NSCEB
National Security Commission on Emerging Biotechnology

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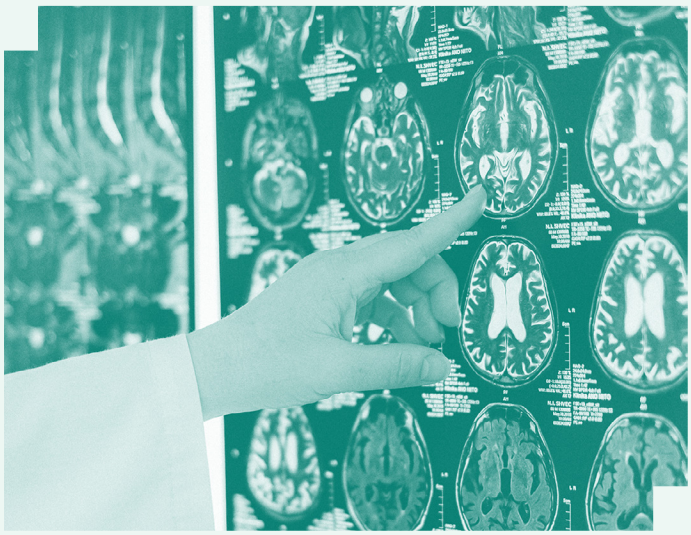
Securing U.S. Leadership in Brain-Computer Interfaces

The United States has historically led the world in research and development of Brain-Computer Interfaces (BCIs), but China is emerging as the new global leader in BCIs through targeted investment and rapid growth in the sector.

BCIs have the potential to treat patients with neurological diseases, enhance American warfighter capabilities, and train the next-generation of artificial intelligence (AI) models with brain data. China already recognizes the strategic significance of BCIs and has unleashed a coordinated, full-stack strategy to close the gap in BCI commercialization, manufacturing, and data. In March 2026, China became the first country to approve an implantable BCI for commercial use, signaling that China's strategy can successfully reach deployment faster than the United States by overcoming the regulatory hurdles to rapidly move the technology from first-in-human clinical trials to approval and reimbursement.[1]

The United States has no comparable national strategy or commercially available implantable BCI, putting U.S. leadership and its ability to capitalize on the benefits of BCIs at risk.

In April 2026, the National Security Commission on Emerging Biotechnology (NSCEB) convened leading experts across industry, venture capital, academia, and government to identify key bottlenecks and discuss next steps that policymakers could take to secure U.S. BCI leadership.



Background on BCI Technologies

BCIs are technologies that interact with electrical activity in a person's brain. Depending on the application, BCIs can record activity from a patient's brain (e.g., a patient using their brain to control a prosthetic arm), provide input back into the brain (e.g., reestablishing a patient's sense of smell), or accomplish both functions. These systems allow patients to use only their brain to interact with computers, communication systems, sensory systems, prosthetic limbs, and different types of medical therapies. There are two major categories of BCI technologies. Non-invasive BCIs are worn external to the body, and implantable BCIs require surgery to place the device on or within a person's brain tissue. Several American BCI companies have begun U.S. clinical trials using implantable BCIs to treat medical conditions such as paralysis, Amyotrophic Lateral Sclerosis (ALS), and brainstem stroke.[2]

Critical Drivers of BCI

Whoever leads in BCI will have a strategic advantage across health, economic, and national security. Neurological conditions—the leading cause of illness and disability globally—now affect more than three billion people worldwide.[3] In addition to helping patients control prosthetics and recover lost motor function, countries could leverage BCIs to augment military operations, including controlling swarms of drones "at the speed of thought."[4] Additionally, while treating brain data as a strategic resource could provide enormous advantages for AI development and patient care, competitors such as China currently have no neural-data-specific privacy or security regulations to slow them down.[5] Allowing adversaries to access sensitive data and drive global BCI innovation risks ceding the technical and ethical leadership that will shape the next-generation of human-machine interaction.

The United States has historically led technology development in this sector, with the Defense Advanced Research Projects Agency (DARPA) and the National Institutes of Health (NIH) driving the effort for the past two decades, and, in recent years, with a growing private sector accelerating clinical trials and commercialization. However, new treatments for neurological conditions have only a 5.9% chance of FDA approval from Phase I and take an average of 11.1 years to reach approval.[6] Regulatory bottlenecks, coupled with funding issues, are drying up the U.S. BCI innovation pipeline, and the global landscape is shifting fast in China's favor.

In July 2025, the Chinese government issued a coordinated strategy for BCIs that designates the technology as a national "future industry," alongside quantum and 6G. The strategy states that, by 2030, China will significantly enhance its BCI innovation capacity, forming a safe, secure, and reliable industrial system.[7]

Key Bottlenecks for American BCI

Lack of U.S. strategy and coordination

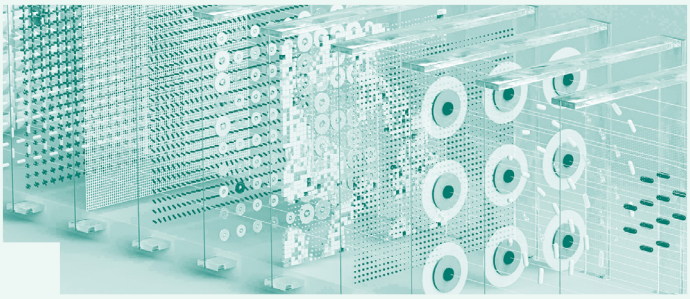
Various U.S. government entities—including DARPA, NIH, the Advanced Research Projects Agency for Health (ARPA-H), the National Science Foundation (NSF), the Department of Veterans Affairs (VA), and the Food and Drug Administration (FDA)— fund or regulate parts of BCIs without aligned milestones or coordinated interagency strategies. In addition, NIH funding for the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative, the primary source of government funding for neurobiology, has dropped by about 50% over the past three years, and the authorization will expire in 2027.[8] BCI research relies heavily on animal research, particularly non-human primate (NHP) testing, and China has historically been the leading source of NHPs bred for scientific purposes.[9] The United States faces a shortage of NHPs due to import disruptions and increased demand.[10] Additionally, the U.S. government is trying to move away from animal testing and toward new experimental models.[11] Taken together, these factors will create a bottleneck in BCI technology development that may help China take the lead.

Technical challenges for BCIs:

The BCI community faces several technical barriers to commercialization. First, many implants tend to fail after the first year, often for reasons like signal degradation and short battery life linked to mechanical failures.[12] Next-generation materials, coatings, electronics, and batteries are needed to solve these challenges.[13] Second, most current implants require invasive brain surgery that can only be performed at select hospitals.[14] In order to scale the technology and reach more patients, new strategies will require minimally invasive approaches that can be performed in more locations. Increasing the functionality of microchips and electronics will enable a wider variety of use cases.

Data integration to ensure better performance of BCIs

The BCI community lacks the data infrastructure and integration needed to better train predictive models and prevent duplicative research and development efforts. Current implantable BCIs are trained on limited datasets and serve a specific function. [15] Researchers need databases for both clinical performance—to understand how and why BCIs are successful or not—and for basic neuroscience discovery. These and other BCI-related data will accelerate discovery and development by providing appropriate training data for the next generation of AI models.



Updating regulation and reimbursement systems

There is currently a mismatch between the institutional FDA process and the rapid advancement of BCIs. While there are many devices in clinical trials and the FDA is working toward commercial approval of an implantable BCI, there is no clear pathway because the FDA process cannot keep up with the speed of innovation and iteration of cutting-edge BCI technologies.[16] Even if a BCI were approved, there is currently no active Centers for Medicare & Medicaid Services (CMS) reimbursement coverage for implantable BCIs, further preventing patients from reliably accessing a device and economic growth for companies.[17] This lack of reimbursement also disincentivizes investment in the technology, since there is no clear payment structure once a product is through regulatory approvals. Additionally, an invasive BCI that is classified as a novel Class III device requiring premarket approval (PMA) today can face an FDA review cycle of 12–18 months after submission.

Next Steps for Policymakers

Policymakers can take concrete steps to address the above-mentioned challenges and ensure that the United States leads the world in BCI research and commercialization. The following recommendations are primarily derived from the Commission's April 2025 report, *Charting the Future of Biotechnology*, and its January 2026 discussion paper, *The Future of Biotechnology Regulation: Modernizing Medical Biotechnology Regulation*.[18]

April 2025 Report Recommendations

Recommendation 1.1a

Establish a National Biotechnology Coordination Office (NBCO).

BCI development currently sits at the intersection of at least six federal entities—DARPA, NIH, ARPA-H, NSF, the VA, and the FDA—which fund or regulate parts of the technology without aligned milestones or a coordinated interagency strategy. The NBCO would build a national strategy and coordinate federal efforts for specific enabling technologies such as BCIs, aligning agency milestones and addressing shared bottlenecks.

Recommendation 4.3b

Initiate a grand research challenge focused on making biotechnology predictably engineerable.

This would bolster resources for the research and data collection needed to advance fields such as neurobiology and neural engineering that underpin BCI development, directly addressing the technical barriers currently holding back commercialization. For example, researchers could create a digital model of neural circuits to predict brain tissue behavior, informing the next-generation materials, coatings, and batteries needed to address signal degradation and short battery life linked to mechanical failures, which cause many implants to fail within their first year.

Recommendation 4.1a

Create a Web of Biological Data to serve as a single point of entry for researchers to access high-quality data.

The BCI community lacks the data infrastructure and integration to better train predictive models and prevent duplicative research and development efforts. A Web of Biological Data would increase access to and integration of neural, biological, and clinical data across institutions. These and other BCI-related data will accelerate discovery and development by providing appropriate training data for the next generation of AI models.

Recommendations 2.1a & 2.1b

Create simple pathways to market and exempt familiar products from unnecessary regulation. Prepare for novel products to come to market.

The current FDA regulatory process is not keeping up with the speed of innovation and iteration of cutting-edge BCI technologies. This recommendation and the regulatory policy options below would clarify guidance, streamline overlapping processes, and unlock regulatory capacity to accelerate the commercialization of promising, novel technologies such as BCIs.

January 2026 Medical Biotechnology Regulation Discussion Paper Policy Options

Med. Policy Options 6–10

Conduct faster, fairer clinical trials.

Layered bureaucracy significantly slows clinical trials in the United States and pushes developers to conduct clinical trials abroad. Other countries, such as Australia and China, are attracting developers due to investigator-initiated pathways and faster patient recruitment. Reducing unnecessary delays while maintaining the FDA's standards for safety and effectiveness would help ensure that patients gain timely access to transformative technologies. For example, Congress could direct the Department of Health and Human Services (HHS) to require centralized institutional review board (IRB) review for FDA-regulated multi-site BCI clinical trials and direct the FDA to apply a risk-based approach to clinical holds on Phase I BCI trials to close the gap in trial start times between the U.S. and countries such as China.

Med. Policy Option 2

Help developers meet data expectations.

Without clear guidance on data expectations and common deficiencies, submissions by BCI developers could face repeated rounds of revisions and delays. The FDA's current tool for signaling issues, Complete Response Letters, are so heavily redacted that they flag risk to investors while giving BCI developers little they can actually act. Congress could direct the FDA to publish aggregated, de-identified reports of deficiencies common to BCI submissions and to standardize deficiency letters into a four-part structure: what was submitted, why it was insufficient, what is required, and the scientific rationale, so developers can resolve issues faster and reach patients sooner.[20]

New Policy Option

Ensure BCI technologies are explicitly included in the new FDA and CMS RAPID program.

Even if a BCI were approved, there is currently no active CMS reimbursement coverage for implantable BCIs, further preventing patients from reliably accessing a device and disincentivizing investment in the technology. In April 2026, the FDA and CMS announced the Regulatory Alignment for Predictable and Immediate Device (RAPID) program, which links manufacturers to CMS experts early in the FDA review process so that evidence generated for market authorization can also support Medicare coverage decisions, potentially reducing the time between FDA approval and national coverage from about a year to as little as two months.[21] Because BCIs sit at the intersection of strategic technology and medical breakthroughs, incorporating them into RAPID could both accelerate patient access to life-changing devices and help ensure that the U.S. maintains its lead in this critical sector.

References

1. https://www.scientificamerican.com/article/china-just-approved-its-first-brain-implant-for-commercial-use-a-world-first/; https://startupfortune.com/china-has-turned-brain-implants-into-a-commercial-medical-race/
2. Clinicaltrials.gov
3. https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(24)00038-3/fulltext
4. https://www.technologyreview.com/2019/10/16/132269/us-military-super-soldiers-control-drones-brain-computer-interfaces/amp; https://blogs.icrc.org/law-and-policy/2025/08/21/warfare-at-the-speed-of-thought-can-brain-computer-interfaces-comply-with-ihl/
5. https://www.arnoldporter.com/en/perspectives/advisories/2025/07/neural-data-privacy-regulation; https://academic.oup.com/jlb/article/12/1/lsaf006/8113730
6. https://media.crai.com/wp-content/uploads/2024/09/13110655/Approaching-the-final-frontier-golden-decade-of-drug-development-for-the-central-nervous-system-Sept2024.pdf
7. https://cset.georgetown.edu/publication/china-bci-implementation-opinions/
8. https://braininitiative.nih.gov/funding/understanding-brain-initiative-budget
9. https://www.nature.com/articles/s44222-025-00313-6; https://www.nationalacademies.org/read/26857/chapter/5#88
10. https://unherd.com/2021/02/chinas-plan-for-medical-domination/?edition=us; https://www.nationalacademies.org/read/26857/chapter/5#77chinas-plan-for-medical-domination/?edition=us; https://www.nationalacademies.org/read/26857/chapter/5#77
11. https://www.cnn.com/2026/03/20/health/animal-testing-methods-technology
12. https://www.nature.com/articles/s41427-025-00613-8; https://pmc.ncbi.nlm.nih.gov/articles/PMC6991888/; https://link.springer.com/article/10.1186/s42234-025-00168-7
13. https://www.nature.com/articles/s41427-025-00613-8
14. https://www.jneurosci.org/content/43/45/7575
15. https://pmc.ncbi.nlm.nih.gov/articles/PMC7556208/
16. https://clinicaltrials.gov/search?intr=Brain%20computer%20interface&viewType=Card
17. https://www.healthaffairs.org/content/forefront/unlocking-future-medicare-and-brain-computer-interfaces; https://www.gao.gov/products/gao-25-106952
18. https://www.biotech.senate.gov/final-report/chapters/; https://www.biotech.senate.gov/wp-content/uploads/2026/02/NSCEB-Future-of-Regs-Medical-FINAL.pdf
19. https://www.congress.gov/bill/119th-congress/house-bill/2756; https://www.congress.gov/bill/119th-congress/senate-bill/1387/text
20. https://www.fda.gov/media/151712/download
21. https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices

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