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The rise of CNS technologies: Trends reshaping CNS care

Introduction

CRA's Life Sciences Practice has been exploring innovation and challenges in central nervous system (CNS) drug development for some time.[1] In this article, we focus on how innovation in technology-driven solutions has gained momentum in recent years. AI in particular has enabled innovation in this field by enhancing signal processing, personalization, scalability, and accessibility of CNS interventions.

We have identified three key areas of technological innovation within CNS that are attracting significant interest, namely brain-computer interfaces (BCIs), wearable technologies, and digital health software. Together, these areas present new opportunities for patients and manufacturers amid persistent challenges surrounding CNS pharmacological innovation.

A new era of brain-computer interfaces

Though BCIs have been under investigation in humans since 1973, when EEG signals were first used to control a cursor on a computer screen, the field has evolved rapidly in recent years.[2,3] Historically, innovation was constrained by a fundamental trade-off. Invasive systems, requiring surgical implantation into the brain, offered superior signal quality and precision, enabling more accurate decoding of neural activity, but were limited by surgical risk, cost, and lower patient acceptance. Non-invasive systems, on the other hand, offered greater accessibility and safety, but suffered from lower signal quality and reduced performance.

A number of recent technological breakthroughs are now reshaping this landscape. Companies such as Medtronic and Newronika are advancing AI-enabled adaptive deep brain stimulation (DBS) platforms for Parkinson's disease that dynamically adjust therapy in response to real-time neural feedback, thereby improving therapeutic outcomes and reinforcing the performance advantages traditionally associated with invasive approaches[4,5]. At the same time, companies such as Synchron and Precision Neuroscience are pursuing a minimally invasive approach, using endovascular implantation and thin cortical surface electrode arrays, respectively, combined with AI-driven signal

decoding to interpret neural activity without open-brain surgery.[6,7] These innovations are intended to improve patient accessibility while narrowing performance gaps with fully invasive systems and highlight a broader trend toward leveraging AI to enhance both the performance and accessibility of BCI systems.

At the same time, competition across the BCI sector has intensified, placing growing pressure on invasive BCI developers to sustain their value proposition and technological edge. For example, Neuralink, one of the key players in the BCI field, is responding to increasing competitive pressure, particularly from the emergence of minimally invasive approaches designed by companies such as Synchron and Precision Neuroscience, by scaling up production and expanding clinical use cases.[8]

In addition, the regulatory environment surrounding BCIs is evolving, with increasing clarity for BCI developers. In May 2021, the FDA published guidance for developers of implanted BCIs seeking Investigational Device Exemption (IDE) approval for conducting clinical studies in patients with paralysis or amputation. This guidance provided greater clarity on FDA expectations surrounding clinical trial design and safety assessment for BCIs. Since then, several BCI developers obtained IDE approval, as outlined in *Table 1*.

Table 1: Timeline of IDE approvals for BCIs following FDA guidance published in May 2021.

Date of IDE approval	Product (company)	Indication	Type	Details
Jul 2021	Stentrode (Synchron)	ALS	Non-invasive	Uses a minimally-invasive endovascular implantation approach for neural signal recording, ultimately restoring motor control using thoughts alone[9]
May 2023	N1 implant (Neuralink)	ALS and cervical spinal cord injury	Invasive	(Note: first rejected in 2022 due to safety concerns) Wirelessly transmits neural signaling to external devices, ultimately restoring motor control using thoughts alone[10]
May 2024	Brain Interchange (CorTec)	Stroke rehabilitation	Invasive	Uses a closed-loop system to combine neural signal recording with adaptive stimulation[11]
Nov 2025	Connexus BCI (Paradromics)	Severe loss of motor control	Invasive	Wirelessly transmits neural signaling to external devices, ultimately restoring speech and enabling computer control[12]

Altogether, the evolving field of BCIs offers exciting new opportunities for manufacturers to enhance their CNS portfolios. In March 2026, Neuracle Technology received marketing approval from China's National Medical Products Administration (NMPA) for their invasive BCI designed for patients with paralysis, making it the first BCI in the world approved for commercial use.[13] This milestone highlights the magnitude of progress since the first BCI system investigated in humans in 1973, which was limited to basic EEG-driven cursor control, compared to today's increasingly precise, adaptive, and clinically deployable technologies. With an estimated 278 BCI companies globally as of February 2026, the global BCI market is projected to be worth $80 billion by 2035.[14]

Evolution of wearables

Meanwhile, innovation in CNS wearables is expanding rapidly across both diagnostic and therapeutic domains. By enabling continuous monitoring and intervention, these technologies are reshaping how CNS conditions are detected and monitored.

Data generated by widely adopted consumer technologies, such as smartphones and smartwatches, are increasingly being leveraged for early detection of cognitive and neurological changes, which has the potential to transform the CNS care pathway. For example, a recent virtual observational study (N=23,004 US adults) supports the feasibility of using data collected via routine use of iPhones and Apple Watches to detect mild cognitive impairment.[15] Similarly, the EpiWatch prescription app designed for the Apple Watch has demonstrated high sensitivity in detecting tonic-clonic seizures with a low false alarm rate, enabling timely caregiver alerts and supporting real-time monitoring of neurological events.[16] By monitoring digital biomarkers, clinicians may be able to intervene sooner and offer more personalized care, thereby improving prognosis and slowing disease progression.

Towards continuous CNS monitoring: lessons from diabetes care

A useful analogue for the evolving role of wearable technologies in CNS can be found in the adoption of continuous glucose monitoring (CGM) in diabetes care. CGM systems transformed disease management by providing real-time, longitudinal data that improved both clinical decision-making and patient autonomy.[17] CGM succeeded not because it generated more data, but because it changed the treatment paradigm.

A similar trend is emerging in CNS care. Wearable technologies and digital biomarkers are beginning to enable continuous, real-world insights into patient neurological function.[18] Investment in diagnostic-enabling CNS technologies creates opportunities to support earlier disease identification, improved patient stratification, and more tailored treatment and patient management approaches across multiple stages of the care pathway.

In parallel, prescription-grade wearables are emerging as scalable, non-invasive therapeutic options that monitor and modulate neurological function. For example, the Felix NeuroAI wristband targets essential tremor through AI-driven neuromodulation,[19] while Naox's in-ear EEG device can record and transmit neural signals for epileptic patients.[20] Both devices were granted FDA 510(k) clearance within the last 12 months, enabling commercial uptake. Some CNS wearables are also being developed to complement pharmacotherapy, rather than replace it. One such example is the AI-driven EPISERAS earpiece sensor, designed to detect oncoming seizures in patients with drug-resistant epilepsy, thereby supporting patients and caregivers in daily monitoring.[21] In addition, the FL-100 headset provides at-home neuromodulation for the treatment of depression, and can be used either as standalone therapy or as an adjunct to pharmacological options.[22] Together, these developments point towards an integrated care model in which wearables and pharmaceuticals may be used in combination to optimize patient outcomes.

Perseverance of digital health software

Finally, it is worth highlighting the continued interest in digital health software for CNS indications, with innovation in this field observed alongside growing maturity in regulatory pathways. As has been highlighted in prior CRA Insights,[23,24] digital software remains a viable option for manufacturers in areas where there is limited progress in pharmacological research and reimbursement. And, new digital software entrants generally remain psychotherapy-based, continuing to offer low-risk, scalable, and accessible treatment options that may complement, or even reduce reliance upon, pharmacotherapy. One example is the CT-155 app, co-developed by Click Therapeutics and Boehringer Ingelheim, which delivers cognitive behavioral therapy sessions for the treatmentCT-155 received breakthrough device designation from the FDA in 2024 and reported favorable Phase 3 trial outcomes later in 2025.[25]

The case of Pear Therapeutics, however, highlights the persistent reimbursement challenges facing digital software in the CNS field. Despite having three FDA-approved apps for mental health conditions, with high willingness to prescribe amongst healthcare providers, the hesitancy of insurers to cover the cost of digital products jeopardized the profitability of the company, which eventually filed for bankruptcy.[26] The relative immaturity of the sector, lack of well-established reimbursement pathways, and the need for more robust, real-world evidence to are cited as being required support broader coverage.[27]

Together, these trends highlight how CNS innovation is increasingly extending beyond traditional pharmacological approaches, creating new opportunities for manufacturers to reshape care pathways. While emerging modalities such as BCIs offer long-term potential, and digital software offers accessible interventions, more established wearable technologies are already demonstrating success in other therapeutic areas (e.g., with continuous glucose monitoring and continuous positive airway pressure). Wearables, therefore, may represent the most immediate and accessible route for pharmaceutical companies to differentiate existing portfolios and enhance patient management.

Implications & how CRA can help

As pharmacological progress continues to face challenges in CNS indications, leveraging innovations in technologies such as BCIs, wearables, and digital health applications may offer an attractive opportunity in a growing market space. These technologies open doors to patient populations that continue to remain underserved, from psychiatric conditions to neurodegenerative diseases.

As these innovations gain traction, they will have significant implications for CNS portfolio strategy, including:

- **Opportunity assessment:** Identifying which existing or pipeline CNS assets are best positioned to benefit from complementation with digital or technology-enabled interventions
- **Therapeutic area expansion:** Assessing where new technological innovation creates the strongest commercial upside
- **Competitive positioning:** Understanding how early engagement with CNS technologies can shape leadership in markets with limited recent pharmacological innovation

- **Investment focus:** Redirecting R&D resources toward technological innovation to capture long-term value
- **Lifecycle management:** Leverage technology partnerships to extend asset value through improved functional outcome measurement

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