Open-source AIMDs drive clinical adoption of bioelectronic medicine

Potential clinical applications of AIMDs in bioelectronic medicine includes many chronic diseases, such as overactive bladder, sleep apnea, heart failure, rheumatoid arthritis, inflammatory bowel disease, hypertension, thyroiditis, psoriasis, type 1 and type 2 diabetes, and obesity, which are worth at least $100 billion in the U.S. alone. Once these AIMDs are widely available on the market, it will be a major shift in how the medicine is practiced.

Multiple forces are now at play to make this vision a reality, with most promoting the progress and a few hindering it. Two promoting forces are a technology push and a market pull, while a force hindering bioelectronic medicine development is the "valley of death" in obtaining the initial startup funding advancing the technology readiness from a laboratory prototype to an FDA investigational device exemption approval for clinical study.

The technology push is a bottom-up force referring to a collective effort by multiple R&D teams toward developing more effective and minimally invasive technologies for interfacing with autonomic nerves, including stimulation of the vagal and sacral nerves (VNS/SNS) and high-frequency electrical block of the sympathetic nerves.

The market pull is a top-down force, which aims to accelerate the development of bioelectronic technologies that are most urgently required due to an unmet clinical need. As most major chronic diseases are poorly addressed by biopharma therapies, there has been considerable enthusiasm among clinicians about applying various VNS/SNS therapies using AIMDs. AIMD therapies for overactive bladder, sleep apnea, heart failure have been FDA approved, while AIMD therapies for rheumatoid arthritis, inflammatory bowel disease, and hypertension progressed to the clinical testing phase. However, the majority of potential therapies are still at a rodent proof-of-principle stage and are desperately lacking access to reliable AIMDs for a transition to large-animal and clinical testing.

In 2022, the NIH's SPARC program launched their new Human Open Research Neural Engineering Technologies (HORNET) Initiative, aimed at bridging the technology push and the market pull in order to tackle the "valley of death" obstacle by funding development of clinical-grade AIMDs and nerve stimulation leads. This initiative would allow rapid technology maturation, modularity, advanced communications, and inter-connectivity to achieve their readiness for the FDA IDE clinical studies. The NIH awarded $22.5 million total to two teams of investigators, the CARSS team based at the University of Southern California, Medipace and Med-Ally, and the COSMIIC team based at Case Western Reserve University and University of Michigan.

The CARSS AIMD is focused on VNS and SNS by developing an assortment of implantable stimulation leads for interfacing with the sacral nerve and the vagus, including both the main vagal nerve trunks and their thoracic, abdominal, and pelvic branches. For enabling closed-loop and on-demand control of the nerve stimulation based on the activity of various internal organs, the CARSS system will develop a range of implantable sensing leads, including ECG, EMG, acceleration, temperature, mechanical, and electrochemical sensing.

The COSMIIC AIMD is focused on multi-channel stimulation and will also implement the closed-loop control, including autonomous operation without the need of external controllers. Among its unique capabilities, the COSMIIC system will provide the: high-frequency electrical nerve conduction block functionality, novel high-density connector for the electrode arrays, and wireless communication to connect the implantable and wearable sensors and actuators.

By adopting open-architecture hardware, open-source software, and interaction between two HORNET teams, this SPARC-funded effort aims to develop a modular inter-operable AIMDs that is well-suited for targeting peripheral nerves and spinal cord roots. Such AIMDs could be rapidly applied toward a wide range of clinical applications. Bioelectronic medicine technology is probably still a few years away from the game-changing “AlphaGo” moment that propelled AI industry forward in 2016. Still, the HORNET initiative will likely accelerate the progress toward establishing bioelectronic medicine as an essential component of medical practice and treatment.

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