 'The Age of the Longevity Economy' (Brookings Institution, 29 January 2024), www.brookings.edu/articles/the-age-of-the-longevity-economy, accessed 22 June 2026.

29 'Facebook Announces Acquisition of Brain Computing Start-up CTRL Labs' CNBC (23 September 2019), www.cnbc.com/2019/09/23/facebook-announces-acquisition-of-brain-computing-start-up-ctrl-labs.html, accessed 11 June 2026.

30 US Patent Application 2023/0225659 A1, Biosignal Sensing Device Using Dynamic Selection of Electrodes (filed 9 January 2023, published 20 July 2023) (Azemi and others, assigned to Apple Inc), https://patents.google.com/patent/US20230225659A1/en, accessed 11 June 2026.

31 'Apple Teams Up with a Brain-Computer Startup to Turn Thoughts Into Device Control' Fast Company (13 May 2025, www.fastcompany.com/91333747/apple-partners-with-a-brain-computer-startup-to-turn-thoughts-into-device-control, accessed 11 June 2026.

32 Kaushik P and others, 'Decoding the Cognitive States of Attention and Distraction in a Real-Life Setting Using EEG' (2022) 12 Scientific Reports.

33 Ding Y and others, 'EEG-Based Brain-Computer Interface Enables Real-Time Robotic Hand Control at Individual Finger Level' (2025) 16 Nature Communications.

34 Apicella A and others, 'EEG-Based Measurement System for Monitoring Student Engagement in Learning 4.0' (2022) 12 Scientific Reports.

35 Prabowo DW and others, 'A Systematic Literature Review of Emotion Recognition Using EEG Signals' (2023) 82 Cognitive Systems Research 101152.

36 'Neurotechnology Market Size to Hit USD 59.02 Billion by 2035' (Precedence Research), www.precedenceresearch.com/neurotechnology-market, accessed 11 June 2026.

37 State Council of the People's Republic of China, 'Guidance on Deeply Implementing the "Artificial Intelligence+" Action' (26 August 2025), www.gov.cn/zhengce/zhengceku/202508/content_7035603.htm, accessed 11 June 2026.

38 UNESCO, Recommendation on the Ethics of Neurotechnology (11 November 2025), www.unesco.org/en/legal-affairs/recommendation-ethics-neurotechnology, accessed 11 June 2026.

39 Magee P, Ienca M and Farahany N, 'Beyond Neural Data: Cognitive Biometrics and Mental Privacy' (2024) 112 Neuron 3017.

40 Somnee, 'Somnee 2.0: Your All-in-One Sleep Solution' (Somnee, https://somneesleep.com, accessed 11 June 2026.

41 ChooseMuse, 'The Brain Sensing Headband Store with Worldwide Shipping' (Muse), https://choosemuse.com, accessed 11 June 2026.

42 'Better Focus, Better Performance.' (Mendi.io), www.mendi.io, accessed 11 June 2026.

43 'FocusCalm For Sports Teams & Athletes' (FocusCalm), https://focuscalm.com/pages.

44 'Emotiv MW20: EEG Neuro Earphones for Brain Activity Tracking' (Emotiv MW20 | EEG Neuro Earphones for Brain Activity Tracking, www.emotiv.com/mw20?srsltid=AfmBOopN8hDWa4cDlDYnDuJlSx9-g9IdjqyzJskJmHzHk-WU5REBGAE, accessed 11 June 2026.

45 'Reliable and User-Friendly Neurotechnology' (Bitbrain), www.bitbrain.com, accessed 11 June 2026.

46 Bernáez Timón L and Mahieu V, 'Promise and Peril in Wellness Neurotech' (Centre for Future Generations, 1 April 2026).

47 Nandini D and others, 'An Ensemble Deep Learning Framework for Emotion Recognition through Wearable Devices Multi-Modal Physiological Signals' (2025) 15 Scientific Reports.

48 He C and others, 'Wearable EEG Devices in the Detection of Mild Cognitive Impairment: A Systematic Review' (2026) 9 npj Digital Medicine.

49 Markov K, Elgendi M and Menon C, 'Evaluating the Performance of Wearable EEG Sleep Monitoring Devices: A Meta-Analysis Approach' (2025) 2 npj Biomedical Innovations.

50 Kaushik P and others, 'Decoding the Cognitive States of Attention and Distraction in a Real-Life Setting Using EEG' (2022) 12 Scientific Reports.

51 Apicella A and others, 'EEG-Based Measurement System for Monitoring Student Engagement in Learning 4.0' (2022) 12 Scientific Reports.

52 Kaveh R and others, 'Wireless Ear EEG to Monitor Drowsiness' (2024) 15 Nature Communications.

53 Kakhi K and others, 'Fatigue Monitoring Using Wearables and AI: Trends, Challenges, and Future Opportunities' (2025) 195 Computers in Biology and Medicine 110461.

54 Guenther S, Kosmyna N and Maes P, 'Image Classification and Reconstruction from Low-Density EEG' (2024) 14 Scientific Reports.

55 Prabowo DW and others, 'A Systematic Literature Review of Emotion Recognition Using EEG Signals' (2023) 82 Cognitive Systems Research 101152.

56 d'Ascoli S and others, 'Towards Decoding Individual Words from Non-Invasive Brain Recordings' (2025) 16 Nature Communications.

57 Défossez A and others, 'Decoding Speech Perception from Non-Invasive Brain Recordings' (2023) 5 Nature Machine Intelligence 1097.

58 Huang L, Varlet M and Grootswagers T, 'Robust neural decoding with low-density EEG' (2025) Scientific Reports.

59 Wexler A and Reiner PB, 'Oversight of Direct-to-Consumer Neurotechnologies' (2019) 363 Science 234.

60 Steindl E, 'Consumer Neuro Devices within EU Product Safety Law: Are We Prepared for Big Tech Ante Portas?' (2024) 52 Computer Law & Security Review 105945.

61 Coates McCall I and others, 'Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies' (2019) 102 Neuron 728.

62 Wexler A and Thibault R, 'Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications' (2018) 3 Journal of Cognitive Enhancement 131.

63 Food and Drug Administration, General/Specific Intended Use—Guidance for Industry (4 November 1998), www.fda.gov/regulatory-information/search-fda-guidance-documents/generalspecific-intended-use-guidance-industry, accessed 11 June 2026.

64 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, art 2(12).

65 Ienca M, Haselager P and Emanuel EJ, 'Brain Leaks and Consumer Neurotechnology' (2018) 36 Nature Biotechnology 805.

66 Nita A Farahany, The Battle for Your Brain: Defending the Right to Think Freely in the Age of Neurotechnology (St Martin's Press 2023).

67 Smuck M and others, 'The Emerging Clinical Role of Wearables: Factors for Successful Implementation in Healthcare' (2021) 4 npj Digital Medicine.

68 Stangl M, Maoz SL and Suthana N, 'Mobile Cognition: Imaging the Human Brain in the "Real World"' (2023) 24 Nature Reviews Neuroscience 347.

69 Wall C, Hetherington V and Godfrey A, 'Beyond the Clinic: The Rise of Wearables and Smartphones in Decentralising Healthcare' (2023) 6 npj Digital Medicine.

70 Dubois J and others, 'A Functional Neuroimaging Biomarker of Mild Cognitive Impairment Using TD-FNIRS' (2025) 1 npj Dementia.

71 He C and others, 'Wearable EEG Devices in the Detection of Mild Cognitive Impairment: A Systematic Review' (2026) 9 npj Digital Medicine.

72 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

73 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

74 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

75 Bernáez Timón L and Mahieu V, 'Clarifying the Grey Zone: A Proposal' (Centre for Future Generations, 2026).

76 Label2Enable, 'Home' (Label2Enable), https://label2enable.eu, accessed 22 June 2026.

77 'EBC Introduces the Seal of Responsible Neurotechnologies' (International Brain Initiative, 22 April 2026), https://www.internationalbraininitiative.org/news/byrh7h55cn7mebheaoobic2zxqqkl7, accessed 22 June 2026.

78 European Brain Council, 'European Charter for the Responsible Development of Neurotechnologies' (European Brain Council, April 2025), www.braincouncil.eu/european-charter-for-the-responsible-development-of-neurotechnologies, accessed 22 June 2026.

79 Bernáez Timón L and Mahieu V, 'How Neurotech Companies Navigate the Grey Zone' (Centre for Future Generations, 2026).

80 'Medication-Free Depression Treatment at Home' (Flow Neuroscience), www.flowneuroscience.com, accessed 11 June 2026.

81 'Insomnia Relief with Neurostimulator Device – Modius Sleep' (Neurovalens), https://neurovalens.com, accessed 11 June 2026.

82 'FDA Grants World's First Neuromodulation Device to Treat Symptoms of PTSD' (Neurovalens, 26 May 2026), https://neurovalens.com/nv_news/fda-grants-worlds-first-neuromodulation-device-to-treat-symptoms-of-ptsd, accessed 11 June 2026.

83 University of Oxford, 'New Ultrasound Helmet Enables Deep Brain Stimulation in People Without Surgery' (University of Oxford, 9 September 2025), www.ox.ac.uk/news/2025-09-09-new-ultrasound-helmet-enables-deep-brain-stimulation-people-without-surgery, accessed 22 June 2026.

84 'Neurotechnology, Elon Musk and the Goal of Human Enhancement' (The Guardian, 1 January 2018), www.theguardian.com/technology/2018/jan/01/elon-musk-neurotechnology-human-enhancement-brain-computer-interfaces, accessed 22 June 2026.

85 Wascher E and others, 'Neuroergonomics on the Go: An Evaluation of the Potential of Mobile EEG for Workplace Assessment and Design' (2021) 65 Human Factors: The Journal of the Human Factors and Ergonomics Society 86.

86 Shelkke T, Jain DR and Singh M, 'The Impact of Neurotechnology on Employee Motivation and Workplace Productivity' (2025) 4 GLIMS Journal of Management Review and Transformation.

87 Brandt-Rauf PW and Ayaz H, 'Occupational Health and Neuroergonomics' (2024) 66 Journal of Occupational & Environmental Medicine 456.

88 'Neurable for Teams' (Neurable), www.neurable.com/partner/neurable-for-teams, accessed 11 June 2026.

89 'MeSpace Names Neurable as Official Research Partner to Explore How Workspace Design Impacts Cognitive Performance' (PR Newswire, 15 October 2025), www.prnewswire.com/news-releases/mespace-names-neurable-as-official-research-partner-to-explore-how-workspace-design-impacts-cognitive-performance-302584151.html, accessed 11 June 2026.

90 Toppinen-Tanner S and others, 'Burnout as a Predictor of Medically Certified Sick-Leave Absences and Their Diagnosed Causes' (2005) 31 Behavioral Medicine 18.

91 Martinez W and others, 'Understanding the Ethical Concerns for Neurotechnology in the Future of Work' [2022] 2022 Symposium on Human-Computer Interaction for Work 1.

92 Venthur B and others, 'Novel Applications of BCI Technology: Psychophysiological Optimization of Working Conditions in Industry' [2010] 2010 IEEE International Conference on Systems, Man and Cybernetics 417.

93 'Project Overview ' Ddog' (MIT Media Lab), www.media.mit.edu/projects/ddog/overview, accessed 11 June 2026.

94 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

95 Kellmeyer P, 'Big Brain Data: On the Responsible Use of Brain Data from Clinical and Consumer-Directed Neurotechnological Devices' (2018) 14 Neuroethics 83.

96 Ienca M and others, 'Towards a Governance Framework for Brain Data' (2022) 15 Neuroethics.

97 Radu R, 'Cognitive Frontiers: Neurotechnology and Global Internet Governance' (2025) 7 Frontiers in Digital Health

98 Jared Genser, Stephen Damianos and Rafael Yuste, Safeguarding Brain Data: Assessing the Privacy Practices of Consumer Neurotechnology Companies (Neurorights Foundation 2024, https://perseus-strategies.com/wp-content/uploads/FINAL_Consumer_Neurotechnology_Report_Neurorights_Foundation_April-1.pdf, accessed 22 June 2026.

99 Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down detailed rules for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the reclassification of groups of certain active products without an intended medical purpose.

100 Baeken C and others, 'European Reclassification of Non-Invasive Brain Stimulation as Class III Medical Devices: A Call to Action' (2023) 16 Brain Stimulation 564.

101 Antal A and others, 'Note of Concern Regarding the Sources of Scientific Evidence Used to Justify the Reclassification of Non-Invasive Brain Stimulation (NIBS) Devices without an Intended Medical Purpose into Class III' (2025) 18 Brain Stimulation 103.

102 Antal A and others, 'The Consequences of the New European Reclassification of Non-Invasive Brain Stimulation Devices and the Medical Device Regulations Pose an Existential Threat to Research and Treatment: An Invited Opinion Paper' (2024) 163 Clinical Neurophysiology 280.

103 Food and Drug Administration, General Wellness: Policy for Low Risk Devices (6 January 2026), www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices, accessed 11 June 2026.

104 Wexler A and Reiner PB, 'Oversight of Direct-to-Consumer Neurotechnologies' (2019) 363 Science 234.

105 'White House, Tech Leaders Commit to Create Patient-Centric Healthcare Ecosystem' (29 July 2025), www.cms.gov/newsroom/press-releases/white-house-tech-leaders-commit-create-patient-centric-healthcare-ecosystem, accessed 11 June 2026.

106 'Control for Whom? Keeping an Eye on the Dark Side of US's New Wearables Campaign' Tech Policy Press (2 October 2025), www.techpolicy.press/control-for-whom-keeping-an-eye-on-the-dark-side-of-americas-new-wearables-campaign, accessed 11 June 2026.

107 'Samphire Headband'(Samphire Neuroscience), www.samphireneuro.com/en-us/products/headband, accessed 11 June 2026.

108 'Samphire Neuroscience—Women's Health & Neuroscience Solutions' (Samphire Neuroscience), www.samphireneuro.com/en-eu, accessed 11 June 2026.

109 Bublitz C, Molnár-Gábor F and Soekadar SR, 'Implications of the Novel EU AI Act for Neurotechnologies' (2024) 112 Neuron 3013.

110 European Commission, Guidelines on prohibited artificial intelligence practices established by Regulation (EU) 2024/1689 (AI Act) (4 February 2025), https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-prohibited-artificial-intelligence-ai-practices-defined-ai-act, accessed 11 June 2026.

111 Bublitz Jan Christoph, Philipp Kellmeyer and Fruzsina Molnár-Gábor, 'Brain Stimulation May Be a Subliminal Technique Under the European Union's Artificial Intelligence Act' (April 2025), European Journal of Neuroscience 61(8) e70115.

112 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), art 99.

113 European Commission, Draft Guidelines on the Classification of High-Risk AI Systems (18 May 2026), https://digital-strategy.ec.europa.eu/en/library/draft-commission-guidelines-classification-high-risk-ai-systems, accessed 11 June 2026.

114 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), art 50.

115 Council of the European Union, 'Artificial Intelligence: Council and Parliament Agree to Simplify and Streamline Rules' (Press Release, 7 May 2026), www.consilium.europa.eu/en/press/press-releases/2026/05/07/artificial-intelligence-council-and-parliament-agree-to-simplify-and-streamline-rules, accessed 11 June 2026.

116 Ienca M, 'On Neurorights' (2021) 15 Frontiers in Human Neuroscience.

117 European Expert Group on Human Rights and Emerging Technologies, 'A Plea to Make Neural Data a Special Category in the GDPR', https://drive.google.com/file/d/1_Y3SOykzvWyB-sx7OuY1yDFkvSZzZW0o/view?usp=sharing, accessed 22 June 2026.

118 Elisabeth Steindl, A Datafied Mind: Untangling EU Regulation of Emotion Technology and Neurotechnology (Cambridge University Press 2025).

119 Ienca M and Malgieri G, 'Mental Data Protection and the GDPR' [2021] SSRN Electronic Journal.

120 S 2925, Management of Individuals' Neural Data Act of 2025 (MIND Act of 2025), 119th Congress (29 September 2025), www.congress.gov/bill/119th-congress/senate-bill/2925/text/is, accessed 11 June 2026.

121 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 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) OJ L 119/1, art 44.

122 'US and UK Refuse to Sign Paris Summit Declaration on "inclusive" Ai' (The Guardian, 11 February 2025), www.theguardian.com/technology/2025/feb/11/us-uk-paris-ai-summit-artificial-intelligence-declaration, accessed 11 June 2026.

123 IEEE Engineering in Medicine and Biology Society, 'IEEE P2731: Standard for a Unified Terminology for Brain-Computer Interfaces' (2019), https://sagroups.ieee.org/2731, accessed 11 June 2026.

124 OECD, Recommendation of the Council on Responsible Innovation in Neurotechnology (OECD/LEGAL/0457, adopted 11 December 2019), https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457, accessed 11 June 2026.

125 Chen Y and others, 'Several Inaccurate or Erroneous Conceptions and Misleading Propaganda about Brain-Computer Interfaces' (2024) 18 Frontiers in Human Neuroscience.

126 Rusconi E and Mitchener-Nissen T, 'The Role of Expectations, Hype and Ethics in Neuroimaging and Neuromodulation Futures' (2014) 8 Frontiers in Systems Neuroscience.

127 'Passive BCIS: Key to Ai Potential' (Zander Labs), www.zanderlabs.com/blog/passive-bcis-key-to-ai-potential, accessed 11 June 2026.

128 'Revolution in Neuro-Adaptive Human-Machine Interaction' (Cyberagentur, 16 January 2025), www.cyberagentur.de/en/press/30-million-euros-largest-research-financing-in-europe-to-cottbuser-startup, accessed 11 June 2026.

129 Regulation (EU) 2025/327 of the European Parliament and of the Council of 12 February 2025 on the European Health Data Space (European Health Data Space Regulation) OJ L 56.

130 'Silicon Valley wants to put a chip in your brain', (Politico), www.politico.com/news/magazine/2026/05/15/silicon-valley-ai-transhumanism-brain-data-00900799, accessed 11 June 2026.

131 Mahieu V and Cevik, M O'Mapping Neurotech Governance' (Centre for Future Generations, 16 October 2025), https://cfg.eu/neurotech-governance-map, accessed 11 June 2026.

132 Fieldhouse R and You X, 'China Approves Brain Chip to Treat Paralysis — a World First' (2026) 651 Nature 865.

133 Giordano James, 'Cognitive Warfare 2026: NATO's Chief Scientist Report as Sentinel Call for Operational Readiness' Strategic Insights (6 January 2026), https://digitalcommons.ndu.edu/strategic-insights/44, accessed 11 June 2026.

134 A 'New Therapeutic Brain Implants Could Defy the Need for Surgery' (MIT News, 5 November 2025), news.mit.edu/2025/new therapeutic-brain-implants-defy-surgery-need-1105, accessed 22 June 2026

135 Lex Fridman, 'Elon Musk: Neuralink and the Future of Humanity — Transcript' (Lex Fridman Podcast, 2 August 2024), https://lexfridman.com/elon-musk-and-neuralink-team-transcript, accessed 22 June 2026

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