

Research paper

# East Asian perspective of responsible research and innovation in neurotechnology

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## ABSTRACT

After more than half a century of research and development (R&D), Brain-computer interface (BCI)-based Neurotechnology continues to progress as one of the leading technologies of the 2020s worldwide. Various reports and academic literature in Europe and the United States (U.S.) have outlined the trends in the R&D of neurotechnology and the consideration of ethical issues, and the importance of the formulation of ethical principles, guidance and industrial standards as well as the development of relevant human resources has been discussed. However, limited number studies have focused on neurotechnology R&D, the dissemination of neuroethics related to the academic foundation advancing the discussion on ethical principles, guidance and standards or human resource development in the Asian region. This study fills in this gap in understanding of Eastern Asian (China, Korea and Japan) situation based on the participation in activities to develop ethical principles, guidance, and industrial standards for appropriate use of neurotechnology, in addition to literature survey and clinical registries' search investigation reflecting the trends in neurotechnology R&D as well as its social implication in Asian region. The current study compared the results with the situation in Europa and the U.S. and discussed issues that need to be addressed in the future and discussed the significance and potential of corporate consortium initiatives in Japan and examples of ethics and governance activities in Asian Countries.

## 1. Introduction

Neurotechnology is an industrial field that has developed rapidly over the past decade, as well as an academic research tool to further expand our understanding of human brain function. The OECD defines the term of neurotechnology as "*devices and procedures that are used to access, monitor, investigate, assess, manipulate, and emulate the structure and function of neural systems*" (OECD, 2019), and the Institute of Electrical and Electronics Engineers (IEEE) defines "*Neurotechnology*" refers to *any technology that provides greater insight into brain or nervous system activity, or affects brain or nervous system function*" (<https://brain.ieee.org/topics/neurotechnologies-the-next-technology-frontier/>). From the researchers' point of view, it is also explained as "is defined as the

assembly of methods and instruments that enable a direct connection of technical components with the nervous system" by Müller and Rotter (2017). These definitions have in common the sensing of the functions of the cranial nervous system and its linkage to various devices. Based on the above and taking into consideration the target and method of linkage, neurotechnology in this paper would be defined as "the procedure of connecting the functional activities of the nervous system to computers or devices in a unidirectional or bidirectional manner using electronic information and communication engineering methods, and the value derived from this procedure". According to this definition, neurotechnology may encompass a wide range of technologies, whether they are invasive to the nervous system or not. Thus, the industry sector of neurotechnology may cover not only the products of devices

**Abbreviations:** BCI, Brain-computer interface; CAN, Consortium for Applied Neuroscience; FDA-CDHR, Food and Drug Administration Center for Devices and Radiological Health; IoNx, Institute of Neuroethics; IBI, International Brain Initiative; IEEE, Institute of Electrical and Electronics Engineers; IEC, International Electrotechnical Commission; ISO, International Organization for Standardization; IoB, Internet-of-Brains; JRCT, Japan Registry of Clinical Trials; JST-CRDS, Japan Science and Technology Agency Center for Research and Development Strategy; METI, Ministry of Economy, Trade and Industry; MEXT, Ministry of Education, Culture, Sports, Science and Technology; MOFA, Ministry of Foreign Affairs; MHLW, Ministry of Health, Labour and Welfare; MIC, Ministry of Internal Affairs and Communications; OECD, Organization for Economic Co-operation and Development; R&D, research and development; UNESCO, United Nations Educational, Scientific and Cultural Organization; UNHRC, United Nation Human Rights Council; UMIN CTR, University Hospital Medical Information Network Clinical Trials Registry.

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connected to the brain, but also the packages of systems and services as pointed like "refers to products, systems, and services developed by integrating knowledge and techniques in neuroscience and engineering" (Neurotech Guidebook Development Committee, 2023). Regarding its potential as an academic research tool, it would evoke research addressing the creation of innovative paradigms for human understanding as expressed that "have the potential to radically change how to understand human cognition and behaviour" (OECD, 2019).

Brain-Computer Interface (BCI) is positioned as a fundamental technology for establishing Neurotechnology as a system and service. In an OECD working paper (García and Winickoff, 2022), the authors state that "BCIs are "used to sense and decode neuronal activity patterns by external devices – linking thought commands to external devices" Thus, a basic BCI system includes a sensor to capture the brain signal, a computer (which converts the signal into an algorithm), and a computer element to control an external device." It is also explained that "A BCI is a system that records CNS activity and translates it into artificial output that replaces, restores, enhances, supplements, or improves natural CNS outputs; it thereby modifies the interactions of the CNS with the rest of the body or with the external world", by Wolpaw's group (Wolpaw et al., 2020). The current paper follows these definitions and treats BCI as the procedures and engineering elements involved in detecting, recording, analyzing, and converting nervous system activity into meaningful information that can be used to control external devices and computer elements.

Although the terminology and conceptual design of BCI was proposed in 1973 based on the accumulation of EEG studies on humans that began in the 1920s (Vidal, 1973), the research leading to BCI was developed long before that, including animal studies as one of the major areas of "Neural Control of Movement (NCM)" (Wang et al., 2022). From the earliest stages of NCM, the idea of utilizing the neural signals for the medical benefit of people with movement disorders was latent. This idea has been realized over time with the development of the elemental technology fields related to BCI (for example computer science, information and communication engineering, artificial intelligence, computational neuroscience, etc.) and with the cooperation of the clinical medicines. In the early 2000s, BCI with unit recording reached the stage of clinical research (Hochberg, et al., 2006), then through the 2010s, applied research using BCI and research on improving and upgrading elemental technologies such as sensing, signal processing and decoding became popular (Alharbi, 2023; Kawala-Sterniuk et al. 2021; Maiseli et al. 2023; Saha et al., 2021). Around the same time, the U.S. Food and Drug Administration Center for Devices and Radiological Health (FDA-CDHR) initiated a study to prepare for an approval review of BCI based on its practical feasibility in clinical practice (Bowsher et al., 2016); the FDA-CDHR issued "leap-frog" guidance in May 2021 with recommendations for the design of nonclinical and clinical testing using BCI devices for patients with paralysis or amputation (Department of Health and Human Services et al., 2021), also see <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-spur-development-innovative-devices-including>). Now in the 2020s, BCI-based neurotechnology is expected to build and develop into a versatile and comprehensive industry sector that includes not only medicines, but also quality of life improvement in various daily life situations, working environment improvement, legal applications, and applications in entertainment and sports (Saha et al., 2021). Through such history, BCI, together with other social implementation efforts on brain imaging, brain big data, brain stimulation etc., is collectively called neurotechnology in broader context. The neurotechnology market continues to expand with the entry of various companies, including major telecommunication companies and start-ups, including Asian companies (for example, <https://www.araya.org/en/>; <https://www.neurophet.com/>; <https://brainu.co.kr/>), and the global market for industries related to neurotechnology is expected to reach \$24.2 billion by 2027 (UNESCO, 2023). With the development of such wide-ranging industrial applications, concerns about military applications of neurotechnology and countermeasures were raised beyond

the realm of medical ethics and bioethics (National Research Council, 2008 and 2009), and the discussions on concerns about the impact of neurotechnology on the real world have been one of the main topics of neuroethics since the 2010s (Garden et al., 2019; Mathews et al., 2023; Nuffield Council on Bioethics, 2013). Neuroethics is a field that was declared established in 2002 (Marcus, 2002). Academically, it is defined as "a multi-disciplinary and inter-disciplinary endeavor - examines the implications of the neurosciences on human beings in general and on their self-understanding and their social interactions in particular" (in the abstract of Clausen and Levy, 2014). It has also been mentioned not only in academic papers but also in reports issued by government agencies, non-profit organizations, and international organizations on the social implications of and responses to the advancement and industrialization of neuroscience research (O'Shaughnessy et al., 2023).

What kind of research and development (R&D) of neurotechnology is currently underway in Asia in the context of the global trends described above? And what kind of preparations are being made for social implementation of neurotechnology based on the regional, social, cultural, and economic background of Asia? The importance of considering cultural diversity in non-Western countries and regions, including Asia, has often been noted in discussions on further development of neuroethics (Global Neuroethics Summit Delegates et al., 2018; Emerging Issues Task Force, International Neuroethics Society, 2019), but there have been limited discussions and studies addressing specific cultural characteristics in this field (Fukushi et al., 2017; Sakura, 2012; Wang et al. 2019; Wu and Fukushi, 2012). On the other hand, there are studies using cognitive neuroscience and cultural psychology methodologies to elucidate cultural differences in neural mechanisms related to ethics and values (for example, Yang et al. 2019, also see Khalaila et al. 2023; Kitayama and Park, 2010). In light of such situation, the IEEE Brain Neuroethics designs their activity under the theme of "Ethical, Legal, Social, and Cultural Implications of Neurotechnology," which emphasizes the consideration of cultural differences and diversity (<https://brain.ieee.org/publications/neuroethics-framework/addressing-the-ethical-legal-social-cultural-implications-of-neurotechnology/>).

This paper focuses on China, South Korea (Korea), and Japan in Asia for the following reasons: 1) member countries belonging International Brain Initiative (IBI), a liaison organization large-scale projects around the world that promote elemental research in neurotechnology, 2) neurotechnology R&D for medical purposes can be found on the clinical trials registry site, 3) progress of neurotechnology R&D, including for non-medical purposes as well, is also confirmed as patent application information, and 4) Clear signs of participation in national and international ethical principles, guidance, and industry standards review efforts can be found. The first part of the report will review the status of R&D for clinical and industrial applications of Neurotechnology in East Asia, as well as the activities for principles, ethical and technical guidance, and industrial standards for social implementation. Then, taking up the case of Japan, the paper will discuss the position of professional human resources involved in Neuroethics in East Asia and the direction that should be taken in the future for the sound social implementation of Neurotechnology.

## 2. Procedures to obtain current state of East Asia through quantitative indicators and qualitative survey analysis

### 2.1. Quantitative indicators

In the current study, three objective indicators of the current status of China, Korea, and Japan from difference perspectives were quantitatively obtained. First, two surveys of scholarly articles on BCI were referred as information on bibliometric analysis, which is an indicator to measure the scale and focus areas of academic and basic research implementation. The reason for this is that basic research on BCI has been accumulated over many years as a fundamental technology for Neurotechnology, and the term BCI has been included in the guidance

by FDA-CDHR as well as in the consideration of industrial standards by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In this study, a bibliometric analysis of scholarly articles on BCI research in the Scopus data from 1982 to August 2022 (Maiseli et al., 2023) and a survey study on bibliometric analysis of peer-reviewed review articles on BCI research extracted using One Search, a data mining tool that accesses 252 databases including BioOne, Google Scholar, JSTOR, ProQuest, and PubMed (Alharbi, 2023) were referenced. The former is suitable for identifying general trends in BCI research for one of the world's largest scientific literature databases, while the latter is for peer-reviewed review articles extracted from a variety of scientific literature databases to identify trends in the countries including group of researchers with higher expertise and broader knowledge of BCI research.

Next, the registration status of clinical trials using BCI on ClinicalTrials.gov (<https://clinicaltrials.gov/>), a well-known clinical trial registration site that covers clinical trial trends worldwide, was examined as an indicator to measure the status of efforts for medical applications. The term "Brain-Computer Interface" or the abbreviation "BCI" was searched in the Intervention search field of ClinicalTrials.gov, as well as a list of terms that could be registered as analogues of BCI (Brain-Computer Interface, Brain-Machine Interface, Neural Interface, Brain chip, neural chip, neural device, neural implant, and so on). The extracted results were reviewed and deleted duplicates and trials with no relevance to BCI, and the country of origin of the institution conducting the clinical trial was identified by the information in the "Locations" field. Focusing on Asian countries and regions, the number of registrations was tabulated by the status, developmental phases, and conditions. Since information on clinical trials in Japan is not registered in Clinicaltrials.gov, the Japan Registry of Clinical Trials (JRCT) (<https://jrct.niph.go.jp/search?language=en>) and the University Hospital Medical Information Network (UMIN) - Clinical Trial Registry (CTR) (<https://jrct.niph.go.jp/search?language=en>) were used alternatively. Since it was difficult to extract accurate registration information in English, due to the original registration language and the search condition settings, English-language information was obtained by using the trial registration numbers extracted from the Japanese-language sites of each registry. The information obtained after inputting "Brain-Computer Interface" or "BCI" and its analogues in Japanese were carefully examined to delete duplicates and no relevance.

Finally, with respect to patent trends reflecting industrial technological developments closer to actual commercialization, the quantitative information contained in the United Nations Educational, Scientific and Cultural Organization (UNESCO) research report (2023) was referenced. The study report was based on preprint papers of analyses using information on patent applications to the world's five largest patent offices (Korean Intellectual Property Office, European Patent Office, Japan Patent Office, China National Intellectual Property Administration and United States Patent and Trademark Office, here after IP5) from the European Patent Office's World Patent Statistics database for the period 2000–2020 (Bekamiri, et al., 2021; Hain et al., 2022), with additional analysis. As a reference for the evaluation of each indicator, trends in other Asian countries and the world as a whole were also referenced and mentioned in the current paper as necessary.

## 2.2. Qualitative survey analysis

In addition to the above three quantitative indicators, the survey analysis on domestic and international efforts related to principles, ethical and technical guidance, and industrial standards for the social implementation of neurotechnology was included as a fourth viewpoint. Neurotechnology and related fields of neuroscience research have continued to develop in the context of modern science, led by Europe and the U.S. As described in the Introduction, R&D for practical use of neurotechnology is now progressing and the market is expanding. In order for the products of neurotechnology to gain a market and spread, it

is essential that the standards related to the safety of the products themselves and the ones for information and communication technology be secured first. Thus, the status of standards development is a valid indicator that reflects the progress of product market establishment and social implementation. Also, in terms of how neurotechnology should be treated as a social infrastructure and service, the status of the formulation of domestic and international rules that address ethical concerns regarding the provision and use of neurotechnology, and the one related to the sharing of underlying ethical principles and philosophy are also necessary indicators.

Table 1 indicates a chronological list of the guidelines, consultations, policy recommendations, and research reports—covering the clinical application of research results related to neuroscience, social implementation, and the impact of the advancement of neurotechnology on humans and society—published in English by international organizations, government agencies, and other non-profit bodies since the establishment of neuroethics as an academic field in 2002. With the increase in the number of published reports, the stakeholders involved in the discussions have expanded beyond the scope of academic research, but there have always been several neuroethicists at the center of the discussions, by creating a forum for discussion, bringing stakeholders together, leading discussions, and even providing evidence to guide the decision-making of organizations and contributing to the production of report documents (Global Neuroethics Summit Delegates et al., 2018; Ienca, 2021; International Brain Initiative, 2020; Vitale et al. 2022; and World Economic Forum, 2019). Such "nodal" or "key point" researchers responded to the philosophy of Responsible Research and Innovation (RRI), which was being promoted in EU at the same time and created the theoretical basis for the current initiatives by international organizations and others related to ethical design of neurotechnology R&D (Garden et al., 2016; Gardner and Williams, 2015). RRI is an argumentative concept that began to be discussed in 2011, which calls for ethical responses to research and development of advanced technologies from a policy perspective. Since the Rome Declaration on Responsible Research and Innovation in European Commission ([https://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=8196](https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=8196)) was adopted in 2014, funding support for RRI practices have also been allocated in EU (Tabarés et al., 2022). It is conceivable that R&D and social implementation related to Neurotechnology were also discussed in this context in Europe and spread to the U.S., leading to RRI activities related to Neurotechnology by international organizations (OECD, 2017; O'Shaughnessy et al., 2023; Salles et al., 2019). Based on the information in Table 1 and other sources, an overview of international organizations, professional associations, and private organizations that are promoting RRI activities related to Neurotechnology as of February 2024 can be summarized as follows.

OECD Committee for Scientific and Technological Policy (CSTP): OECD published the recommendations for neurotechnology R&D and social implementation in the context of RRI (OECD 2019). They continue the engagement and monitoring through collaboration with the Global Forum on Technology (<https://www.oecd.org/digital/global-forum-on-technology/>).

UNESCO: Followed by publishing the report of the study on the impact of neurotechnology in terms of the protection of fundamental human rights (International Bioethics Committee, 2021), UNESCO hosted the International Conference on Ethics of Neurotechnology in 2023 (<https://www.unesco.org/en/articles/ethics-neurotechnology-unesco-leaders-and-top-experts-call-solid-governance>). They are further in the process of establishing an expert group to develop relevant recommendations.

United Nation Human Rights Council (UNHRC): As per resolution 51/3 (<https://www.ohchr.org/en/hr-bodies/hrc/advisory-committee/neurotechnologies-and-human-rights>), the Advisory Committee was requested to conduct a study on the impact of neurotechnology on human rights and report back to the Council at its 57th session. The Advisory Committee's drafting team is finalizing the report after

**Table 1**

Guidance, consultations, policy recommendations, and research reports issued by government agencies, non-profit organizations, foundations, and international organizations around the world that address the clinical application and social implementation of Neuroscience-related research results and the impact of advances in neurotechnology on humans and society (as of March 1, 2024).

	Organization/Project	Organization/Project relevant URL	Title of Publication	Publication Year	Publication URL
1	Meeting of Minds Europe	N/A	37 Recommendations on Brain Science European Citizens' Assessment Report	2006	N/A
2	National Research Council	<a href="https://www.nationalacademies.org/">https://www.nationalacademies.org/</a>	Emerging Cognitive Neuroscience and Related Technologies	2008	<a href="https://doi.org/10.17226/12177">https://doi.org/10.17226/12177</a>
3	National Research Council	<a href="https://www.nationalacademies.org/">https://www.nationalacademies.org/</a>	Opportunities in Neuroscience for Future Army Applications	2009	<a href="https://doi.org/10.17226/12500">https://doi.org/10.17226/12500</a>
4	Royal Society	<a href="https://royalsociety.org/">https://royalsociety.org/</a>	Brain Waves Module 1: Neuroscience, society and policy	2011	<a href="https://royalsociety.org/-/media/Royal_Society_Content/policy/publications/2011/4294974932.pdf">https://royalsociety.org/-/media/Royal_Society_Content/policy/publications/2011/4294974932.pdf</a>
5	Royal Society	<a href="https://royalsociety.org/">https://royalsociety.org/</a>	Brain Waves Module 2: Neuroscience: implications for education and lifelong learning	2011	<a href="https://royalsociety.org/-/media/Royal_Society_Content/policy/publications/2011/4294975733.pdf">https://royalsociety.org/-/media/Royal_Society_Content/policy/publications/2011/4294975733.pdf</a>
6	Royal Society	<a href="https://royalsociety.org/">https://royalsociety.org/</a>	Brain Waves Module 3: Neuroscience, conflict, and security	2011	<a href="https://royalsociety.org/-/media/Royal_Society_Content/policy/projects/brain-waves/2012-02-06-BW3.pdf">https://royalsociety.org/-/media/Royal_Society_Content/policy/projects/brain-waves/2012-02-06-BW3.pdf</a>
7	Royal Society	<a href="https://royalsociety.org/">https://royalsociety.org/</a>	Brain Waves Module 4: Neuroscience and the law	2011	<a href="https://royalsociety.org/-/media/Royal_Society_Content/policy/projects/brain-waves/Brain-Waves-4.pdf">https://royalsociety.org/-/media/Royal_Society_Content/policy/projects/brain-waves/Brain-Waves-4.pdf</a>
8	Nuffield Council on Bioethics	<a href="https://www.nuffieldbioethics.org/">https://www.nuffieldbioethics.org/</a>	Novel Neurotechnologies: Intervening in the Brain	2013	<a href="https://www.nuffieldbioethics.org/assets/pdfs/Novel-neurotechnologies-report.pdf">https://www.nuffieldbioethics.org/assets/pdfs/Novel-neurotechnologies-report.pdf</a>
9	Bioethics Advisory Committee Singapore	<a href="https://www.bioethics-singapore.gov.sg/">https://www.bioethics-singapore.gov.sg/</a>	Ethical, Legal and Social Issues in Neuroscience Research.	2013	<a href="https://www.bioethics-singapore.gov.sg/files/publications/consultation-papers/neuroscience-cp.pdf">https://www.bioethics-singapore.gov.sg/files/publications/consultation-papers/neuroscience-cp.pdf</a>
10	Brain Research through Advancing Innovative Neurotechnologies Working Group	<a href="https://braininitiative.nih.gov/">https://braininitiative.nih.gov/</a>	BRAIN 2025 A Scientific Vision	2014	<a href="https://braininitiative.nih.gov/sites/default/files/pdfs/brain2025_508c.pdf">https://braininitiative.nih.gov/sites/default/files/pdfs/brain2025_508c.pdf</a>
11	CeReB: The Center for Responsible Brainwave Technologies	N/A	The Ethics of Brain Wave Technology Issues, Principles and Guidelines	2014	<a href="https://static1.squarespace.com/static/5344501be4b0d532fc42e22f/t/5390ceee4b0fe2199de93cc/1401999084766/the+ethics+of+brainwave+technology.pdf">https://static1.squarespace.com/static/5344501be4b0d532fc42e22f/t/5390ceee4b0fe2199de93cc/1401999084766/the+ethics+of+brainwave+technology.pdf</a>
12	Presidential Commission for the Study of Bioethical Issues	<a href="https://bioethicsarchive.georgetown.edu/pcsbi/index.html">https://bioethicsarchive.georgetown.edu/pcsbi/index.html</a>	GRAY MATTERS Vol.1Integrative Approaches for Neuroscience, Ethics, and Society	2014	<a href="https://repository.library.georgetown.edu/bitstream/handle/10822/709231/GrayMattersVol1.pdf?sequence=1">https://repository.library.georgetown.edu/bitstream/handle/10822/709231/GrayMattersVol1.pdf?sequence=1</a>
13	Presidential Commission for the Study of Bioethical Issues	<a href="https://bioethicsarchive.georgetown.edu/pcsbi/index.html">https://bioethicsarchive.georgetown.edu/pcsbi/index.html</a>	GRAY MATTERS Vol.2Topics at the Intersection of Neuroscience, Ethics, and Society	2015	<a href="https://repository.library.georgetown.edu/bitstream/handle/10822/712920/Gray%20Matters%20vol%202.pdf">https://repository.library.georgetown.edu/bitstream/handle/10822/712920/Gray%20Matters%20vol%202.pdf</a>
14	OECD Committee for Scientific and Technological Policy	<a href="https://www.oecd.org/sti/emerging-tech/">https://www.oecd.org/sti/emerging-tech/</a>	Neurotechnology and society: Strengthening responsible innovation in brain science	2017	<a href="https://doi.org/10.1787/f31e10ab-en">https://doi.org/10.1787/f31e10ab-en</a>
15	OECD Committee for Scientific and Technological Policy	Emerging technologies - OECD	Recommendation of the Council on Responsible Innovation in Neurotechnology	2019	<a href="https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457">https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457</a>
16	Royal Society	<a href="https://royalsociety.org/">https://royalsociety.org/</a>	iHuman Blurring lines between mind and machine	2019	<a href="https://royalsociety.org/-/media/policy/projects/ihuman/report-neural-interfaces.pdf">https://royalsociety.org/-/media/policy/projects/ihuman/report-neural-interfaces.pdf</a>
17	World Economic Forum	<a href="https://www.weforum.org/">https://www.weforum.org/</a>	Empowering 8 Billion Minds Enabling Better Mental Health for All via the Ethical Adoption of Technologies.	2019	<a href="https://www3.weforum.org/docs/WEF_Future%20Council_Mental_Health_and_Tech_Report.pdf">https://www3.weforum.org/docs/WEF_Future%20Council_Mental_Health_and_Tech_Report.pdf</a>
18	U.S. ARMY Combat Capabilities Development Command Chemical Biological Center	<a href="https://www.cbc.devcom.army.mil/">https://www.cbc.devcom.army.mil/</a>	Cyborg Soldier 2050: Human/Machine Fusion and the Implications for the Future of the DOD	2019	<a href="https://www.mysterywire.com/wp-content/uploads/sites/106/2019/12/Cyborg-Soldier-2050-CBC-TR-1599.pdf">https://www.mysterywire.com/wp-content/uploads/sites/106/2019/12/Cyborg-Soldier-2050-CBC-TR-1599.pdf</a>
19	BRAIN Initiative's Multi-Council Working Group	<a href="https://braininitiative.nih.gov/about/multi-council-working-group">https://braininitiative.nih.gov/about/multi-council-working-group</a>	The brain initiative and Neuroethics: Enabling and enhancing neuroscience advances for society.	2019	<a href="https://braininitiative.nih.gov/sites/default/files/images/bns_roadmap_11_october_2019_sent_to_acd_for_oct_2019_revised_10282019_508c.pdf">https://braininitiative.nih.gov/sites/default/files/images/bns_roadmap_11_october_2019_sent_to_acd_for_oct_2019_revised_10282019_508c.pdf</a>
20	IEEE Standards Association	<a href="https://standards.ieee.org/industry-connections/neurotechnologies-for-brain-machine-interfacing/">https://standards.ieee.org/industry-connections/neurotechnologies-for-brain-machine-interfacing/</a>	Standard roadmap. Neurotechnologies for brain-machine interfacing.	2020	<a href="https://standards.ieee.org/wp-content/uploads/import/documents/presentations/ieee-neurotech-for-bmi-standards-roadmap.pdf">https://standards.ieee.org/wp-content/uploads/import/documents/presentations/ieee-neurotech-for-bmi-standards-roadmap.pdf</a>
21	BNCI Horizon 2020	<a href="https://bnci-horizon-2020.eu/">https://bnci-horizon-2020.eu/</a>	The future in brain/neural-computer interaction.	2020	<a href="https://openlib.tugraz.at/download.php?id=56194931c6b87&amp;location=browse">https://openlib.tugraz.at/download.php?id=56194931c6b87&amp;location=browse</a>
22	International Bioethics Committee of UNESCO	<a href="https://www.unesco.org/en/ethics-science-technology/ibc">https://www.unesco.org/en/ethics-science-technology/ibc</a>	Report of the International Bioethics Committee of UNESCO on the ethical issues of neurotechnology.	2021	<a href="https://unesdoc.unesco.org/ark:/48223/pf0000378724">https://unesdoc.unesco.org/ark:/48223/pf0000378724</a>

(continued on next page)

Table 1 (continued)

	Organization/Project	Organization/Project relevant URL	Title of Publication	Publication Year	Publication URL
23	U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health	<a href="https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health">https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health</a>	Implanted Brain-Computer Interface (BCI) Devices for Patients with Non-clinical Testing and Clinical Considerations Guidance for Industry and Food and Drug Administration Staff	2021	<a href="https://www.fda.gov/media/120362/download">https://www.fda.gov/media/120362/download</a>
24	Committee on Bioethics (DH-BIO) Council of Europe	<a href="https://www.coe.int/en/web/bioethics/home">https://www.coe.int/en/web/bioethics/home</a>	Common Human Rights Challenges Raised by Different Application of Neurotechnologies in the Biomedical Field	2021	<a href="https://rm.coe.int/report-final-en/1680a429f3">https://rm.coe.int/report-final-en/1680a429f3</a>
25	Bioethics Advisory Committee Singapore	<a href="https://www.bioethics-singapore.gov.sg/">https://www.bioethics-singapore.gov.sg/</a>	Neuroscience Research Report	2021	<a href="https://file.go.gov.sg/bacneurosciencereport.pdf">https://file.go.gov.sg/bacneurosciencereport.pdf</a>
26	Neurorights Foundation	<a href="https://neurorightsfoundation.org/">https://neurorightsfoundation.org/</a>	International Human Rights Protection Gaps in the Age of Neurotechnology	2022	<a href="https://ntc.columbia.edu/wp-content/uploads/2022/05/NeurorightsFoundationPUBLICAnalysis5.6.22.pdf">https://ntc.columbia.edu/wp-content/uploads/2022/05/NeurorightsFoundationPUBLICAnalysis5.6.22.pdf</a>
27	The Law Society	<a href="https://www.lawsociety.org.uk/">https://www.lawsociety.org.uk/</a>	Horizon Report for The Law Society Neurotechnology, law and the legal profession	2022	<a href="https://collimateur.uqam.ca/wp-content/uploads/sites/11/2022/09/Neurotechnology-law-and-the-legal-profession-full-report-Aug-2022.pdf">https://collimateur.uqam.ca/wp-content/uploads/sites/11/2022/09/Neurotechnology-law-and-the-legal-profession-full-report-Aug-2022.pdf</a>
28	Regulatory Horizons Council	<a href="https://www.gov.uk/government/groups/regulatory-horizons-council-rhc">https://www.gov.uk/government/groups/regulatory-horizons-council-rhc</a>	Neurotechnology Regulation	2022	<a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1121251/RHC_Report_on_Neurotechnology_Regulation.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1121251/RHC_Report_on_Neurotechnology_Regulation.pdf</a>
29	United Nation Human Rights Council	<a href="https://www.ohchr.org/en/hr-bodies/hrc/advisory-committee/neurotechnologies-and-human-rights">https://www.ohchr.org/en/hr-bodies/hrc/advisory-committee/neurotechnologies-and-human-rights</a>	resolution 51/3	2022	<a href="https://daccess-ods.un.org/access.nsf/Get?OpenAgent&amp;DS=A/HRC/RES/51/3&amp;Lang=E">https://daccess-ods.un.org/access.nsf/Get?OpenAgent&amp;DS=A/HRC/RES/51/3&amp;Lang=E</a>
30	United Nation Human Rights Council	<a href="https://www.ohchr.org/en/hr-bodies/hrc/advisory-committee/neurotechnologies-and-human-rights">https://www.ohchr.org/en/hr-bodies/hrc/advisory-committee/neurotechnologies-and-human-rights</a>	Draft report on impact, opportunities and challenges of neurotechnology with regard to the promotion and protection of all human rights (A/HRC/AC/31/CRP.1)	2023	<a href="https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/sessions/session31/a-hrc-ac-31-crp-1.docx">https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/sessions/session31/a-hrc-ac-31-crp-1.docx</a>
31	Human Brain Project, EBRAINS	<a href="https://www.ebrains.eu/">https://www.ebrains.eu/</a>	European citizens' views on data sharing in brain research.	2023	<a href="https://tekno.dk/app/uploads/2023/02/HBP-Citizen-views-on-data-sharing.pdf">https://tekno.dk/app/uploads/2023/02/HBP-Citizen-views-on-data-sharing.pdf</a>
32	UNESCO	<a href="https://www.unesco.org/en/ethics-neurotech">https://www.unesco.org/en/ethics-neurotech</a>	Unveiling the Neurotechnology Landscape: Scientific Advancements Innovations and Major Trends.	2023	<a href="https://unesdoc.unesco.org/ark:/48223/pf0000386137">https://unesdoc.unesco.org/ark:/48223/pf0000386137</a>
33	Neurotech Guidebook Development Committee	<a href="https://brains.link/en/braintech_guidebook">https://brains.link/en/braintech_guidebook</a>	Neurotech guidebook: Where is Neurotech today?	2023	<a href="https://doi.org/10.14991/K052004002">https://doi.org/10.14991/K052004002</a>
34	Neurotech Evidence Evaluation Committee	<a href="https://brains.link/en/braintech_guidebook">https://brains.link/en/braintech_guidebook</a>	Neurotech evidence book: examining Neurotech's efficacy and safety.	2023	<a href="https://doi.org/10.14991/K052004004">https://doi.org/10.14991/K052004004</a>

collecting input from Member States and experts (<https://www.ohchr.org/en/hr-bodies/hrc/advisory-committee/neurotechnologies-and-human-rights>; <https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/sessions/session31/a-hrc-ac-31-l-1-e.pdf>).

ISO and IEC: ISO prepares international standards for industrial technology in general, and IEC prepares ones specifically for electrical and electronic matters. They have established ISO/IEC JTC 1/SC 43 Brain-computer interfaces in 2022 as a joint technical committee to develop international standards for BCI in the information technology context (<https://www.iso.org/committee/9082407.html>). This group aims to develop industrial standards related to BCI, with the exception of items related to technology for implanting products into the human body and medical devices. Members of the Liaison Committees under this group, that examines international standards to be harmonized with each other, include Telecommunications and Information Exchange between Systems (ISO/IEC JTC 1/SC 6), Internet of Things and the Digital Twin (ISO/IEC JTC 1/SC 41), Artificial Intelligence (ISO/IEC JTC 1/SC 42) under the ISO/IEC JTC in addition to Active Assisted Living (IEC/SyC AAL), Communication Technologies and Architectures (IEC/SyC COMM), Medical Equipment, Software, and Systems (IEC/TC 62), Audio, Video and Multimedia Systems and Equipment (IEC/TC 100), and Wearable Electronic Devices and Technologies (IEC/TC 124) under the IEC. As of February 2024, the BCI is working on a document (ISO/TC 215) to define terms related to BCI industry standards.

IEEE: The IEEE, a professional association in the field of electrical

and telegraphic engineering, established Neuroethics Framework within the Brain subcommittee in 2018, where industry and neuroethics communities collaborate to discuss ethical R&D and social implementation of neurotechnology by purpose of use, including Medical, Wellness, Legal, Military/ National Security, Work & Employment, Education, Sports and Competitions, Entertainment, Analytics (<https://brain.ieee.org/publications/ieee-neuroethics-framework/>). The Industry Connections Neurotechnologies for Brain-Machine Interfacing project within the IEEE Standards Association (SA) published a roadmap for the development of international standards for BCI technology (IEEE SA Industry Connection, 2020). Those who led these activities formed the group "P7700 Recommended Practice for the Responsible Design and Development of Neurotechnologies" to develop recommendations and guidance for managing and evaluating BCI R&D and appropriate use (<https://standards.ieee.org/ieee/7700/11038/>) in 2022 and began full-scale activities in 2023. These activities have been coordinated by IEEE staff and feature the participation of experts on a volunteer basis.

IBI: The IBI was established in 2017 as an international congress body of national and European projects in neuroscience research in major countries of the world (U.S., Canada, China, Korea, Australia, and Japan). One of the main objectives of IBI in the first phase (2017–2021) was the dissemination and practical application of Neuroethics, and a working group was established. In the second phase, the working group continues to exist, but its membership, mode of activities, and involvement with Asian countries have changed since the first phase, as described later (<https://www.internationalbraininitiative.org/neuroeth>

ics).

**Institute of Neuroethics (IoNX):** A private organization established by researchers who participated in the BRAIN Initiative in U.S., IoNX is the first think tank specializing in neuroethics in the world. They cooperate with the activities of the OECD and the National Academy of Science (<https://instituteofneuroethics.org/>).

**BrainMind:** BrainMind is a private community of neurotechnology stakeholders, including, neuroscience researchers, entrepreneurs, investors, philanthropists, academic institutions, and so on, working together to build an ecosystem to accelerate high-impact innovation. For that purpose, they established a collaborative relationship with the OECD and established the BrainMind-OECD Neuroethics Advisory Committee (<https://brainmind.org/neuroethics>).

The current paper provides an overview of how organizations and experts in China, Korea, and Japan participate in the activities of above organizations and the ethical responses to Neurotechnology and neuroscience research in their countries (ethical guidelines, council reports, research projects, etc.).

### 3. Overview of objective indicators

#### 3.1. Bibliometrics

According to the paper dealing bibliometric analysis of academic papers on BCI using Scopus data from 1982 to August 2022, the U.S. has the largest cumulative number of papers, accounting for 17.3% of the analyzed group of papers, followed by China in second place (14.6%), then Germany (5.7%), the United Kingdom (5.02%) and Japan (5.01%) (Maiseli et al., 2023). Looking at the annual trend of the cumulative number of academic papers, the Asian continent, and East Asia in particular, has seen a rapid increase in the number of papers published since the mid-2010s (see Figure 2 in Maiseli et al., 2023). Fig. 1 shows the annual change in the cumulative number of papers in each country from 1999, when the first paper on BCI was published in the Asian region, to 2022. While the number of academic papers published in China has been steadily increasing, Korea and Japan have shown a slowing trend in recent years, and Korea was to fall behind India in 2022. Table 2 summarizes the total number of academic papers based on Scopus data on BCI research (Maiseli et al., 2023) and review articles extracted based on bibliographic data in One Search (Alharbi, 2023), by country. While Japan has a relatively large number of academic papers published, it is surprising that the number of review papers published zero, as reported

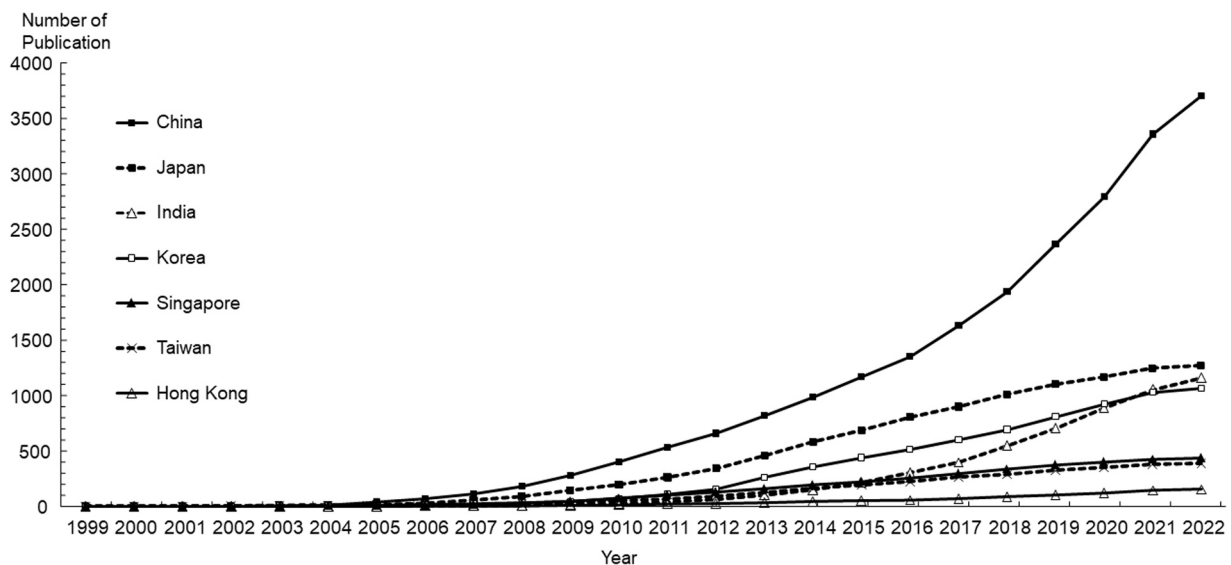
in Alharbi's paper (2023). According to the publication of review papers, China has a remarkably high number of publications among Asian countries, followed by Korea, India, and Taiwan. Regarding the countries of authorship of review papers, there was a bias toward North America and Europe until 2010, but after 2010, the number of authors expanded to Asia, Australia, and Latin America (Alharbi, 2023). These trends, together with the fact that the number of academic papers published in Asian countries increased in the 2010s in the analysis by Maiseli's group (2023), are considered to support the fact that globalization as academic research on BCI was taking place in the 2010s

#### 3.2. Clinical trial registration

As shown in Table 3, in Clinicaltrials.gov one can find 10 registrations from China, 7 from Hong Kong, 4 from India, 2 from Korea, 19 from Singapore and 6 from Taiwan in East and South Asia. Of these, 20 were completed (2 in China, 5 in Hong Kong, 12 in Singapore, and 1 in India) and only one was terminated (in India) (Table 3a). Four cases were registered with information on clinical trial phases by Singapore (1 in Phase 1, 2 in Phase 2, and 1 in Phase 2/3), of which the Phase 2/3 trial was funded by the Singapore government (Table 3b). In Japan, 20 clinical trials were found in two national registries. Of these, 10 were completed, 3 were terminated, and 7 recruiting. Six trials were registered with information on clinical trial phases (2 in Phase 1, 2 in Phase 2, and 2 in Phase 2/3), but none of them were sponsored by a medical product company (Table 3a). In terms of disease condition, all countries and regions included in the analysis registered clinical trials on treatment and rehabilitation of paralysis in stroke patients, accounting for half of the total registrations (Table 3c). China registered a large number of clinical trials in the area of motor disorders, Singapore registered a large number of clinical trials in the area of psychiatric disorders, and Japan two trials for the development of communication tools for amyotrophic lateral sclerosis (Table 3c).

#### 3.3. Patent applications

While the U.S. ranked first in UNESCO's survey, accounted for 47% of all IP5 applications, it should be noted that the three East Asian countries accounted for about 30% of all IP5 patent applications, with South Korea (11%), China (10%), and Japan (7%) coming in second, third, and fourth, respectively (UNESCO, 2023). In particular, Korea and China saw a sharp increase in patent applications in the 2010s, with



**Fig. 1.** Cumulative number of BCI-related publications by countries and region in Asia. Data set was obtained from the Supplementary data file of Maiseli, 2023, accessed via <https://docs.google.com/spreadsheets/d/1I3kylsgrMKVPzLhYZawFLOowOHxBg3EJ/edit?rtfpof=true> (1999–2022).

**Table 2**

Number of BCI-related publications by Asian countries and regions from 1982 to 2022 (upper row) and BCI-related review article publications by Asian countries and regions from 1999 to 2022 (lower row).\*,\*\*

	Country/Region						
	China	Japan	India	Korea	Singapore	Taiwan	Hong Kong
Total Number of Publication (1982–2022)	3705	1270	1162	1068	436	387	154
Total Number of Review Article Publication (1999–2022)	73	0	19	23	0	7	0

\* Data set was obtained from the Supplementary data file of Maiseli, 2023, accessed via <https://docs.google.com/spreadsheets/d/12mknGXSRmGEOOnjSWpzi9D8ma6yB-ulo/edit#gid=2017343566>

\*\* The number was obtained from in the main text of the article by Alharbi, 2023

**Table 3a**

Number of studies registered to ClinicalTrials.gov and other relevant national registries of clinical studies from Asian countries and regions from 2005–2023 (categorized by Status).

Country/Region	Total number of studies							
	Number of registered studies	Completed	Terminated	Recruiting	Active (not recruiting)	Not yet recruiting	Enrolling by Invitation	Unknown status
China	10	2	0	3	1	1	1	2
Hong Kong	7	5	0	0	0	0	0	2
India	4	1	1	2	0	0	0	0
Korea	2	0	0	0	1	0	0	1
Singapore	19	12	0	3	1	1	0	2
Taiwan	6	0	0	3	0	0	0	3
Japan*	20	10	3	7	0	0	0	0

\* Data from the University Hospital Medical Information Network Clinical Trials Registry Japan Registry of Clinical Trials (UMIN-CTR) and Japan Registry of Clinical Trials ( JRCT )

**Table 3b**

Number of studies registered to ClinicalTrials.gov and other relevant national registries of clinical studies from Asian countries and regions from 2005–2023 (Categorized by Phases).

Country/Region	Total number of studies						
	Number of registered studies	PHASE1	PHASE2	PHASE3	PHASE2/PHASE3	N/A	Blank
China	10	0	0	0	0	9	1
Hong Kong	7	0	0	0	0	7	0
India	4	0	0	0	0	3	1
Korea	2	0	0	0	0	2	0
Singapore	19	1	2	0	1	15	0
Taiwan	6	0	0	0	0	2	4
Japan*	20	2	2	0	2	6	8

\* Data from the University Hospital Medical Information Network Clinical Trials Registry Japan Registry of Clinical Trials (UMIN-CTR) and Japan Registry of Clinical Trials ( JRCT )

**Table 3c**

Number of studies registered to ClinicalTrials.gov and other relevant national registries of clinical studies from Asian countries and regions from 2005–2023 (categorized by Disease Condition).

Country/Region	Total number of studies									
	Number of registered studies	Stroke	ALS	Dementia (including Alzheimer disease and MCI)	ADHD	Depression	Other Psychiatric Disorder	Pain	Movement Disorder/ Impairment	Other
China	10	4	0	1	1	1	0	0	3	0
Hong Kong	7	6	0	0	0	1	0	0	0	0
India	4	1	0	0	0	0	0	0	2	1
Korea	2	2	0	0	0	0	0	0	0	0
Singapore	19	8	0	2	2	0	5	1	1	0
Taiwan	6	2	0	0	0	0	0	0	1	3
Japan*	20	11	2	1	0	1	0	1	1	3

\* Data from the University Hospital Medical Information Network Clinical Trials Registry Japan Registry of Clinical Trials (UMIN-CTR) and Japan Registry of Clinical Trials ( JRCT )

China’s patent applications in 2020 slightly higher than those of the U. S. (UNESCO, 2023). Table 4 summarizes indicators related to the number of patent applications in China, Korea, and Japan based on the report published by UNESCO (2023). One common feature of China and Korea is the large number of applications from their own research

institutions (including universities). According to the technological fields with higher values for revealed technological advantage (RTA), an indicator of expertise, China and Korea included fields related to information technology and biomedicines, while Japan included telecommunications, audiovisual technology, and optics. Based on two

**Table 4**  
Trend in Neurotechnology-related patent applications from 2000 to 2021.\*

	Country		
	China	Korea	Japan
Ranking of Number patent applications (fractionalized)	3rd	2nd	4th
Forward Citations (cohort rank)	0.68	0.66	0.67
DOCDB family size (cohort rank)	0.66	0.54	0.68
Top five neurotech patent applicants with number of applications	Ping An Technology (Shenzhen) Co., Ltd. 105 Huawei Technologies Co., Ltd. 37 Zhejiang University 30 Tencent Technology (Shenzhen) Co., Ltd. 25 Shenzhen Institutes of Advanced Technology 23	Samsung Electronics Co., Ltd. 72 Korea Advanced Institute of Science & Technology 52 Electronics and Telecommunications Research Institute 46 LG Electronics, Inc. 26 Korea University Research and Business Foundation	Fujitsu Ltd. 78 Sony Corporation 69 Hitachi, Ltd. 54 Canon Inc. 39 NEC Corporation 25
Top five technology field based on the revealed technological advantage (RTA) in neurotechnology	Computer technology 1.58 IT methods for management 1.24 Analysis of biological materials 1.11 Measurement 1.04 Furniture, games 1.01	Transport 2.16 IT methods for management 1.91 Medical technology 1.3 Furniture, games 1.24 Digital communication 1.23	Telecommunications 3.34 Audio-visual technology 1.78 Digital communication 1.35 Computer technology 1.24 Optics 1.16

\* Ranking and number of indicators were obtained from the figure 9, and tables 2, 3 and 4 of the UNESCO, 2023.

indicators, Forward Citations showing the actual citation of the patent after filing and DOCDB family size, which indicates the degree to which the patent family of the patent application is protected by other countries, one can find that patents applied for from China and Japan tended to be valued and protected in other countries, while the one from Korea tended to be less likely protected in other countries.

**4. Participation in the activities of principles, ethical and technical guidance, and industrial standards**

**4.1. International activities**

The contribution of Asian countries in activities related to international organizations is limited, but not non-existent. The following is an overview of the participation of East Asian countries in each of the international activities described in Section 2.2, as summarized in Table 5.

OECD CSTP: OECD member countries Korea and Japan participated in expert meetings and workshops in the Recommendation (OECD, 2019) preparation process and continue to cooperate with monitoring

**Table 5**  
Participation in the activities of international organizations that are working on the formulation of ethical principles, guidelines or industrial standards for Neurotechnology.

Organization	Country		
	China	Korea	Japan
OECD CSTP	Meeting Host	Member Country	Member Country
UNESCO	Invited Speaker	N/A	Invited Speaker
UNHRC	Advisory Committee Member	Advisory Committee Member	N/A
ISO/IEC JTC 1/SC 43	Secretariat	P Member	P Member
IEEE Neuroethics Framework	N/A	N/A	Volunteer
IEEE SA P7700	Non-Voting Member	N/A	Voting Member
IBI Neuroethics Working Group	Member	Meeting Host/Member	Member
IoNX	N/A	Advisory Committee Member	Advisory Committee Member
BrainMind	Advisory Committee Member	Invited Discussant	Brain Mind Ecosystem Member

and implementation activity led by the Global Forum on Technology. In particular, the Korean Delegation to the OECD hosted the first workshop to discuss concrete plan for implementation of the Recommendation (<https://web.archive.oecd.org/2021-09-16/580722-neurotechnology-in-and-for-society.htm>). Although China is not an OECD member country, they hosted the workshop organized by the Working Party on Bio-, Nano- and Converging Technologies (BNCT) in 2018 ([https://one.oecd.org/document/DSTI/STP/BNCT\(2018\)5/FINAL/en/pdf](https://one.oecd.org/document/DSTI/STP/BNCT(2018)5/FINAL/en/pdf)).

UNESCO: Two Japanese experts were invited discussants at the International Conference held in 2023, along with a Chinese expert (<https://www.unesco.org/en/neuroethics-conference/speakers?hub=85592>), and one of whom will be recommended by the Government of Japan to UNESCO as one of the members of the expert panel that will draft the Recommendation on the Ethics of Neurotechnology.

UNHRC: Korea was one of six countries that submitted comments as a member state in response to the UNHRC Advisory Committee’s call for contributions (<https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/neurotechnology/01-states/ac-submission-states-rok.docx>). This may be due to the participation of Korean expert member of the Advisory Committee in the Drafting Group for the Research and Study Report on the Impact of Neurotechnology on Human Rights, which also includes expert members from China.

ISO/IEC: State Council of China plays a role of Secretary for the ISO/IEC JTC 1/SC 43 group. Under the leadership of China, 12 Participating Members (P-Members) and 9 Observer Members (O-Members) are participating. From Asia, India, Korea, and Japan are participating as P-Members, and Singapore is participating as an O-Member (as of February 2024). As of February 2024, only the progress process regarding the drafting the document to define the terminology associated with this International Standard (ISO/IEC CD 8663 Information Technology-Brain-computer Interface - Vocabulary) has been made public, and the progress of other activities has not yet been informed (<https://www.iso.org/standard/83268.html?browse=tc>).

IEEE Neuroethics Framework: The nine working groups introduced in Section 2.2 collaborate with each other and report their achievements and discuss new activity plans at the General Meeting once or twice a year mainly through online. As of February 2024, Japanese researchers are participating as volunteers in the Wellness, Legal, and Entertainment working groups (<https://brain.ieee.org/publications/ieee-neuroethics-framework/#1650473358596-3b015535-1a81>). In particular, members in the Wellness Working Group held Regional Workshops in Europe, Latin America, and Japan on the draft of the whitepaper prepared mainly by researchers in North America, where the invited



participants provided opinions on revisions and questions regarding the content of the whitepaper, for example, the interpretation of the concept of “wellness” in that paper. The result of the workshop will be integrated and reflected in the final version of the whitepaper for the publication, as well as in the relevant articles prepared by the working group members. As of February 2024, no experts from China or Korea are participating in this activity.

IEEE P7700: Experts from China and Japan are participating in the activities. The working group as a whole consists of about 20 experts who participate in regular online meetings and are divided into subgroups to discuss the methodology of creating the recommendation and to define terms related to ethics and governance to be mentioned in the recommendation.

IBI Neuroethics Working Group: In East Asia, the most significant contribution to this group in the first phase of IBI was made by researchers affiliated with the Korea Brain Research Institute (KBRI) in Korea. KBRI hosted Global Neuroethics Summit (GNS), a conference body that was integrated with the first phase of this working group, contributed to the exchange between the Asian and Western Neuroethics communities, the globalization of Neuroethics, and the strengthening of educational activities for neuroscience researchers and the general public (Das et al., 2022; Global Neuroethics Summit Delegates, 2018). It should be noted that the working group members in the second phase of the IBI are not limited to researchers funded by IBI member projects, and independent neuroethics experts from China, Korea, and Japan are invited (<https://www.internationalbraininitiative.org/neuroethics>). Therefore, the collaborative relationship between the GNS and IBI has entered a phase of exploring new possibilities.

IoNX: Researchers who were at the center of the planning and operation of the GNS were involved in the establishment of this institute. Through the connections of Dr. Karen Rommelfanger, the director of IoNX, experts from Korea and Japan who participated in the Organizing Committee of the GNS have cooperated in the activities as an Advisory Council of IoNX (<https://instituteofneuroethics.org/network>).

BrainMind: one of the Core Advisors of this organization is the Founder of a Chinese company (<https://brainmind.org/team>). In addition, Korean expert participates in the BrainMind-OECD Neuroethics Advisory Committee, and Chinese and Japanese experts have been invited to the Advisory Meeting held in 2021 (<https://brainmind.org/neuroethics>). Individuals who wish to participate in BrainMind’s activities and international conferences must apply for membership in the BrainMind Ecosystem, pass a screening process, and be invited. At least one Japanese person is registered as a BrainMind Ecosystem member, but information on how many people from Asian countries are registered is not available in public.

Table 5 indicates that research institutions and experts from China, Korea and Japan participate to a certain extent in international activities, and it appears that the main activities are covered by these three countries. However, a close examination of the details of their participation reveals that in certain cases they were not involved in decision-making positions or just hosted/were invited transient meetings. Furthermore, the number of experts participating such activities is limited to 1–2, which is very small compared to the scale of participation from Europe and the U.S., and the same experts are involved in multiple activities in duplicate. Taken together, one should be careful that the degree of substantial involvement in each of activities fluctuates depending on the motivation of individual experts and the situation in which they are placed.

#### 4.2. Activities in the home country

In China, the Artificial Intelligence Ethics Subcommittee of the National Science and Technology Ethics Commission issued ethical guidelines on BCI research in February 2024 ([https://www.gov.cn/lianbo/bumen/202402/content\\_6930611.htm](https://www.gov.cn/lianbo/bumen/202402/content_6930611.htm) in Chinese; <https://cset.georgetown.edu/publication/china-bci-ethics/> in English translation).

This is the first national ethical guideline on neurotechnology in the East Asian region. It is noteworthy that China, which had not previously issued clear results on the promotion of neuroethics at the national project level, has formulated such guidelines ahead of Japan and South Korea. On the other hand, Korea has been promoting neuroscientific research in general under the Brain Research Promotion Act (BRPA) enacted in 1998. Regarding the promotion of neuroethics, in the 2018 amendment of the BRPA, the parliamentarians proposed the academic and policy promotion of neuroethics, including the establishment of the Neuroethics Committee and the Policy Center for Neuroethics under the Ministry of Science and ICT. Nevertheless, this amendment proposal has been postponed and has not been realized as of 2023 (Kang et al., 2023). In light of this situation the Neuroethics Research Society under the Korean Bioethics Association proposed the Neuroethics Guideline in 2023 and activities are ongoing with the aim of promoting interdisciplinary discussions to make it effective as a national ethical guideline in the future (Yoo et al., 2023).

In Japan, the Ethical Guidelines for Medical and Biological Research Involving Human Subjects ([https://www.lifescience.mext.go.jp/files/pdf/n2373\\_01.pdf](https://www.lifescience.mext.go.jp/files/pdf/n2373_01.pdf) in Japanese) comprehensively protects human subjects in neuroscience research as well as another biomedical research. Ethical guidelines specific to neuroscience are developed at the academic society (for example, Guidelines for ethics-related problems with “non-invasive research on human brain function” by the Japan Neuroscience Society [https://www.jnss.org/en/human\\_ethic?u=fe521915544a3eefcf27ec898525cb34&c=7](https://www.jnss.org/en/human_ethic?u=fe521915544a3eefcf27ec898525cb34&c=7)) or project level (for example, see <https://neuro-elsi.jp/template-web/wp-content/uploads/72625360b8449e662063fc6b2ae162f5.pdf> in Japanese) and have limited effectiveness.

### 5. Current situation and efforts to improve international presence in Japan

Up to this point, this paper has overviewed the progress of neurotechnology and examined the status R&D and neuroethics-related activities in East Asia, but focusing on Japan, one can see a different history of involvement with neurotechnology and Neuroethics and participation in international activities than in China and Korea. While China and Korea have emerged with a rapid increase in the number of academic papers and patent applications, especially since the mid-2010s, Japan has been one of the frontrunners in this field since BCI was still being fundamentally investigated. Furthermore, since the early days when neuroethics was established as an academic field, Japanese researchers have participated in international conferences and published papers in international journals to demonstrate their presence and introduce and raise awareness of neuroethics within their own country (Fukushi et al. 2007; Illes et al., 2005). With the closure of the research group that led to the initial activities of neuroethics in Japan, its international presence declined, and domestic interdisciplinary discussions stagnated. The situation continued for some time, since it was difficult to introduce neuroethics into university and graduate education and recruit professional personnel due to delays in training people suitable for being in an educational position (Gaillard, 2018; Fukushi et al., 2017). During this period, researchers in bioethics, philosophy of science, philosophy of religion and law, science communication, and other fields with an interest in neuroethics engaged in autonomous and decentralized academic research. Establishment of the IBI in 2017 triggered the change of that situation. This section outlines the current situation in Japan and discuss the factors and implications associated with the changes in the situation since 2017.

#### 5.1. Framework for clinical trials

Japan is considered to be one of the countries with a good foundation for clinical application, as not only basic research on BCI technology is, but also medical device evaluation indices have been studied and a

notice (December 15, 2010, Pharmaceutical and Food Safety Bureau No. 1215–1, [https://www.mhlw.go.jp/web/t\\_doc?dataId=00tb6598&dataType=1&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=00tb6598&dataType=1&pageNo=1) in Japanese) was issued by the Ministry of Health, Labour and Welfare (MHLW). Japanese stroke treatment guidelines recognized the high evidentiary nature of the use of BCI as a rehabilitation device for upper limb dysfunction, although the recommendation is still weak ([https://www.jsts.gr.jp/img/guideline2021\\_kaitei2023.pdf](https://www.jsts.gr.jp/img/guideline2021_kaitei2023.pdf) in Japanese). In Japan, clinical trials and post-marketing surveillance conducted to apply for approval of pharmaceuticals and medical devices, as well as the Quality Management System (QMS) inspection for certification of medical devices, are governed by the Pharmaceuticals and Medical Devices Act. Regarding the notification of clinical studies and human subjects research not covered by the Pharmaceuticals and Medical Devices Act, the Clinical Research Act, which came into effect in 2018, defines their classification and how to register them in the registry, and established new category of clinical research called “Specified Clinical Trials” (Taruno et al., 2022). The Clinical Research Act stipulates how to conduct Specified Clinical Trials sponsored and funded by pharmaceutical and medical device marketing authorization holders, as well as the clinical studies conducted as part of human research to confirm the efficacy and safety of unapproved or inapplicable pharmaceuticals and medical devices. In response, the MHLW established the Japan Registry of Clinical Trials (JRCT, <https://jrct.niph.go.jp/en-top>), which registers clinical trials defined in the Pharmaceuticals and Medical Devices Act and the Specified Clinical Trials defined in the Clinical Research Act. Other interventional and observational human subjects research have been registered under the Ethical Guidelines for Medical and Biological Research Involving Human Subjects in several databases that existed prior to the enactment of the Clinical Trials Act. The National Institute of Health Sciences, an independent administrative agency under the MHLW, operates a portal site across databases to enable centralized management and retrieval of information on clinical trials. This institute worked for consolidation of existing registries, and the databases currently in operation in Japan are the JRCT and the UMIN Clinical Trials Registry operated by the University Hospital Medical Information Network (UMIN). JRCT is accredited by the WHO Primary Registry, and UMIN-CTR is a database compliant with the standards of the International Committee of Medical Journal Editors. Clinical trials of BCI conducted on human subjects are also registered in these two registries as introduced in the previous section.

## 5.2. Initiatives for industrial applications of neurotechnology

As noted earlier, Japan ranked fourth in the world in terms of the number of patent applications filed in the IP5. Furthermore, among the patent applicants located in Japan, the top five patent applications are all global companies such as Fujitsu Ltd., Sony Corporation, Hitachi, Ltd., Canon Inc., and NEC Corporation (UNESCO, 2023) that have proven track records in the fields of electronics, information and communications, and electrical engineering. This indicates that R&D on BCIs in Japan has the potential for industrial applications. On the other hand, companies of various sizes in Japan are interested in commercializing neurotechnology, meaning that organized activities of those companies may hold the key to capturing domestic and international markets for future industrial applications. Two representative organizations, the Consortium for Applied Neuroscience (CAN) (<https://www.can-neuro.org/> in Japanese) and the Braintech Consortium (<https://brain-tech.jp/> in Japanese) might be key players. The CAN was established in 2020 as a general incorporated association to establish and promote a framework for industry-academia collaboration in industrial applications of brain science; however, its origins as a voluntary organization date back to 2010. Its mission is providing a forum for private companies and researchers in different fields to meet and exchange information and organizing seminars to teach ethical legal and social implications of neuroscience R&D. To achieve this mission, the organization has

established various membership status that are open to academia, public interest groups, and individuals, as well as general business, and welcomes a diverse range of organizations and individuals. Currently, there are 36 open-member companies (including 3 sponsoring members). Although none the top five companies in patent applications mentioned in the UNESCO survey report are listed there, CAN include prominent Japanese companies in the fields of electronics, telecommunications, electrical engineering, and materials engineering, suggesting that a wide range of industries are interested in neurotechnology in Japan. Three public and corporate organizations are listed as affiliate members, one of which is the Union of Brain Science Association in Japan (<http://www.brainscience-union.jp/> in Japanese), an association of basic and clinical neuroscience research societies in Japan. In February 2024, CAN launched the “Applied Brain Science Certification Examination System (tentative in English),” a system that grants the certification of “Applied Brain Science Practitioner (tentative in English)” to those who have acquired basic knowledge of the fundamental technology and commercialization of neurotechnology, passed the specified examination, and aim to improve the quality of related companies in Japan (<https://www.can-neuro.org/certification/> in Japanese). Taken together CAN might be positioned as an influential organization with respect to industrial applications of neurotechnology in Japan through the collaboration of member companies and organizations from diverse professions.

Another industrial community, the Braintech Consortium, intends to create an ecosystem for the industrialization of neurotechnology by creating human networking opportunities for professionals such as researchers, businesspeople, and investors interested in neurotechnology. To this end, they have lowered the hurdles for participation by actively utilizing social networking services and online events and have provided opportunities for various members to acquire knowledge and exchange the human resources needed to socially implement neurotechnological applications, including neuroethics. While only one company in the broadcasting business has publicly been announced as a corporate member, individuals of start-up companies, interested investors, young researchers, and graduate and undergraduate students interested in entrepreneurship, and employees of companies on the user side of neurotechnology have participated. The Braintech Consortium also features activities such as pitch events to attract investors and encourage them to support startups.

## 5.3. Participation in the activities of principles, ethical and technical guidance, and industrial standards

As pointed out earlier, since the introduction of neuroethics, Japanese neurotechnology stakeholders have become aware of the ethical concerns and importance of developing rules regarding BCIs. Thus, research studies on incidental findings (Fujita et al., 2014; Seki et al., 2009), consultations on human research using BCIs (Mizushima and Sakura, 2012; Sakura and Mizushima, 2010), ethical concerns in the application of decoded neurofeedback (Nakazawa et al., 2016) and guideline for the domestic research project member institutions developments (<https://neuro-elsi.jp/template-web/wp-content/uploads/72625360b8449e662063fc6b2ae162f5.pdf> in Japanese) have been conducted in neurotechnology-relevant research projects. Other research groups conducted surveys on ethical concerns in neuroscience research (Nakazawa et al., 2022; <https://www.jst.go.jp/erato/ikegaya/elsi/survey-report.pdf> in Japanese) and international trend analysis on the scope of application of deep brain stimulation to neuropsychiatric disorders, its implementation criteria, and ethical considerations (Takagi, 2012). Nevertheless, development of government guidelines and progress toward participation in the activities of principles, ethical and technical guidance, and industrial standards were slow.

The situation changed in 2017 with the launch of IBI, a federation of neuroscience research projects in major countries and regions. In its first

phase (2017–2021), IBI established working groups to address four issues through international cooperation. One of the working groups was established for neuroethics; Japanese research projects were required to send members to this group. The collaborators who participated the working group activities contributed to obtaining an accurate understanding of the trends in international neuroethics research and the current position of Japan in this field (*Global Neuroethics Summit Delegates, 2018*). They also identified critical ethical issues in neuroscience research in Japan, summarized them, and discussed future activities to promote neuroethics in the future (*Sadato et al., 2019; Nakazawa et al., 2022*). At about the same time, Japanese Neuroscience researchers working on the practical application of neurotechnology began to participate in international discussions on the need to address ethical issues and develop rules (*Clausen et al., 2017; Yuste et al. 2017*). In this momentum, R&D funding, "Realization of a society in which human beings can be free from limitations of body, brain, space, and time by 2050" was launched under the Moonshot R&D Initiative by the Cabinet office (<https://www.jst.go.jp/moonshot/en/program/goal1/index.html>). The members of a research project of Moonshot R&D called "Liberation from Biological Limitations via Physical, Cognitive and Perceptual Augmentation" shortened as "Internet-of-Brains" (IoB) launched a committee to develop a self-regulatory proposal with the support of Japanese R&D personnel, translate it into English and disseminate it internationally, and get involved in creating rules for ethically and appropriately performing R&D (see [https://brains.link/en/braintech\\_guidebook](https://brains.link/en/braintech_guidebook)). With the cooperation of researchers both in Japan and abroad, they introduced a systematic review method used in creating medical practice guidelines, such as those in the Cochrane Reviews (<https://www.cochranelibrary.com/about/about-cochrane-reviews>) and drafted the corresponding text while examining the effectiveness and safety of neurotechnology products. Before publication, the draft was peer-reviewed by the External Review Board, which specializes in bioethics, social science, and technology. First, a guidebook explaining the current status of commercialization and precautions for using each technological development item was published for users of neurotechnology, including the general public. Next, an evidence book summarizing the scientific evidence on the efficacy and safety of neurotechnology was published. These two studies can be revised and reprinted in response to the suggestions and requests of readers to reflect both the progress of technological development and real-world demands. This is significant not only in raising awareness regarding professional ethics and interest in international standards among parties involved in R&D but also in establishing a mechanism in Japan to disseminate information and alert more end-users of neurotechnology. Furthermore, as shown in *Table 5*, the creation and publication of the English version of these guidebooks (*Neurotech Evidence Evaluation Committee, 2023; Neurotech Guidebook Development Committee, 2023*) aided in getting Japan involved in the activities of international organizations such as UNESCO and IEEE and made a significant contribution to enhancing its presence in the field of international rulemaking for socially implementing neurotechnology.

The IoB project also established a research unit called "Internet of Brains"-Society (IoB-S, <https://www.iob-s.com/>), where legal practitioners, constitutional scholars, and neuroethicists work together to identify and address legal issues associated with socially implementing neurotechnology and conduct research on neurolaw. IoB-S member researchers are promoting awareness of Neurotechnology, Neuroethics, and Neurolaw to the legal profession in the country. They are also working to establish an international joint academic research system in these fields and make presentations at international conferences to enhance the presence of Japan. Several IoB-S member researchers also participate in IEEE and ISO rulemaking activities, and IoB-S is the only Japanese organization that is interconnected with IBI, IoNX, IEEE and ISO/IEC JTC1.

## 6. Discussion

The current study summarizes the status of various activities related to neurotechnology and relevant neuroethics in East Asian countries from the viewpoints of clinical application, industrial application, and international activities for principles, ethical and technical guidance, and industrial standards development. The following discussion will examine the emergence of China and Korea in industrial applications and Japan's full-fledged efforts to engage in international activities related to Neuroethics.

### 6.1. Limitations of the study and references to other countries

In this study, only three East Asian countries, China, Korea and Japan were focused on the analysis of academic research, clinical applications, patent applications, and participation in activities related to appropriate use and R&D of Neurotechnology. The reasons for this, as mentioned earlier, are that they are the member countries of the IBI and whole information used as objective indicators in this study could be explicitly extracted, and that explicit participating organizations and collaborators were identified in the activities to review ethical principles, guidance, and industry standards. The results captured the characteristics of R&D and social implementation efforts in each country but did not explore the socioeconomic or cultural factors that might explain these differences. The social acceptance of neurotechnology and the influence of culture and values on neuroethics have also been subjects of research that East Asian researchers are interested in (*Fukushi et al., 2017; Sakura, 2012; Wang et al., 2019; Wu and Fukushi, 2012*). Along with the process of developing policy and ethical responses to social implementation of neurotechnology, research from sociological, economic, cultural anthropological, and religious perspectives on East Asia might be developed in an integrated manner with neuroethics.

It should be noted that the comprehensiveness of the quantitative and qualitative indicators covered in this study does not necessarily mean that other Asian countries are lagging behind in R&D of Neurotechnology as well as its appropriate use or neuroethics. In fact, focusing on the clinical development, it is worth noting that Singapore is one of the leading countries in Asia, especially with regard to BCI application. As shown in *Table 3*, Singapore has the largest number of clinical trials registered on Clinicaltrials.gov in Asia, and a certain number of them have reached the clinical trial phase, including the one funded by the Singaporean government. Singapore's advantage in clinical development of neurotechnology can be attributed to the fact that the Singapore Bioethics Advisory Committee has taken an official position on the clinical application of neurotechnology from a relatively early stage, paving the way for its implementation in society. In 2013, this committee published a consultation paper (*Bioethics Advisory Committee Singapore, 2013*) in which it had summarized the R&D trends and clinical applicability of BCI, neuroimaging, brain stimulation, stem cell therapy, and neuropharmaceuticals at the time and discussed the ethical, legal, and social issues that are common when developing recommendations for addressing these issues. In preparing the Paper, an international panel of experts was established to advise on the content. As shown in *Table 1*, this was the first case that a government agency has published guidance specifically on the R&D and regulation of neuroscience as a medical technology. This might have saved researchers and sponsors a great deal of time and effort when conducting clinical research and studies in Singapore. The fact that feedback comments on the guidance paper had been actively solicited from individuals and organizations strongly endorsed the commitment of the nation to supporting neurotechnology R&D and addressing ethical and social issues. In 2021, the committee published a research report on R&D related to neurotechnology for medical and non-medical purposes, considering the convergent and rapid development of information and communication technologies and artificial intelligence with BCI technologies (*Bioethics Advisory Committee Singapore, 2021*). That report included 13

recommendations for providing responses to ethical concerns in neurotechnology R&D and specific recommendations for obtaining informed consent and withdrawing consent for clinical research and supporting the participation of adults and children who are vulnerable in such research. The report also included responses to feedback comments from the 2013 report. Singapore, which has demonstrated a way to promote ethical responses to the clinical application of neurotechnology led by governmental bodies from a medium- to long-term perspective, reflects that neuroethics can bridge the gap between existing medical ethics and bioethics, thereby acting as a reference for other Asian countries in developing new clinical applications in this field. Indeed, China and Korea have begun to work on domestic research guidelines, as described earlier.

In Japan, based on information from domestic registration sites, 20 clinical trial registrations existed, a number surpassing that of Singapore, but zero clinical trials were registered under the sponsorship of companies seeking regulatory approval. This suggests that although Japan's BCI has developed as academic research and reached a level conducive to clinical application, some barriers exist in the process of commercializing it as a medical device and preparing for application for regulatory approval. In the future, it will be essential for researchers involved in R&D to promote not only the pursuit of research results related to therapeutic and rehabilitation effects, but also the enhancement of strategies for product commercialization and the updating of medical device evaluation indicators established in 2008, with the involvement of industry and regulatory authorities. In considering such promotion strategies, the development of BCI R&D governance at the national level, as in Singapore, should also be considered.

The other limit of this study is that the paper did not focus on regulatory effort related to protection and management specific to neural data, which has become increasingly discussed as neurotechnology has progressed. In case of academic or clinical research, the IBI established the specific working group of neural data standardization in which the member projects continue the discussion to appropriate consent for the data acquisition as well as rules for sharing in addition to ensuring technical compatibility between organizations and nations (Eke et al., 2022). Some countries have policies in their national legal systems to explicitly incorporate the protection of Neural data into their fundamental human rights (Baselga-Garriga et al., 2022; Cornejo-Plaza et al., 2024), which means that the protection and management of neural data is one of the hot topic about the impact of neurotechnology on human rights discussed among international organizations (International Bioethics Committee, 2021; OECD 2019; also see <https://www.ohchr.org/sites/default/files/documents/hrbodies/hrcouncil/advisorycommittee/sessions/session31/a-hrc-ac-31-crp-1.docx>). With regard to the sharing of neural data, efforts in Europe and the United States are beginning to integrate the format and curation processes of neural data from multiple countries, to practice ethical use (<https://www.ebrains.eu/data/share-data/share-data-process>), and to archive data repositories built in large-scale studies (for example, <https://www.braininitiative.org/toolmakers/resources/data-archive-for-the-brain-initiative-dabi/>; <https://www.dandiarchive.org/>; also see Subash et al., 2023). While some Asian countries are aware of the technical challenges of large-scale neural data repositories and the issues of fostering awareness and concrete measures for ethical use in terms of Neuroethics and FAIR principles (Nakazawa et al., 2022; Wang et al., 2019), at this point, there is not enough publicly available information to conduct a systematic analysis, so we did not include it as a subject of insight in this paper. However, as the R&D of Neurotechnology has progressed and domestic responses to neuroethics and governance in general in Asian countries have followed the West, ethical discussions on neural data will also need to be closely monitored as a subject of investigation and analysis in the future.

## 6.2. Asian breakthroughs in industrial applications

In terms of industrial applications, China, Korea, and Japan have a track record of patent applications that rivals those of Europe and the U.S., which means that they are subjected to detailed patent analysis aiming to understand global trends in neurotechnology. This might be a reflection of the growing presence of East Asia in neurotechnology field and its potential to influence the world with its R&D output. With regard to China, however, the potential application of Neurotechnology to military technology, including the results of national neuroscience research projects, has been pointed out, and the U.S. in particular is highly interested in this trend (Kosal and Putney, 2023). The military or dual use of neurotechnology is not necessarily the main focus of this study but can be noted as a possible influence on Chinese (and U.S.) indicators of industrial applications. It was also pointed out that Korean patents are less likely to be subject to protection in other countries. Additionally, in common with the three East Asian countries, the degree of involvement in formulating industrial standards and ethical recommendation for social implementation of neurotechnology was lower, or less experiences than those in Europe and the U.S.. More self-help efforts are required for socially implementing developed technologies.

In Japan, there are consortia of companies related to neurotechnology, CAN and Braintech Consortium, and industries of various sizes and occupations are interested in this field and are trying to make practical use of neurotechnology and implement it in society. Both consortiums are similar in that it is unclear whether they are actively engaged in international activities such as operating English-language websites and disseminating English-language documents or not. One can estimate that the priority of these consortia is to strengthen cooperation among domestic companies, but it is difficult to believe that the participating companies are targeting only Japan as a potential market. It is also important to develop international activities at an early stage and link them with consortiums in Europe, the U.S. and Asia in order to compete with global companies that have expertise in international patent strategies and business development. Especially, the internationalization of the CAN would be an urgent priority in order for the "Applied Brain Science Certification Examination System" to gain international recognition and credibility.

## 6.3. Potential contribution to international governance of neurotechnology

The current study revealed that research institutions and experts in Japan, China, and Korea have a certain degree of participation in international activities for principles, ethical and technical guidance, and industrial standards for the R&D and social implementation of neurotechnology. In particular, Chinese and Korean experts were involved in the preparation of reports at UNHRC, and China plays a secretariat role in ISO/IEC standard development activities. However, not everything is working well. The qualitative survey in this paper has once again clarified the problem that among neuroethicists based in Asia, the number of those with the academic background, research achievements, and experience to be involved in international activities is still small compared to those in Europe and the U.S., and their voice is relatively weak. This is thought to be reflected in the current stagnant progress in the discussion of international standards under the leadership of the State Council of China, for their first chair experience of a subgroup of ISO/IEC JTC 1.

From the time neuroethics was established as an academic discipline in Europe and the U.S., educational opportunities such as workshops and summer schools for doctoral personnel were provided to obtain professional human resources at an early stage. Additionally, in response to technological innovations, the importance of ethics education for neuroscience researchers and clinicians of neuropsychiatric disorders has been recognized (Giacobbe et al., 2023; Sahakian and Morein-Zamir, 2009), and there has been much trial and error in developing not only

academic research systems but also educational systems in universities. (Abu-Odeh et al., 2015; Elkin et al., 2012). Currently there are opportunities to study neuroethics as a minor in university curricula, particularly the philosophy and bioethics departments, are accepting students majoring in neuroethics. In Europe, a university alliance called NeurotechEU was established based on the European Universities Initiative launched in 2017 (<https://theneurotech.eu/>). NeurotechEU includes European Union member states and nine universities from the United Kingdom and Turkey. This alliance provides educational opportunities to acquire basic knowledge about neurotechnology and expertise in developing advanced technologies as well as practical skills to implement them in various applied fields, including medicine, and create new businesses. As a result of these efforts, many international activities are now working with second- and third-generation professionals who benefited from the early education system of neuroethics and were trained by “nodal” or “key point” researchers from the early 2000 s to the 2010 s

The rapid establishment of human resource development systems and educational environments in Western universities has not been successfully pursued in East Asia. In fact, a survey on introducing neuroethics education in Japanese research universities shows that as of 2023, there are still no cases in which neuroethics has been introduced as an independent subject (Fukushi, 2023). The reasons for the lack of progress in fostering human resources for neuroethics may differ from country to country, but a lack of human resources teaching neuroethics and inadequate research budgets are common (Kang et al., 2023; Nakazawa et al., 2022; Normile, 2022). Fortunately, a path toward overcoming this situation is opening, with people emerging in Chinese and Japanese universities to host laboratories for academic research in neuroethics (for example, <https://philosophy.fudan.edu.cn/64/7f/c14253a222335/page.htm> in Chinese, and <https://seeds.office.hiroshima-u.ac.jp/profile/en.290b391a69933ad1520e17560c007669.html>). A human resource development system was also created at a Korean research institution in collaboration with a U.S. university (Jeong et al., 2019). Moreover, both Japan and Korea have supported neuroethics research groups within national neuroscience research projects, albeit on a small scale, and they have achieved academic results (Jeong et al., 2019; Kataoka et al., 2023; Sakura and Mizushima, 2010; Takimoto and Shimanouchi, 2023). Also in China, the importance of incorporating neuroethical research into national neuroscience research projects is being considered (Wang et al., 2019). Although East Asian countries are still lagging behind Europe and U.S. in this area, it is expected that there will be progress in these countries toward developing human resources that can contribute to ethics and rulemaking and facilitate international discussions in response to the development of BCI research and its social implementation.

Japan would be mostly expected to increase its involvement in the formulation of international rules for Neurotechnology in Asia and to improve its presence in the world soon. In the past, its research projects in Japan have mainly focused on formulating rules within domestic research projects and studies on social acceptance and developing countermeasures, and they have not sufficiently addressed the dissemination of results in English and the contribution of these activities to international rule formulation. Rather, the focus has been on developing domestic rules by understanding or following international trends, meaning a lack of the concept of active involvement in international activities. However, the activities of the IoB project overcame the difficulties in this situation and made it possible to ask the world for proposals on appropriately using Japan-originated neurotechnological applications in accordance with the Japanese legal system and social customs. Similar developments are spilling over into other national research projects. The neuroethics research group of the Strategic Research Program for Brain Sciences (SRPBS) developed guidelines for clinical research on patients with psychiatric disorders and published the results in an English-language academic paper (Takimoto and Shimanouchi, 2023). Other research communities such as brain organoids

have emerged to participate in international discussions on the ethical issues posed by advanced technologies in neuroscience (Sawai et al., 2022). The results of these multiple activities would be hopeful to be reflected in the international activities of principles, ethical and technical guidance, and industrial standards. In Japan, activities led by governmental bodies have also become active in recent years. The Center for Research and Development Strategy at the Japan Science and Technology Agency (JST-CRDS) has been working with the OECD-CSTP as the Japanese contact organization of the Anticipatory policy framework for emerging technology governance, by working with relevant Japanese ministries, agencies, and academia on the governance of R&D and social implementation of advanced science and technology including Neurotechnology (JST-CRDS, 2023; OECD, 2023). Additionally, Japanese ministries and agencies are increasing their interest in neurotechnology not only for R&D purposes but also its use as a target technology for economic security and information and communication regulations. The Ministry of Foreign Affairs (MOFA) has designated synthetic biology and neurotechnology as “Emerging Technologies Influencing the Future of Nation’s Economic and National Security” and conducted an international survey and analysis of the potential impact of global R&D trends in these technologies on the economic security policy of Japan (<http://www.ifeng.or.jp/publication/synthetic-biology-20220508/> in Japanese). The Ministry of Internal Affairs and Communications (MIC), which has jurisdiction over information- and telecommunication-related businesses in Japan, has been intermittently examining ethical issues related to brain-originated information and communication technology and its proper use since the 2010 s (for example, [https://www.soumu.go.jp/main\\_content/000114261.pdf](https://www.soumu.go.jp/main_content/000114261.pdf); [https://www.soumu.go.jp/main\\_sosiki/joho\\_tsusin/policyreports/joho\\_tsusin/gijutsusenryaku/ainou/index.html](https://www.soumu.go.jp/main_sosiki/joho_tsusin/policyreports/joho_tsusin/gijutsusenryaku/ainou/index.html); <https://cinet.jp/japanese/research/projects/aitech/>, in Japanese). Although many of the activities and studies have not been internationally disseminated, it is first essential to establish a framework in which these activities are consolidated, rather than remaining independent and sporadic. The next step is to utilize these activities to provide a unified view that contributes to strategies and ethical guidelines for domestic R&D and industrial development of neurotechnology. Such actions would be important to improve the effectiveness of domestic industrial application, to develop a governance structure, and to respond to international competition and international cooperation. One can expect that JST-CRDS, an OECD-CSTP contact point, play a key role to aggregate domestic activities and deliverables of diverse origins, and built a network linking academic and industrial organization to ministries including Ministry of Economy, Trade and Industry (METI), which has jurisdiction over industrial standards, and Ministry of Education, Culture, Sports, Science and Technology (MEXT) in addition to MHLW, MOFA, MIC. It is also important that experts involved in Neuroethics and Neurolaw, as well as researchers and developers of Neurotechnology, should actively cooperate with them.

## 7. Conclusion

The current study confirms that East Asia is a region with great potential in the global Neurotechnology R&D and market. Based on clinical trial registrations. With regard to clinical development, Japan has one of the leading clinical trial registries in the Asian region, but there are indications that there are issues with collaboration between academia and industry in commercialization. On the other hand, China and Korea are following Singapore in creating domestic neuroscience research guidelines. In terms of patent applications related to industrial applications, China, Korea, and Japan followed the U.S. based on the number of applications filed in IP5. Regarding international activities on principles, ethical and technical guidance, and industrial standards related to social implementation, although there were participation from East Asian countries and the opportunity of secretariat of the international standards, they lagged behind Europe and the U.S. in the development of

human resources capable of designing the review process and leading discussions for consensus building. Many European and U.S. neuroethicists participate in the multiple activities in overlapping way for responsible R&D and social implementation of neurotechnology, where they are building a network of mutual collaboration by sharing information and making proposals of governing as “nodal points” or “key persons” themselves. Following such successful cases, neurotechnology researchers and neuroethicists in Japan have initiated the international dissemination of the results of domestic rulemaking activities and strengthened their participation in international networks. Taking a cue from the efforts of Western countries that have taken the lead, the key to converting the potential for clinical and industrial applications in East Asia into real would be for China, Korea, and Japan to develop their own guidelines and participation in international activities, and to train and produce human resources who will actively participate in a variety of international organizations/projects.

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The author declares no ethical approval statement.

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### CRediT authorship contribution statement

The author confirms sole responsibility for the following: study conception and design, data collection, analysis and interpretation of results, and manuscript preparation.

### Declaration of generative AI and AI-assisted technologies in the writing process

The author declares no use of generative AI and AI-assisted technologies in the writing process.

### Declaration of Competing Interest

The author declares no conflict of interest.

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