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# Using data-driven insights from the nervous system to build neural digital therapies

**BIOS Health uses artificial intelligence (AI)-powered neural interfaces to understand the basis of chronic diseases and accelerate the development of treatments.**

In April 2003, scientists completed the sequencing of the human genome, and this led to breakthroughs in genetic research and testing, and in molecular and genetic therapeutics. The Human Genome Project also enabled the field of computational and mathematical approaches to manage ever bigger biological datasets. Strides in big-data analysis and application have made a new generation of healthcare possible. As part of that revolution, BIOS Health, founded in 2015, is using artificial intelligence (AI) to read, write and analyse data from the nervous system.

"We have built on the omics and precision-medicine culture to create therapies informed by neural data in real time," said Emil Hewage, CEO and co-founder of BIOS Health. "We are the only provider of a form of neural sequencing."

BIOS uses neural interfaces and AI to read neural data in real time and understand what is needed to correct the 'neural code'. This information is used to develop better and more-targeted therapeutic drugs and devices—the latter being 'advanced bioelectronics'—or neural digital therapies, which use insights from the nervous system.

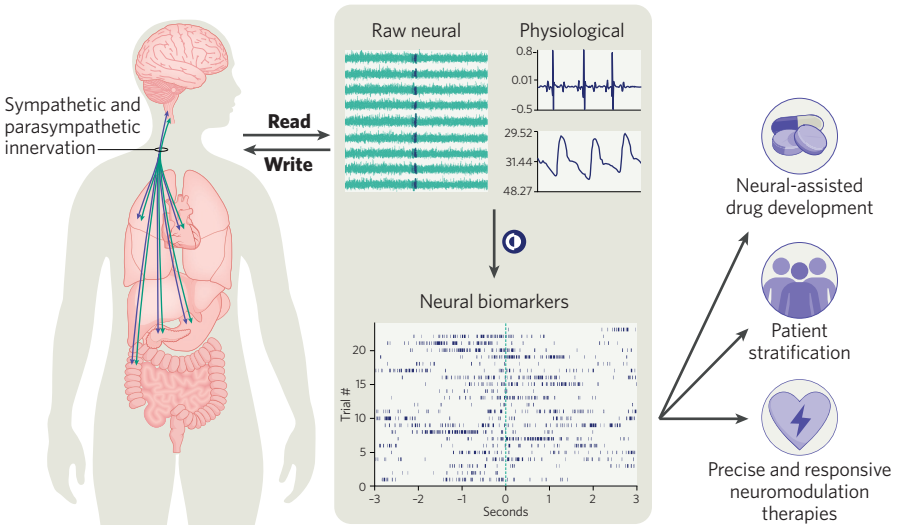


**Fig. 1 | BIOS neural interface converts raw neural data into actionable biomarkers.**

## Informing therapeutic development in real time

BIOS Health has developed an interface that can read signals from neural tissue. The signal data are collected and analysed using the company's AI platform to create sets of signals that can be used as neural biomarkers (Fig. 1).

"We now have vast sets of data, and have built libraries to house the data, as well as tools for its analysis. The neural signatures collected from these datasets allow us to understand the physiology of health and disease," said Hewage.

The tools generated by BIOS can be used for automatic sequencing of the neural code, helping to understand a drug's mechanism of action, as it allows researchers to match up the neural signatures with biomarkers. The tools also enable real-time monitoring of the effect of drug or device interventions in preclinical and clinical trials.

"We can cut the feedback time on efficacy from months to minutes," said Hewage.

Greater understanding of the mechanism of action will help researchers to create better and more-targeted interventions. The use of neural signatures and biomarkers will allow greater stratification of patients in clinical trials. The combination of these could lead to faster development of drugs and devices, smaller clinical trials, and a more efficient and cost-effective route to the market.

In the clinic, measurements of neural activity could also support the calibration of implanted or wearable devices, meaning the physician can tune the device in a single appointment. This would reduce the need for repeat visits, cutting healthcare costs and making the process more patient-friendly.

## Building an AI-driven pipeline

Around one-third of deaths worldwide are caused by cardiovascular disease. In late 2020, BIOS Health launched its Autonomic Therapy Initiative (BIOS ATI), in which it will work with partners to develop AI-powered neural interfaces to deliver treatments for heart disease. BIOS is also developing an in-house pipeline of cardiovascular-disease therapeutics.

"We worked with key opinion leaders at leading cardiovascular centres to understand the neural basis of cardiovascular diseases," said Hewage. "We looked at diseases such as heart failure and neurocardiogenic syncope, and generated real-time neural biomarkers related to these."

Cardiovascular diseases are generally very broad classes and need long trials in thousands of patients. By using biomarkers to subdivide the classes into smaller groups of patients, the process of validation should be faster. BIOS is using the neural data related to cardiovascular disease to create novel therapeutics and diagnostics, and to screen off-patent drugs for potential repurposing.

"We went from a standing start to potential stimulation candidates in less than two years. These are leads that can be titrated fast and with reduced tuning time, and will be going into clinical trials," said Hewage. "We are working with partners to develop clinically usable systems."

BIOS plans to take some of its pipeline assets into the clinic and then to the market. The company will also seek partners and co-develop its other candidates, particularly those outside its core area, including rheumatoid arthritis, diabetes and asthma.

BIOS Health will receive up to $1.4 million from the US National Institutes of Health (NIH) under its Stimulating Peripheral Activity to Relieve Conditions (SPARC) program, in order to provide all SPARC researchers with access to BIOS' neural treatment design technology. This will support the development of therapeutic stimulations to act as replacements for drug therapies.

"We like working with partners with complementary skills, capabilities and datasets, and we look forward to building long-term assets together," said Hewage.

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