Neurotechnologies

Brain health is defined as the state of brain functioning across cognitive, sensory, social-emotional, behavioural and motor domains, allowing a person to realize their full potential over the life course, irrespective of the presence or absence of disorders. Estimates suggest that in 2021 3.4 billion people had a condition affecting the nervous system, meaning around 43% of the world's population. As populations continue to grow and age, the prevalence and burden of brain disorders are bound to raise.

Neurotechnologies have great potential to foster brain health. Medical tools range from Magnetic Resonance Imaging (MRI) and Electroencephalography (EEG) to Deep Brain Stimulation (DBS) and have proved effective both in the diagnosis and management of neurological and psychiatric diseases.

Furthermore, the growing accessibility and portability of neurotechnologies, along with their potential applications in everyday life, have expanded their use beyond the medical field and into the general consumer market. Consequently, in the last decade, the field of neurotechnology applications has grown exponentially, with the neurotechnology market projected to reach more than $24 billion by 2027.

The uses of neurotechnologies both in the medical field and the general consumer market raise crucial ethical and societal issues – notably in terms of human enhancement, regulation and marketing of direct-to-consumer devices, protection of personal brain data and vulnerability of cognitive patterns for commercial or political manipulation.

International context and European regulatory landscape

The field of neurotechnologies is in full swing and fuels global debate over their research, development, use and regulation. Many binding and non-binding mechanisms of governance are available to policymakers and other stakeholders – including laws, regulations and recommendations. Adopted in 2019, the Organisation for Economic Co-operation and Development (OECD) recommendation #457 on Responsible Innovation in Neurotechnology constitutes the first international standard in the field. The United Nations Educational, Scientific and Cultural Organization (UNESCO) report on the Ethical Issues of Neurotechnology (2021) has broken new ground in the domain and the upcoming UNESCO Recommendation on the Ethics of Neurotechnology (2025) is set to bring new knowledge in the debate.

Launched under the Spanish Presidency of the Council of the EU in 2023 and resulting from the agreement of EU's telecommunications and digital ministers, the León Declaration on European Neurotechnology represents a first move to protect digital rights in the development of neurotechnologies at the European level.

Although the EU still lacks specific regulations and directives in this regard, the Medical Devices Regulation (MDR), the General Data Protection Regulation (GDPR) and the more recent European Artificial Intelligence Act (EU AI Act) already provide consumer, competition and general product safety standards relevant for the development of neurotechnologies in the EU.

Medical and non-medical applications

Medical devices, defined in the Medical Devices Regulation, cannot be placed on the European market without conforming to strict safety requirements including the affixation of the CE marking

of conformity – indicating that *a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.*

Non-medical applications include products for neurostimulation and neurofeedback in work, education, entertainment and marketing. These devices often lack appropriate oversight regarding their scientific foundations, efficacy, and ethical supervision: for instance, EGG systems with an intended medical purpose require a pre-market approval, while EEG direct-to-consumer products are only subjected to the CE marking of conformity.

Despite Europeans regulations and international recommendations, gaps and grey areas still exist for the development of neurotechnologies. For instance, the protection of personal brain data deserves additional provisions of data privacy regulations (transparency of collection, processing, sharing and use of personal brain data) because of the unique role of the brain as body's command center; direct-to-consumer devices need guidelines for responsible development that respect the rights of individuals with regards to mental privacy and informed consent; and connected devices must respect hardware, software and data security measures to protect against potential cyber threats.

About the European Charter for the Responsible Development of Neurotechnologies

In order to fill these gaps, the European Brain Council (EBC) brought together players from the EU brain community to discuss ethical and social challenges raised by neurotechnologies. It led to the creation of a Task Force for the elaboration of a European Charter for the Responsible Development of Neurotechnologies.

This Charter was jointly elaborated by a large representation of actors in the field and its wording results from collegial exchanges between public and private sectors. The Charter brings together, in a co-creation, bottom-up approach, key stakeholders in the European brain ecosystem including organisations of people living with mental, neurological or sensory conditions, organisations of professional actors in health, research and ethics, policymakers, small and medium-sized enterprises. [authors and contributors]

At the national level, only a few countries have enacted instruments to protect individual and collective rights in the context of neurotechnologies. It includes France, which in 2022 implemented the OECD Recommendation 457 on Responsible Innovation in Neurotechnologies in the form of the French Charter for the Responsible Development of Neurotechnologies.

Value of a charter

A charter functions as a non-binding agreement that offers a more agile and flexible governance framework, which is especially beneficial for swiftly changing technologies:

- charters can be implemented with little to no bureaucratic hurdles or delays and can be updated more quickly and with less effort than regulations,
- as the commitments outlined in charters are not limited by geography, they often have a global dimension,
- charters foster collaboration among a diverse array of stakeholders who, in conventional regulatory frameworks might be more inclined to oppose each other,
- charters provide a commonly agreed framework that spans researchers, innovators, policy makers and civil society (while regulations typically have a narrower target audience),

- charters are not only complementary to other binding and non-binding laws, but also often constitute a guideline for development of novel governance tools and a promotor for consistency between different legal jurisdictions.

With the ultimate goal to promote a culture of stewardship and trust in neurotechnologies, support greater wellbeing and sustainable economic growth and guide public policy, activities of companies and investments, the European Charter for the Responsible Development of Neurotechnologies builds on existing mechanisms of governance and complements existing legislation by contributing to human-centred risk evaluation, addressing gaps and shading light on grey areas deserving public attention and robust governance. Given the fast-expanding field, the Charter is intended to be dynamic and open to review.

Aims

The Charter aims to provide ethical guidance for the successful development of neurotechnologies in Europe in a manner that:

- promotes equality of access and encourages responsible, human-centred and rights-oriented innovation and business conduct,
- protects individuals, communities and vulnerable populations against any abuse or misuse affecting notions of human identity, freedom of thought, autonomy, privacy and human flourishing,
- informs the general public, clinical practice and policymaking,
- supports the economic growth of the field by strengthening trust between all actors and promoting societal deliberation and citizen participation.

Scope

The Charter focuses on all technologies, procedures and applications, medical and non-medical, used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and functions of the neural systems of natural persons[1].

Signatories

[endorsers]

1 From OECD recommendation