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SHIFT

THE NEUROTECHNOLOGY

Translating medical neurotechnologies into non-clinical contexts

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EXECUTIVE SUMMARY

Neurotechnology is advancing faster than the rules designed to govern it. The migration of devices from clinical to consumer markets is accelerating, driven by AI, miniaturization and commercial pressure. The window for proactive policy action is now open, but will not remain so indefinitely, and the cost of inaction is rising. A key issue is that technologies do not stay in their original category, with devices developed in clinical settings increasingly migrating into consumer markets, often passing through a regulatory grey zone where neither clinical nor consumer rules clearly apply. Understanding this migration dynamic is essential to understanding the field's risks.

Neurotechnology—devices that can read, interpret, or influence brain activity—is rapidly moving out of hospital and laboratory settings into everyday life, offering the promise of earlier diagnosis of neurological disease, mental health support, restored communication for people with paralysis, and new tools for learning and performance. The field spans three overlapping categories: research tools, tightly regulated clinical devices such as deep brain stimulators and cochlear implants, and a rapidly expanding consumer market including devices such as EEG headbands, neurofeedback apps, and gaming brain-computer interfaces. A critical finding is that technologies do not stay in their original category. Devices developed in clinical settings increasingly migrate into consumer markets, often passing through a regulatory grey zone where neither clinical nor consumer rules apply clearly.

Among the technologies most likely to shape the near-term landscape, consumer EEG is the most mature, with recent advances in artificial intelligence dramatically expanding what can be decoded from simple wearable devices. Wearable functional near-infrared spectroscopy (fNIRS) is enabling continuous brain health monitoring during everyday life at previously infeasible scale. Focused ultrasound is perhaps the most transformative emerging modality, capable of stimulating deep brain regions non-invasively, though its development in Europe is currently hampered by regulation widely regarded as disproportionate to its actual risk profile.

These opportunities sit alongside serious risks that the current regulatory landscape is ill-equipped to address. Brain data is uniquely sensitive, yet its legal status remains unclear, and commercial incentives to exploit it are growing.

The potential for employer use of neural monitoring raises profound concerns about coercion and privacy. Many consumer companies make health-adjacent marketing claims without the evidence that would be required of a regulated medical device. Each of these risks is sharpened by the migration dynamic: as devices move across categories, they carry capabilities that existing rules were not designed to govern.

1.

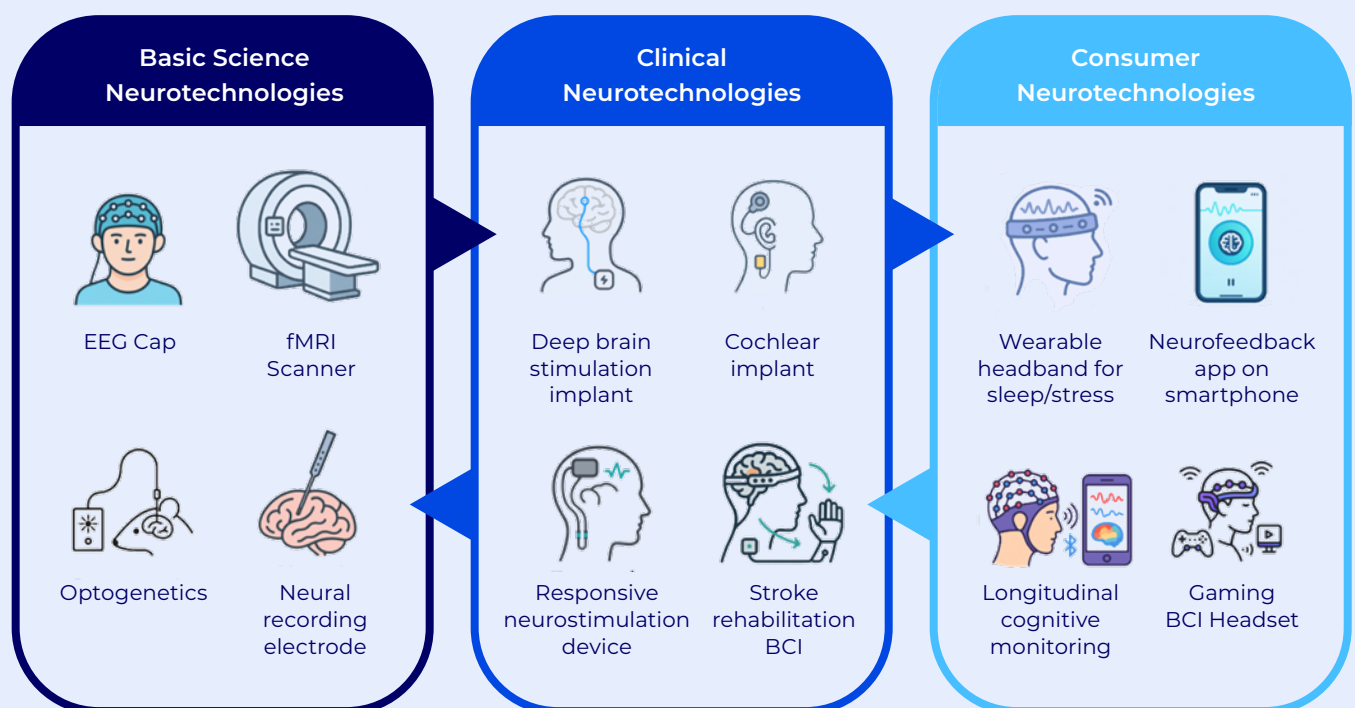
INTRODUCTION

Over the past two decades, neurotechnology has advanced from relatively specialized laboratory and hospital tools into a rapidly expanding ecosystem of devices and platforms that can sense, interpret, and increasingly influence brain and nervous-system activity. This has delivered real social value through earlier diagnosis of neurological disease, improved neurorehabilitation, personalized mental health support, restored communication and mobility, and new forms of human-computer interaction.

While there is an obvious distinction between medical neurotechnologies—those intended for clinical treatment, with all the regulatory hurdles that that entails—and non-medical neurotechnologies, we might actually consider these technologies to occupy three partially overlapping classes (see **Figure 1**).

1 Firstly, there are **tools developed for basic neuroscience discovery research**. These include high-density electro-encephalography (EEG) and magnetoencephalography (MEG), functional magnetic resonance imaging (fMRI), “neuropixels” high density intracortical recording probes, and optogenetic brain

Figure 1.
Translation of neurotechnologies across domain boundaries.
Source: Author's elaboration



stimulation tools that can be used to activate neurons that have been genetically modified to express light-activated channels.

2 Secondly, there are technologies that have been **developed for or translated into clinical care**. These include deep brain stimulation for Parkinson’s disease, cochlear implants, post-stroke neurorehabilitation platforms and responsive neurostimulation for treating drug-resistant epilepsy.

3 Finally, there are **an increasing number of neurotechnologies that are addressing the consumer**, or “wellness”, space. These include wearable devices for sleep and stress monitoring, neurofeedback apps coupled to consumer-grade EEG, focus enhancement devices and gaming-oriented brain-computer interfaces. Of course, devices do not necessarily stay in these categories—and a key focus of this article is the potential for devices to cross these category boundaries (which are in any case fuzzy), for instance by medical neurotechnologies entering the consumer space.

Each of these three classes of neurotechnology operates under a markedly different regulatory framework, and this has significant implications for the safety, accountability, and governance of devices that move between categories. Clinical neurotechnologies face the most stringent oversight. In the United States, implantable and high-risk devices such as deep brain stimulators and responsive neurostimulation systems are classified as Class III medical devices, requiring Pre-Market Approval (PMA) from the Food and Drug Administration (FDA)—the most rigorous of the FDA’s review pathways—as well as compliance with the Investigational Device Exemption (IDE) program during clinical trials¹. In the European Union, equivalent devices must satisfy the requirements of the Medical Device Regulation (EU MDR), a legal framework which came into force in 2021, and introduced substantially stricter conformity assessment procedures than its predecessor².



Clinical research tools that have not yet reached the market, such as novel intracortical recording probes or investigational optogenetic systems for research on human subjects, are governed by a separate but overlapping framework: Institutional Review Boards (IRBs) in the US are mandated to provide independent ethical oversight of all FDA-regulated investigational device studies, evaluating informed consent procedures, risk-benefit ratios, and cybersecurity protections³. Similar research ethics committees exist in the UK and EU.

By contrast, consumer neurotechnologies occupy a far more permissive regulatory environment. Because many consumer-grade EEG headsets, neurofeedback applications, and focus-enhancement devices are marketed as wellness or lifestyle products rather than medical devices, they are largely exempt from the clinical evidence requirements that govern their medical counterparts. A 2025 analysis by the Centre for Future Generations found that consumer-focused neurotechnology companies now outnumber medical ones globally (153 firms versus 118, with the number of consumer neurotechnology companies having overtaken the number of medical ones in 2018)⁴.



Many consumer firms rely on technologies such as EEG precisely because of their portability and exemption from medical device regulations, based upon the intended use. Indeed, such companies often operate in what the same analysis describes as a “grey zone,” deploying health-adjacent marketing language while avoiding clinical trials that would trigger regulatory scrutiny⁵.

In the EU, neurotechnology is not governed by any single dedicated framework but rather by a patchwork of cross-cutting regulations addressing data privacy, product safety, AI, and consumer protection, with the EU AI Act being the first instrument outside the MDR to explicitly reference neurotechnology⁶.

Neural data itself sits at an uncertain intersection of legal frameworks: under the General Data Protection Regulation (GDPR) its classification may be contested, while under the AI Act it would likely be treated as biometric data subject to the highest protections⁷. At the national level, some jurisdictions are beginning to act more specifically: several US states, including California and Colorado, have explicitly included neural data in their privacy laws, and Chile has gone further still, enshrining neurorights in its constitution⁸. Nevertheless, the overarching picture remains one of significant regulatory asymmetry, with the most invasive and potentially consequential technologies subject to the greatest scrutiny, and the most widely deployed consumer devices subject to the least. This asymmetry becomes particularly consequential when, as discussed below, technologies migrate across category boundaries. Addressing this asymmetry requires not only national regulatory reform, but also sustained coordination across institutions and jurisdictions, a challenge that existing international bodies are only beginning to take seriously.



2.

PATHWAYS FOR TRANSLATION OF MEDICAL TECHNOLOGIES INTO NON-CLINICAL CONTEXTS

Medical interventions provide much of the impetus for the development of neurotechnology. In particular, several “star” technologies, the cochlear implant and the development of deep brain stimulation (DBS) technology for alleviating the symptoms of Parkinson’s disease, have become standout examples of the tremendous benefits neurotechnology can bring to society, with over 244,000 DBS devices implanted worldwide⁹, and over one million cochlear implants¹⁰.

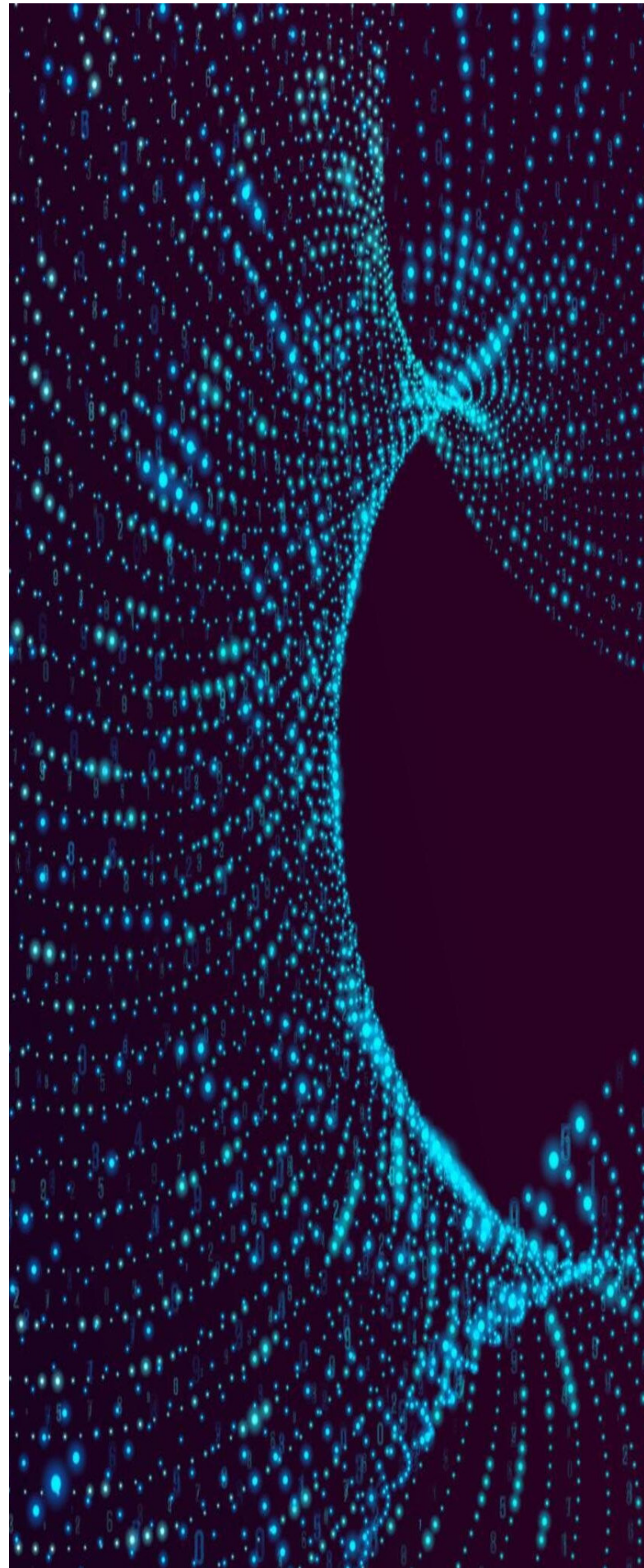
This has of course led to much drive to spread this technological spearhead into wide-spread domains of clinical neuroscience, ranging from treatments for depression, epilepsy, a wide variety of neurodegenerative disorders, restoration of vision, and brain-computer interface devices aimed at giving patients with tetraplegia or locked-in syndrome a chance to have a more normal life. Clinical neurotechnology is currently advancing at a rapid pace, with for instance 67 participants having received implants of invasive brain-computer interfaces as of 2025¹¹. This is leading to pressure to expand the domain of application from clinical to consumer problems—“to confine the ambition of neurotechnology to the clinic would be to leave its greatest potential for human flourishing untapped”¹². In this view, clinical problems are a proving ground for the technology, enabling safety to be validated through the current strict regulatory regime, but with an inevitable flow through to satiation of consumer demand. Nevertheless, there is no current regulatory pathway linking clinical to consumer neurotechnology. The most relevant precedent is the hearing aid, which was until recently considered a Class I or II medical device. In 2022, the US FDA created a new category for over-the-counter hearing aids, which in turn enabled

Apple to achieve FDA approval for the use of their AirPods Pro as a software-based hearing aid¹³. This is perhaps illustrative of a regulatory pathway that *could* exist in wider form for translation of clinical neurotechnologies into consumer markets.

The question of which medical neurotechnologies carry the greatest potential for translation into non-clinical contexts is, in large part, a question of economics, portability, and data yield. It is worth beginning with the technologies that, despite their scientific and clinical power, are unlikely to make that transition in any meaningful timeframe. Structural and functional magnetic resonance imaging (MRI and fMRI), magnetic resonance spectroscopy (MRS), positron emission tomography (PET), and magnetoencephalography (MEG) all offer exceptional spatial or spectral resolution, and remain indispensable tools in both clinical diagnosis and basic neuroscience research. However, each requires infrastructure that is fundamentally incompatible with consumer deployment: MRI and fMRI systems demand superconducting magnets, shielded rooms, and highly trained operators, with capital costs typically exceeding \$1–3 million; PET additionally requires on-site cyclotron facilities or proximity to a radiopharmaceutical supply chain; and MEG, while offering millisecond-level temporal resolution of magnetic brain signals, requires magnetically shielded rooms that place it firmly in the domain of specialist research centers. For the foreseeable future, these modalities will remain confined to hospital and research settings, and their contribution to the consumer neurotechnology landscape is more likely to come through the large normative datasets they have already generated—datasets which increasingly serve as reference standards against which more portable technologies are benchmarked—than through direct deployment.

In an era where the prevailing motto of the Silicon Valley tech industry remains “move fast and break things”, it is important to consider the risks from a regulatory and societal perspective. A cautionary historical precedent is provided by the story of Teletronics Pacing Systems (TPS), an Australian technology company which made significant contributions to cardiac pacemaker technology in the 1960s. Despite having themselves shown the risks of a rigid stylet within an atrial electrode lead, they became exposed to this issue via acquisition of US pacemaker lead manufacturer Cordis Corporation, and eventually had to recall devices and settle class action lawsuits worth hundreds of millions of dollars¹⁴, triggering the restructuring of parent company Pacific Dunlop and the sell off of TPS’s assets (a side effect of this, incidentally, was the floating of sister company Cochlear, now in a globally leading position in implantable hearing solutions). One has to ask what the consequences of such an event would be today—for instance, based on an adverse event in an implantable BCI patient cohort—and consider that it could potentially hold the field back for a generation.

It is thus important firstly, that appropriate regulatory standards in the clinical BCI space are maintained, and secondly, that translation into the consumer neurotech space follows a risk-stratified regulatory regime, according to the potential for harm of the technology in question.





3. TECHNOLOGIES FOR READING OUT BRAIN ACTIVITY

3.1. ELECTROENCEPHALOGRAPHY (EEG)

Of all the neuroimaging modalities, electroencephalography (EEG) has by far the longest history of clinical and research application, and arguably the greatest near-term potential for meaningful consumer translation. First demonstrated by the German psychiatrist Hans Berger in 1924, EEG measures the scalp-level electrical potentials generated by the synchronized activity of large populations of cortical neurons, and has been a workhorse of clinical neurology, particularly in the diagnosis and monitoring of epilepsy and sleep disorders, for the better part of a century. The fundamental biophysics of EEG have not changed, and hardware improvements of recent decades have been incremental: notable advances include the development of dry and semi-dry electrode systems that eliminate the need for conductive gel, and more recently the introduction of flexible polymer electrode arrays that improve skin conformity and reduce impedance, enabling higher-density recordings with greater comfort during extended wear. These are meaningful engineering advances, but they are not the primary force driving EEG's expanding potential.

Rather, the most consequential developments are occurring at the level of data analysis. The emergence of large-scale EEG foundation models—deep learning architectures trained on aggregated datasets spanning thousands of participants and millions of recording hours—is dramatically expanding what can be decoded from scalp EEG signals that were previously considered too noisy or low-dimensional to support sophisticated

inference. A striking illustration of this trajectory is the non-invasive speech decoding demonstration by Araya Inc. in 2024¹⁵, in which a transformer-based model trained on large EEG corpora was used to decode imagined speech from scalp recordings with a degree of accuracy that would have been considered implausible a decade ago. This represents a qualitative shift in the capability envelope of a technology that has been clinically available for nearly a century. A notable corollary of this AI-driven paradigm is that the training datasets themselves become strategically valuable assets: large, well-annotated EEG datasets are difficult and expensive to collect, requiring substantial numbers of participants, careful experimental control, and often clinical infrastructure for ground-truth labelling. This creates significant incentives—commercial, scientific, and geopolitical—around the ownership and governance of neural data at scale, a theme to which we return below.

The growing capacity of AI to decode cognitive and emotional states from scalp EEG signals also raises the prospect that neural data collected for one purpose, such as wellness monitoring, could be repurposed in ways that threaten freedom of thought and mental privacy¹⁶.

3.2. FUNCTIONAL NEAR-INFRARED SPECTROSCOPY (fNIRS)

Functional near-infrared spectroscopy (fNIRS) measures haemodynamic correlates of neural activity by detecting changes in the absorption of near-infrared light by oxygenated and deoxygenated haemoglobin in cortical tissue—a signal that is closely related to the blood-oxygen-level-dependent (BOLD) signal measured by fMRI, and which reflects the same neurovascular coupling mechanisms. Historically, fNIRS systems were limited in channel count and spatial coverage, constraining their utility relative to fMRI. However, a new generation of high-density wearable fNIRS systems (including the Gower Labs, Cortivision and Kernel Flow headsets) has substantially improved spatial sampling and signal quality, bringing the modality meaningfully closer to the performance envelope of conventional fMRI for cortical measurements. The temporal resolution of fNIRS is modestly better than that of a typical fMRI acquisition, though both are ultimately constrained by the sluggishness of the haemodynamic response, which unfolds over several seconds following a neural event. The more fundamental limitation of fNIRS is its inability to image deep subcortical structures: near-infrared light penetrates only approximately 1–2 centimeters into brain tissue, restricting the technique to superficial cortical regions and precluding direct measurement of structures such as the hippocampus, basal ganglia, or brainstem that are of considerable clinical and scientific interest.

Nevertheless, the advantages of fNIRS in the consumer context are substantial. Modern wearable fNIRS systems¹⁷ are low-cost relative to MRI, require no magnetic shielding or cryogenic infrastructure, and are sufficiently portable to be used in naturalistic, ambulatory settings. A variety of consumer-oriented fNIRS platforms have emerged in recent years, with capabilities optimized for wearable applications including neurofeedback.

This portability enables a fundamentally different mode of data collection: rather than capturing brief snapshots of brain activity in artificial laboratory conditions, wearable fNIRS systems can record continuously across many hours of everyday life.

fNIRS devices (whether research grade systems or simpler wearable consumer grade systems), when combined with modern AI-based analysis pipelines, provide a capacity for longitudinal, ecologically valid data collection that creates a virtuous circle in which larger and richer datasets enable more powerful models, which in turn extract more meaningful signal from data that would previously have been considered too noisy to interpret.

An example of this approach in practice is provided by Connectome Health*, a UK-based company currently using high-density wearable fNIRS to track changes in cognitively relevant brain activity features as a function of lifestyle indicators derived from wearable sensor data. This positions fNIRS not merely as a research tool but as a potential platform for longitudinal brain health monitoring at a population scale. Similar brain health cognitive tracking platforms based on EEG have been around for some time (e.g. BrainScope, Cumulus Neuroscience), and we might expect further growth (and multimodal integration) in this sector.

**Disclosure: The author is an advisor and holds financial interests to Connectome Health GmbH.*

3.3. INTRACRANIAL AND IMPLANTED TECHNOLOGIES: REMAINING MEDICAL FOR THE FORESEEABLE FUTURE

Moving from non-invasive to invasive modalities, it is worth briefly considering the landscape of intracranial recording and stimulation technologies, if only to delineate the boundary of what is likely to remain firmly within the medical domain. High-density electrocorticography (ECoG) arrays—electrode grids placed directly on the cortical surface—offer a dramatic improvement in signal quality over scalp EEG. Companies such as Precision Neuroscience, with their minimally invasive Layer 7 cortical interface, are advancing the engineering of these systems considerably; however, the requirement for neurosurgical implantation places them unambiguously in the medical device category, and they are likely to remain there for the foreseeable future. Similarly, fully implanted brain-computer interface (BCI) electrode arrays, such as those developed by Neuralink, Paradromics, and related ventures, offer extraordinary bandwidth for neural recording and stimulation, but their invasiveness, the risks associated with implantation, and the current regulatory frameworks governing Class III implantable devices mean that their near-term application will remain restricted to individuals with significant neurological impairment for whom the risk-benefit calculus clearly favors intervention.

Synchron's® endovascular BCI platform represents an interesting intermediate case. Rather than requiring open craniotomy, Synchron's Stentrode device is delivered via catheter into the superior sagittal sinus, where it records neural signals through the blood vessel wall¹⁸. This approach takes advantage of over seventy years of clinical safety data accumulated from the use of endovascular stents in cardiovascular medicine. This established safety profile makes the regulatory pathway for the Stentrode significantly more tractable than that for penetrating electrode arrays, and one could conceive of a future in which, with appropriate regulatory evolution, such a device might be approvable for use in non-medical contexts by individuals willing to accept the residual procedural risks. However, **two constraints** currently limit this prospect.

1 First, the functional capabilities of the current Stentrode system are most compelling precisely in the scenarios of greatest medical need, such as motor restoration in paralysis or communication in locked-in syndrome; the marginal benefit to a neurologically intact user does not yet justify even a low-risk invasive procedure.

2 Second, the extension of endovascular BCI access to smaller cerebral vessels—which would be necessary to reach cortical regions beyond those accessible from the major sinuses, and which could substantially expand the application domain—has not yet accumulated the equivalent safety record. Until it does, the consumer translation of endovascular BCI technology remains a theoretical rather than imminent prospect.



**Disclosure: The author is an advisor and holds financial interests to Synchron Inc.*

4.

BRAIN STIMULATION TECHNOLOGIES

Deep brain stimulation (DBS) stands as one of the landmark achievements of clinical neurotechnology, offering transformative symptom relief for patients with Parkinson's disease, essential tremor, and treatment-resistant depression. Yet despite this clinical success, DBS serves as a cautionary illustration of the limits of invasive intervention as a platform for broad deployment: even among patients who are clinically eligible, uptake rates remain as low as 5 percent, reflecting the substantial barrier that the requirement for neurosurgical implantation presents to patients and clinicians alike.

If invasiveness constrains uptake even in populations with serious neurological disease, the prospect of DBS-like technologies entering the consumer space is effectively nil. The clinical interest in DBS therefore remains important, but the more consequential story for consumer neurotechnology lies elsewhere: in the rapidly developing landscape of non-invasive brain stimulation.

The existing toolkit of non-invasive brain stimulation includes transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS), and transcranial magnetic stimulation (TMS). Each has attracted substantial research interest and, in the case of tDCS in particular, a degree of popular enthusiasm—the spectacle of teenagers applying 9V battery-driven current to their scalps in pursuit of improved video game reaction times became something of a cultural footnote in the mid-2010s¹⁹.

However, an overall summary of the evidence base for these modalities is that their practical utility remains limited. Effect sizes in cognitive enhancement studies are typically modest and inconsistently replicated; spatial specificity is poor, with current or magnetic fields spreading diffusely across cortical tissue; and the ability to reach subcortical targets of genuine functional interest is negligible. Consequently, the number of neurological disorders that may be treatable by transcranial electrical stimulation may be more limited than initially hoped²⁰. TMS has established clinical niches in the treatment of depression and certain pain conditions, and carries FDA clearance for these indications, but as a consumer enhancement technology it is cumbersome, expensive, and of uncertain benefit. The enthusiasm for DIY tDCS appears largely to have subsided, in part because the evidence that it worked did not convincingly materialize.



The most compelling emerging modality in non-invasive brain stimulation is focused ultrasound (fUS), and it represents a genuinely new capability rather than an incremental refinement of existing approaches. By converging ultrasound beams at a precise intracranial target, fUS can deposit mechanical energy—and thereby modulate neural activity, through mechanisms which are still the subject of scientific study—with a spatial resolution sufficient to target discrete cortical regions and, critically, structures as deep as the hippocampus, which lies well beyond the reach of any traditional electrical or magnetic transcranial technique. Whether fUS can achieve the targeting precision required to selectively engage specific subcortical nuclei, such as the subthalamic nucleus targeted in DBS, remains an open question, and current evidence suggests this remains at the frontier of the technique’s spatial resolution. There is emerging work exploring the possibility of cell-type-selective neuromodulation via ultrasound, exploiting differential mechanical sensitivity across neuronal subtypes; if this proves tractable, it would substantially expand the functional specificity of fUS interventions. The potential application domains are broad and, in several cases, commercially compelling: cognitive enhancement—including improvements in attention, memory consolidation, and learning rate—is among the most discussed, with clinical application to memory disorders such as Alzheimer’s Disease. As with the BCI technologies, consumer applications are also immediately apparent. Plausible near-term applications including adjunctive use alongside language learning or skill acquisition platforms to accelerate learning through targeted hippocampal or prefrontal modulation. Motor learning, sports performance, and reaction time enhancement represent further targets, as does sleep architecture modulation: closed-loop stimulation protocols designed to enhance slow-wave (NREM) sleep are already under active investigation, and the potential to augment restorative sleep quality non-pharmacologically is of obvious consumer interest.

Several of these application domains—particularly cognitive enhancement in competitive or high-stakes contexts—carry genuine ethical complexity. The prospect of pharmacological cognitive enhancement has been debated extensively in bioethics literature; non-invasive neurostimulation raises structurally similar questions around fairness, coercion, and the medicalization of normal cognitive variation, and these will require serious engagement as the technology matures.

The principal obstacle to fUS realizing its consumer potential in the near term is regulatory rather than technical. Recent changes to the EU regulatory framework have effectively reclassified non-invasive focused ultrasound devices under requirements approaching those applied to invasive neurosurgical procedures—a classification that many in the field regard as disproportionate to the actual risk profile of a technique that, in low-intensity neuromodulatory applications, has to date demonstrated a strong safety record²¹. The practical consequence is that the regulatory pathway for fUS in Europe has become sufficiently burdensome as to risk displacing innovation and clinical development to other jurisdictions—the United States, China, and Israel among them—where the regulatory environment remains more permissive. Whether this represents a prudent application of the precautionary principle or an instance of regulatory frameworks failing to keep pace with technological reality is itself a matter of active debate.

What seems clear is that the underlying technology has substantial potential to bridge the medical and consumer domains in ways that few other stimulation modalities can currently match, and that the trajectory of its development will be shaped as much by regulatory and commercial decisions as by the science itself.

A further modality worth briefly noting is vagus nerve stimulation (VNS), particularly in its non-invasive auricular form. The vagus nerve is part of the peripheral rather than central nervous system, but as the primary conduit of the parasympathetic nervous system it is extensively coupled to CNS function via projections to the brainstem and locus coeruleus, and its modulation can produce measurable effects on cortical arousal and neuroplasticity.

Emerging evidence suggests that auricular VNS may have beneficial effects on learning and memory consolidation, plausibly through noradrenergic mechanisms that modulate synaptic plasticity²².

However, significant caveats apply: the literature is uneven, with much published work sitting closer to wellness advocacy than rigorous science; many devices make only superficial contact with auricular vagal fibers without demonstrating selective vagal engagement; and the vagus itself is a complex bundle with projections to multiple organ systems, meaning non-selective stimulation carries potential for unintended autonomic side effects. Nevertheless, the procedural simplicity and low cost of auricular VNS has attracted a crowded consumer market, with companies including Nurosym, Parasymp, Pulsetto, Truvaga, and Sensate offering wearable devices targeting stress, sleep, and cognitive performance—a landscape that reflects the low entry barrier and regulatory permissiveness that currently governs its exploitation as much as the biological potential.



5.

CLOSED-LOOP NEUROTECHNOLOGIES

A closed-loop neurotechnology is a system that measures a neural signal, processes it in real time, and uses the output of that processing to automatically adjust an intervention—whether brain stimulation, sensory feedback, or some other effector—in a dynamic manner. An example is the NeuroPace RNS (responsive neurostimulation) system for treating drug-resistant epilepsy, in which implanted electrodes are monitored for signatures of an impending seizure, and a brief burst of electrical stimulation used to disrupt it. Next generation DBS systems from Medtronic and Abbott Laboratories are also adopting closed-loop approaches to improve treatment of conditions such as Parkinson's disorder²³.



Closed-loop technologies are also well established in the consumer neurotechnology domain, with neurofeedback²⁴—in which real-time neural signals are fed back to the user to enable volitional self-regulation of brain activity—having being very easily translatable to the consumer domain, and widely applied in both clinical and wellness contexts. Neurofeedback requires no stimulation hardware, instead building on an existing readout technology (typically EEG, although other technologies such as fNIRS would also be suitable), and providing feedback via sensory stimulation (such as the radius of a circle displayed on a monitor).

The core concept is well established, with clinical applications in ADHD, epilepsy, and anxiety dating back decades. The principal limitation to date has been the poverty of the signal: scalp EEG features available for real-time feedback—predominantly band-power measures such as alpha or theta/beta ratios—are relatively crude proxies for the underlying neural states they purport to index, and effect sizes in controlled trials have been modest and inconsistently replicated. The emerging availability of richer, AI-derived neural features extracted from large multi-subject EEG datasets may substantially improve the quality and specificity of the feedback signal available in consumer settings.

Application domains are broad, encompassing mindfulness and stress regulation, cognitive performance and attention training, sleep quality enhancement, and accelerated learning—the last of which, combined with closed-loop stimulation, represents a particularly compelling direction for future development.

6.

TRANSLATION ACROSS BOUNDARIES

A question that arises naturally in surveying the consumer neurotechnology landscape is whether the non-medical sector is generating genuinely original innovation, or whether it is predominantly engaged in the downstream adaptation of technologies developed in academic and clinical contexts. To date, innovation has largely followed the latter trajectory.



The dominant pattern of development in neurotechnology follows a pipeline that runs from basic neuroscience research through clinical translation and, increasingly, onward into consumer deployment. EEG travelled this route over the better part of a century; fNIRS and neurofeedback are traversing it now; focused ultrasound is at an earlier stage of the same journey. Some technologies short-circuit the full pipeline—consumer-grade EEG devices, for instance, reached the wellness market without passing through a conventional clinical approval process—but the underlying science and hardware in almost every case originated in academic or medical research contexts. What the consumer sector contributes is not so much fundamental discovery as the engineering, commercial, and user-experience innovation required to make laboratory-grade concepts deployable at scale, at low cost, and in everyday settings. This is a genuinely important contribution, and the feedback it generates, in the form of large real-world datasets and novel use cases, increasingly flows back upstream to inform basic and clinical research.

Indeed, it is worth noting that the clinical-to-consumer direction described above is not the only commercialization pathways in practice. A number of neurotechnology startups follow the reverse trajectory: launching first in the consumer market, where regulatory barriers are lower, to generate revenue and early data, and subsequently pursuing clinical validation and full regulatory approval. Research into industry practice suggests that this dual-track model is becoming increasingly common²⁵, with consumer deployment serving as both a revenue source and as a means of building the evidence base for clinical approval.

This pathway carries its own governance implications: devices may reach large user bases before their safety and efficacy profiles are adequately characterized, and early commercial positioning can shape and/or constrain subsequent clinical development.

The advent of foundation AI models for normative brain imaging datasets may allow the detection of features which are only possible through the scalability obtained in the consumer neurotechnology space—these may be translated back into the clinical domain with potential application as biomarkers for disease states.

Foundation models²⁶ are large AI models trained using self-supervised or unsupervised learning algorithms, which can learn generalized representations of brain activity, and subsequently be fine-tuned for a variety of specialized tasks. Such models are extremely powerful, allowing the detection of small effects and high-dimensional or complex patterns. However, they require huge datasets to train in the first place—dataset sizes that consumer neurotechnology has the capability to provide, with its potential scalability to millions of subjects. Once neural features (such as patterns in an EEG waveform), and their clinical significance validated, they can be translated back into the medical domain as biomarkers for disease conditions. This is important as there are no biomarkers available for psychiatric conditions, and those available for neurodegenerative conditions are largely tied to expensive imaging modalities such as PET and MRI.





7. SOCIETAL SECTORS: BENEFITS, CHALLENGES, AND ETHICAL IMPLICATIONS

The potential beneficiaries of consumer and applied neurotechnology span virtually every major domain of organized social life, each bringing its own opportunities and ethical complexities.

Sport is perhaps the sector where near-term translation is most advanced and (at least in current form) least ethically contested. The use of in-ear EEG systems by professional sports clubs to monitor athletes for neurophysiological signatures of concussion have enabled objective, real-time assessment of potential traumatic brain injury (TBI) at the point of impact. This is a compelling application addressing a well-documented clinical need.

On a longer timescale, longitudinal brain health monitoring programs are beginning to emerge. Connectome Health, for instance, has established a partnership with Italian football club Como 1907 to track brain health biomarkers in athletes over time²⁷, examining how neural activity features co-vary with lifestyle indicators including sleep, physical activity, and recovery metrics. Similarly, Liverpool Football Club has been using EEG headsets developed by German company neuro11 to track brain activity during play and optimize training. NFL quantitative EEG monitoring of footballers has gone beyond post-concussion monitoring for return to field decisions, to longer term monitoring of brain health²⁸. This represents a qualitative shift from reactive injury assessment toward proactive, longitudinal brain health management—a model that, if validated, could have significant implications for athlete welfare and club liability alike.

Education represents another domain of substantial potential. Neurofeedback-assisted attention training, closed-loop learning platforms that adapt to real-time cognitive state, and stimulation-augmented skill acquisition all offer plausible routes to meaningfully improving learning outcomes—particularly for individuals with attentional or learning difficulties. The ethical landscape here is relatively benign when participation is voluntary and the technology is deployed transparently in the learner's interest, though questions around equity of access and the potential for neurological performance metrics to be incorporated into educational assessment warrant careful consideration. Given that a substantial proportion of educational deployments may involve minors, consent for neurotechnology in educational settings will function differently than for adults, and discussion around this issue sits within an active international debate on the rights of minors in relation to emerging technologies, with at its core the UN Convention of the Rights of the Child (UNCRC)²⁹.

A further concern is access: if neurotechnology-assisted learning proves effective, its benefits must not accrue to only those who can afford it. Governments should consider what incentive structures are needed to ensure that socially valuable neurotechnologies reach those who need them most.

The workplace presents a considerably more fraught ethical terrain. The use of neurotechnology for employee monitoring—tracking attentional state, cognitive load, stress, or fatigue via wearable EEG or fNIRS—has attracted serious commercial interest, and the present author has direct experience of being approached by organizations seeking to deploy EEG-based attention monitoring across workforces. The surface-level rationale—improving productivity, identifying fatigue-related safety risks, optimizing task allocation—is not without merit in specific high-stakes contexts such as aviation or heavy industry, where fatigue monitoring has genuine safety value.

However, the broader deployment of continuous neural monitoring in ordinary workplace settings raises profound concerns. The power asymmetry between employer and employee creates conditions in which nominally voluntary consent may be effectively coerced; the inferences drawn from neural data may be inaccurate, discriminatory, or applied to purposes beyond those originally disclosed; and the cumulative effect of pervasive neurophysiological surveillance on employee autonomy, dignity, and psychological safety could be severe. Neural data is uniquely sensitive—it can potentially reveal cognitive states, emotional responses, and even political or social attitudes in ways that other biometric data is not.

The workplace is therefore likely to be one of the most contentious arenas for neurotechnology governance in the coming decade, and one where the absence of specific regulatory frameworks is most acutely felt. The risks are also disproportionate: works with less bargaining power, or in precarious employment (the “gig economy”) are least able to refuse monitoring and most exposed to its consequences.

Security and defense applications—including operator state monitoring for military and emergency service personnel, lie detection or deception research, and interrogation-adjacent applications—raise still more serious ethical concerns that extend beyond the scope of this article, but which are the subject of growing attention in the neuroethics literature^{30, 31} and in policy discussions at NATO and related bodies³². Neurotechnology may play a key role in the new domain of cognitive warfare, with applications including the harvesting of neural data to probe vulnerabilities in targeted populations and assist influence operations³³, the use of neurotechnologies such as transcranial stimulation to fortify soldiers against psychological/cognitive attack, and the use of long-range acoustic or electromagnetic devices³⁴ to disrupt cognition in enemy soldiers.



8.

THE NEAR-TERM OUTLOOK FOR CONSUMER NEUROTECHNOLOGY

The most certain near-term development is the continued expansion of EEG and fNIRS applications, driven primarily by the AI-mediated improvements in signal interpretation discussed above. As foundation models trained on large neural datasets become more widely available—whether through open-science initiatives or commercial licensing—the barrier to building meaningful applications on top of commodity EEG hardware will fall substantially.

Neurofeedback for attention, sleep, and stress regulation will become more effective and more personalized; speech and intent decoding from non-invasive signals will improve; and longitudinal brain health monitoring platforms will proliferate. The datasets generated by these consumer deployments will themselves become increasingly valuable, raising urgent questions about ownership, consent, and secondary use that regulators are only beginning to engage with.

Transcranial direct current stimulation in consumer form is already a commercial reality: devices such as those produced by Flow Neuroscience (see **Box 1**)—which has accumulated a meaningful evidence base for tDCS as an adjunct to psychotherapy in depression—represent the current frontier of what is commercially and regulatorily viable in this space. The next five years are likely to see incremental expansion of this model into adjacent indications, including anxiety, cognitive enhancement, and sleep, though the fundamental limitations of spatial specificity discussed above will constrain how far tDCS alone can take the field.

The most transformative five-year prospect, if the regulatory environment permits, is focused ultrasound. The underlying technology is advancing rapidly, the safety profile in low-intensity neuromodulatory

applications is encouraging, and the application domains—cognitive enhancement, sleep optimization, accelerated learning, sports performance—are commercially compelling. The principal variable is regulatory: if the current EU framework proves as restrictive in practice as its critics contend, the locus of fUS innovation and early consumer deployment is likely to shift to the United States and Asia, with Europe potentially becoming an importer of a technology it had the scientific foundation to lead.

How that regulatory question resolves, and whether it resolves differently in different jurisdictions, may be the single most consequential determinant of the state of the consumer neurotechnology landscape at the end of the decade.



Photo courtesy of Flow Neuroscience

BOX 1. Flow Neuroscience Headset illustration

BOX 1.**Flow Neuroscience: a Case Study at the Clinical/Consumer Neurotechnology Boundary**

Flow Neuroscience was founded in Malmö, Sweden in 2016 by clinical psychologist Daniel Månsson and computational neuroscientist Erik Rehn, with a mission to create effective, drug-free, brain-based treatments for depression that could be used at home. The company developed the FL-100, a wearable headset for transcranial direct current stimulation (tDCS). The device works by delivering a weak electrical current through scalp electrodes positioned over the left dorsolateral prefrontal cortex (DLPFC), a region of the brain chronically underactive in people with depression, with the aim of gradually increasing cortical excitability and restoring healthier neural activity patterns through repeated use. Each session lasts 30 minutes and is guided by a Bluetooth-connected smartphone app, allowing patients to self-administer treatment at home with minimal supervision.

The clinical legitimacy of Flow's device rests on a landmark randomized controlled trial (RCT) published in *Nature Medicine* in October 2024³⁵. This fully remote, multi-site, double-blind placebo-controlled trial enrolled 174 adults with moderate to severe major depressive disorder, allocating them to either active tDCS or sham groups over a 10-week period. The results were strong, with 44.9 percent of the active treatment group achieving remission compared to 21.8 percent in the sham group, and side-effects limited to transient skin irritation. Flow received CE-mark certification in Europe in 2019, FDA Breakthrough Device Designation in 2022 and FDA Premarket Approval in December 2025, making it the first FDA-approved at-home brain stimulation treatment for depression. It is being used across multiple NHS Trusts in the UK.

At the same time, and despite (or perhaps supported by) its clinical credentials, Flow operates with a distinctly consumer-facing model. The FL-100 is now available over the counter in the UK and Europe. The company now has real-world data from over 55,000 users across the EU, UK, Switzerland, Hong Kong and UAE, with 77 percent of users reporting meaningful improvement in depressive symptoms within three weeks³⁶. The device is priced accessibly relative to clinic-based alternatives, and comes with a 30-day money back guarantee. It is due to launch in the US on Sep 1st 2026, where (unlike the UK and EU) and prescription from a healthcare provider will be required.

This dual positioning—simultaneously a rigorously approved Class III medical device and an over-the-counter consumer device—carries both significant benefits and meaningful risks for patient healthcare and wellbeing. The model dramatically expands access to an evidence-based treatment for a condition affecting 280 million people globally, reducing barriers related to cost, geography, stigma and clinic availability. The scale of this real-world deployment in itself generates valuable safety and efficacy data. However, without the requirement for clinical oversight in all markets, patients may self-select for the device without appropriate diagnosis or screening, potentially delaying more suitable treatments. Nevertheless, Flow Neuroscience provides a compelling proof of concept for the democratization of neurotechnology, and a live experiment in negotiating the regulatory challenges at the boundary between the clinical and consumer neurotechnology markets.

9.

SEVEN RECOMMENDATIONS FOR THE GOVERNANCE OF NEUROTECHNOLOGY

How neurotechnologies should be regulated, particularly for non-medical purposes such as consumer applications, has been a topic of much debate over the past few years³⁷, and is unlikely to be completely resolved in the near future. Nevertheless, it is important that the regulatory landscape adapt to advances in neurotechnology, and the propensity described above for neurotechnologies to cross boundaries—from basic science to clinical to consumer, and back again—lead to a number of recommendations for consideration.

The decisions made by regulators, legislators and institutions in the next three to five years will shape the neurotechnology landscape for a generation. The time for action on governance is thus now.

01

Establish a dedicated regulatory pathway for neurotechnology translation

The absence of a formal regulatory bridge between clinical and consumer neurotechnology is a structural anomaly that will hold back progress unnecessarily. The hearing aid / over-the-counter FDA precedent (Apple AirPods Pro) provides a relevant model. **Regulators in the US, UK, and EU should develop tiered, technology-specific translation pathways**, enabling neurotechnologies with established clinical safety records to access consumer markets through a defined, proportionate approval process—rather than falling into an unregulated grey zone by default.

02

Introduce a mandatory neural data protection framework

under a patchwork of GDPR, the AI Act, and inconsistent national legislation. The strategic value of large EEG and fNIRS datasets—and the commercial incentives this creates—makes this urgency acute. There is a need for **dedicated neural data protection legislation** that explicitly classifies neural data as a special category requiring the highest tier of protection, mandates informed, specific, and revocable consent for collection, storage and secondary use, prohibits sale or transfer of neural data to third parties without explicit re-consent, and establishes clear rules on data sovereignty for datasets collected across jurisdictions. Neural data is fundamentally different from other categories of personal data, as it can reveal not only health status but also cognitive states, emotional responses, intentions, and potentially political attitudes. Advances in AI systems enable richer inference from raw signals, and thus the interaction between AI and neurotechnology domains raises governance questions that neither AI regulation nor data protection law currently address adequately. Consent mechanisms designed for static data collection are ill-suited to continuous, AI-mediated neural monitoring, and will need to evolve accordingly.

03

Recalibrate EU focused ultrasound regulation proportionately

The current EU regulatory reclassification of non-invasive focused ultrasound—effectively assimilating it to the requirements applied to invasive neurosurgical devices—is disproportionate to its demonstrated risk profile. **The European Medicines Agency and relevant notified bodies should urgently review the classification of low-intensity transcranial fUS devices**, with a view to establishing a risk-stratified framework that distinguishes clearly between high-intensity therapeutic ultrasound (which warrants stringent oversight) and low-intensity neuromodulatory applications (which may warrant a lighter-touch, evidence-based pathway). More broadly, this case illustrates a recurring problem: regulatory frameworks updated through infrequent legislative cycles cannot keep pace with rapidly evolving technologies. Regulators should establish standing scientific advisory mechanisms—including active neuroscientist representation—enabling continuous dialogue with the research community.



04

Explicitly and proactively regulate workplace neural monitoring

While there are already some frameworks that may have relevance, there is a need for specific regulatory frameworks governing employer use of neural monitoring. For instance, **explicit prohibition of the use of neural data in hiring, performance review or disciplinary hearings**; a default of opt-out rather than opt-in for the use of neurotechnology in the workplace; any workplace neurotechnology deployment should be subject to mandatory independent ethical review. A clear statutory carve-out limiting the use to permissible safety-critical contexts (e.g. in aviation or heavy industry) could cover genuine exceptions.

05

Mandate evidence standards for consumer neurotechnology marketing claims

There is a “grey zone” in which consumer neurotechnology companies deploy health-adjacent marketing language—implying clinical benefit while avoiding the clinical trials that would trigger regulatory scrutiny. This is a consumer protection failure as much as a health governance one. **Consumer protection regulators, working in coordination with health technology assessment bodies, should:** establish minimum evidentiary standards or specific categories of neurotechnology marketing claim (e.g. “improves sleep”, “reduces stress”); require that companies making such claims register with a relevant authority and disclose the evidence base for those claims publicly; empower trading standards and advertising regulators to act against unsubstantiated neural health claims with meaningful sanctions. This should be aligned with existing advertising standards bodies (ASA in the UK, FTC in the USA, equivalent national authorities in the EU). One potential lever that is already in place is the EU’s Unfair Commercial Practices Directive³⁸, which contains specific protections for vulnerable consumers.

06

Establish open, governed repositories for neural training datasets

Large, well-annotated neural datasets are strategically valuable assets. Left ungoverned, this creates incentives for data hoarding, inequitable access, and potential misuse. **Research funders and governments should invest in the creation of open, ethically governed neural data repositories,** modelled on precedents such as the UK Biobank.

07

Coordinate the international regulation of neurotechnology

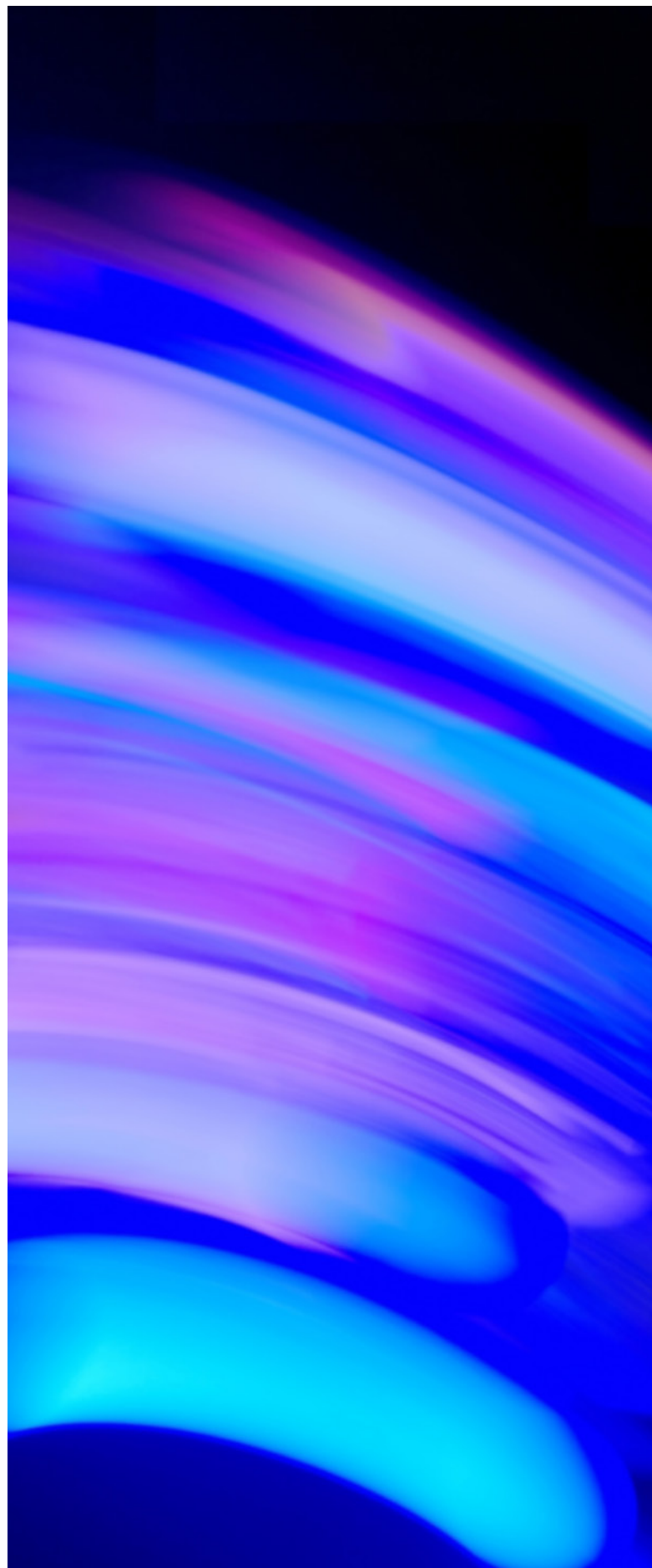
Uncoordinated jurisdictional divergence risks displacing innovation (and risk) to the site of least oversight, which is in no-one's long-term interest. **Proportionate, evidence-based regulatory convergence between the major jurisdictions** is essential to avoid jurisdictional arbitrage and permit the safe exploration of the benefits that neurotechnology can provide to humanity. UNESCO's Recommendation on the Ethics of Neurotechnology (2024)³⁹ provides a multilateral framework for such coordination, including principles on human dignity, data governance and equitable access, and offers a practical starting point for aligning regulatory approaches across jurisdictions.



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