Neural interface technologies: industrial perspectives

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Neural interface technologies (NITs) provide unique information conduits to the human body. These conduits can be applied by industry for products ranging from medical devices to consumer applications. This chapter explores these applications from an industry perspective.

Technology lifecycles

New technologies often face hurdles in their commercialisation journey. Economists capture this as part of the 'technology adoption lifecycle (TALC)' (Rogers, 2003) As illustrated in fFigure 1, the TALC is often represented as a *diffusion of innovation* that proceeds from innovators and early adopters into the majority of the population.

Refinements to this model are introduced when the new technology is 'disruptive', meaning a technology that creates an entirely new way of performing a task (Moore and McKenna, 2006). Many applications of NIT fall under this category. Technologies that are disruptive often face additional hurdles when trying to make the leap across the "chasm" between early adopters, such as those found in the advanced academic communities where neural interfaces are applied today, and the general population. While innovators and early adopters might feel content to explore the capabilities of a technology for its own sake, the pragmatic focus of the early majority requires a different value proposition. This larger group of practitioners needs stronger assurance of success, often across multiple system attributes.

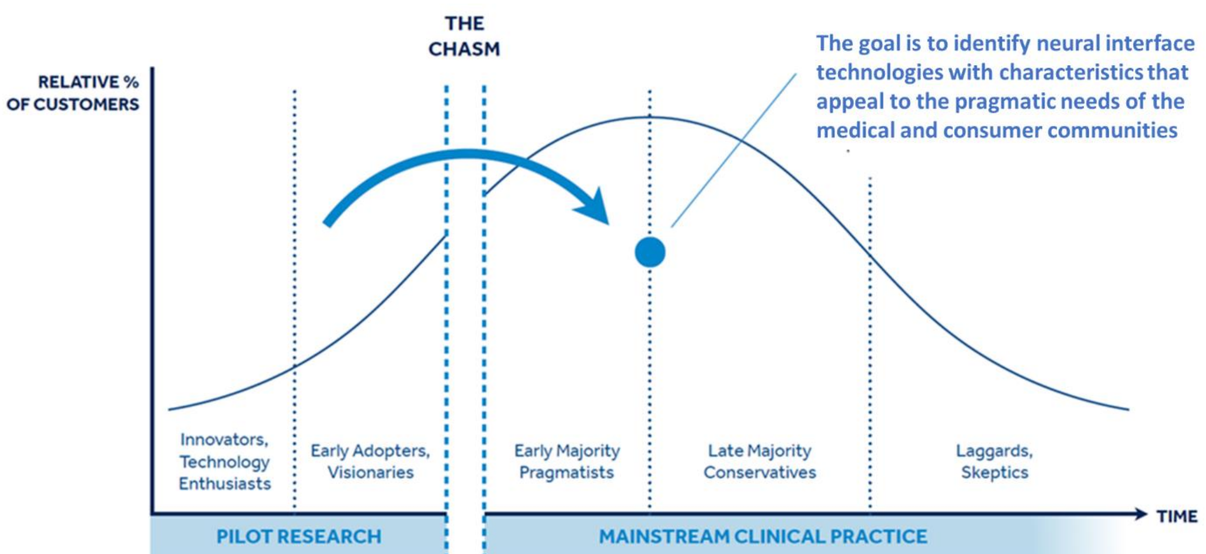

Figure 1. Considering the technology adoption lifecycle (TALC) and implications for translating neural-interfaces both into the clinic and out into the consumer space. Many

projects struggle to jump the chasm from early experiments and proof-of-concept demonstrations to viable mainstream practice – most consumers are looking for pragmatic solutions to problems.

Requirements for neural interface technology

Considering the goal to 'cross the chasm', industrial applications must address the pragmatic needs of most users. These needs span multiple disciplines and require a systems-thinking approach. With this systems mindset, we can identify at least six general factors for consideration in future products, although we will slightly bias to medical applications at the start (figure 2):

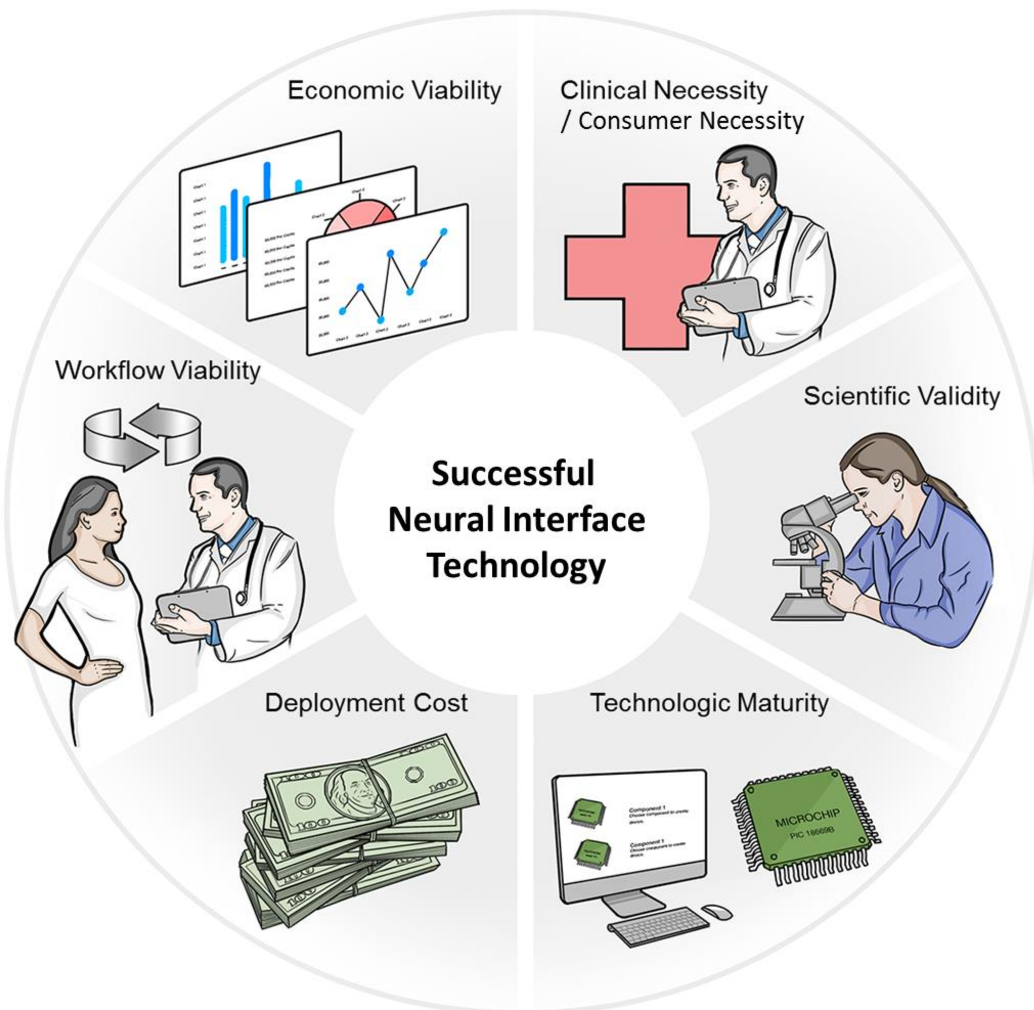

Figure 2. Practical translation constraints for a successful neural interface technology

1. **Clinical or consumer necessity**: The NIT should provide a solution that is not adequately met by existing therapies or consumer products. Understanding this necessity requires familiarity with user needs (for example Huggins, 2011). For example in medical

devices, the benefits must overcome the fears that patients have for invasive technologies, such as the fear of surgery. Even for consumer applications where regulatory hurdles are lower, there is still a need to identify a task that benefits from NIT.

2. **Scientific validity**: A scientific basis for the NIT application helps with regulatory approvals, where needed, and optimizing the design of the system in practice. There is also a need for ethics in the marketing of devices. For example, many ‘mind reading’ gaming headsets are potentially using muscle artifact as key signal inputs. While not essential to the game experience, caution must be taken on how these systems are marketed to consumers, especially when they start to take on a medical application.

3. **Technologic maturity**: NIT requires the development of robust designs which can safely interact with the body. For consumer applications, this maturity might consist of interfacing a wearable headset for a game; while for medical applications, durability for a decade might be required from an implant. Additionally, the NIT must meaningfully improve the system in which it is embedded, compared to other options, to be ultimately adopted by consumers.

4. **Deployment cost**: The cost to bring a novel NIT to the marketplace must be considered and can be substantial. Costs include securing intellectual property, satisfying regulatory constraints in the design and in any required clinical studies, and distribution to physicians, patients or consumers. For medical devices, the service burden and mandated quality controls in manufacturing must also be considered.

5. **Workflow viability**: The NIT must perform the relevant clinical and consumer tasks without prohibitive burden. For example, the challenge of placing and maintaining EEG electrodes on the scalp has arguably limited the adoption of wearable technology – both for medical applications as well as games. Similarly, implanted systems using brain-computer-interfaces (BCIs) that require daily calibration by trained experts are not practical for large-scale deployment. Workflow viability is critical to ultimate scaling of the NIT.

6. **Economic viability**: Economic considerations can often limit the practical translation of technology. For medical technology, the trend towards value-based healthcare requires NIT to provide a net economic value to the healthcare continuum. For consumer applications, economics requires driving the cost of the NIT to a point where users will pay out of pocket for access. For all applications, the size of the potential market also must meet a critical threshold to justify the return on investment. Another critical consideration is the time that it can take to translate technology into the marketplace. Financial analysis by investors will use a “weighted average cost of capital (WACC),” which is the expected annual return for an investment. As the timeline for diffusion persists, the WACC will compound and provide an increasing barrier to investment. Higher risk is also captured in the WACC, as greater risk requires a greater potential reward; financial measures quantify this heuristic. The implication for NIT is that innovators might need to source capital from sources willing to take a more liberal view

than classical finance, especially in the high-risk early stages of the programme. Funding sources like government and foundations must step in to help bridge the capital for projects that might solve major problems but have high risk and an uncertain timeline.

The Benefits of an Industry Roadmap Capturing the Technology Lifecycle

Using this perspective, we can begin to think critically about how NIT can be applied by industry. It is important to differentiate between the interests of early adopters and most users when considering mainstream industry applications. For example, sensory-enabled prosthetic controllers using new implant interfaces and procedures have been explored by government-funded programs. While some progress has been made on prototype prostheses (eg the revolutionary prosthesis project from DARPA (Collinger et al. 2013; Downey et al. 2016) and BrainGate (Ajiboye et al. 2017; Hochberg et al. 2006)), more than a decade and many millions of dollars later, there is still no complete system that is approved by regulators for commercial marketing, or by reimbursement agencies for commercial economic viability. The chasm for this application to reach commercial success will probably prove to be quite large in the near-term, as it arguably fails to meet our criterion for pragmatic users (Ryu and Shenoy. 2009).

To help focus investment, NIT could benefit from an industry roadmap. Roadmaps can help guide the development of applications in a manner that meet the balanced requirements for successful translation, including economics. One historical example of successful application of platform deployment is provided by the innovator, Alfred E Mann. Mann's group developed a 16-channel cochlear implant for the hearing impaired. From this core stimulator, they expanded to a 16-channel spinal cord stimulator for chronic pain. Finally, they built a prototype of what would become the Argus retinal prosthesis using the same core building blocks. Common platforms can help to lower the marginal investment cost for exploring new ideas. But they can also be limiting, and the innovator needs to recognize this trade-off. For example, while the 16-channel retinal implant was useful as a prototype, it was upgraded to a 64-channel system before commercial translation as a humanitarian device exemption. A successful roadmap needs to balance all of these considerations and not over-weight along any dimension.

A future-looking roadmap for NIT is presented in figure 3. First, we consider the natural progression of products arising from NIT. In the short term, industry can look towards applications where NIT can make a difference as an adjunct to existing products. This ecosystem includes a robust environment of manufacturers and regulators to leverage and provides areas where NIT can naturally diffuse into mainstream applications. Two near-term examples of markets represent bookends on the spectrum of potential products: 1) creating improved medical devices with greater personalised treatments, such as improvements to brain modulation devices (figure 4) and 2) enabling more immersive gaming environments for consumers. These trends are driven by the rising incidence of brain disorders, the demand for assistive technologies, and the interest from gaming industries (Frost and Sullivan, 2016). In addition, these applications are in the process of transitioning from early adopters to pragmatists; although they are still at the transition point. In the medium term, these seemingly divergent applications begin to merge in the form of enhanced neurofeedback systems for treating neurological disorders and for neuromarketing, which is still in the early adopter zone. Finally, in the longer term, NIT could evolve to be a natural extension of ourselves, including aspirations for cognitive enhancement, where the notion of self might be fundamentally altered (Frost and Sullivan, 2016). The use of NIT for enhancement still falls into the early stage zone of innovators and technology enthusiasts.

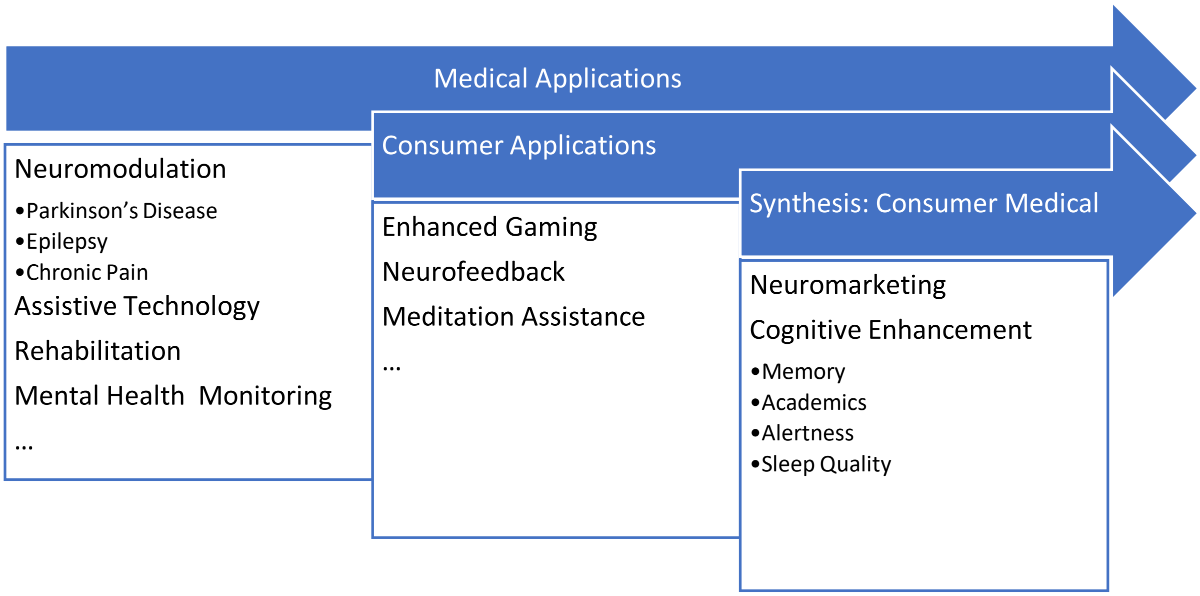

Figure 3. An example of an industry roadmap showing the initial focus of NIT on medical applications, progressing to consumer applications like gaming, and eventually a synthesis of consumer and medical concepts (Frost and Sullivan, 2016).

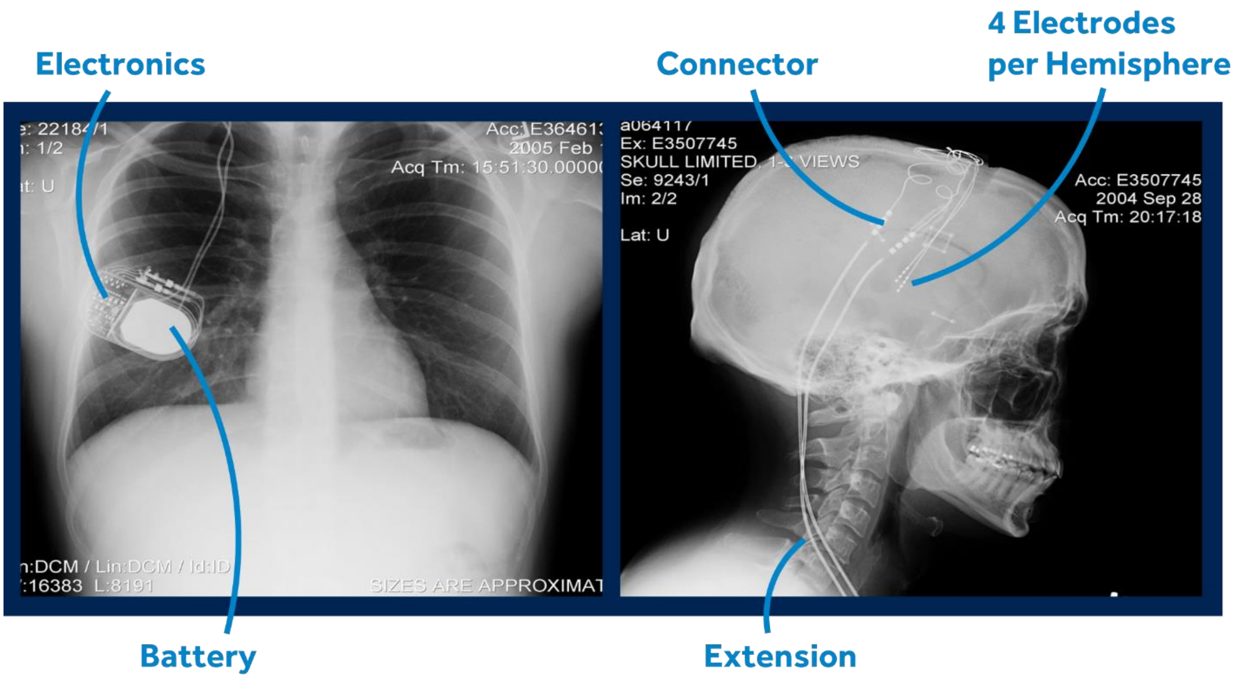

Figure 4. An example of a fully implanted "brain-interface" system for treating neurological disorders with deep brain stimulation (DBS). More than a hundred thousand systems have been deployed to date. The use of NIT for sensing signals to optimize therapy is arguably a natural extension of the technology and clinical practice, as opposed to a disruptive innovation. (Adapted from Bourget et al., 2015)

With such a roadmap in place, industry can work to advance the benefits of unique information conduits to the nervous system while mitigating the risks of NIT. For example, NIT can benefit from the emergence of smart, connected devices. The internet of things (IoT) is already having an impact on competition in a variety of markets, requiring companies to build and support an entirely new technology infrastructure (Porter and Heppelmann, 2014, 2015). NIT can look to platforms that link into this infrastructure to accelerate translation and avoid redundant costs. Risk mitigation approaches can also be shared. For example, the IoT technological boom has led to growing security concerns, highlighted in the media through cases such as car hacking in the auto industry. NIT devices might not only carry sensitive personal data but also put health and safety at potential risk if their functions were compromised. Thus, communication security is a logical first step. NIT also creates novel risks that might benefit from an ethical framework for protecting consumers and patients from misuse. Recent experiences with social media provide a warning of how personal information might be misappropriated, and as NIT potentially provides access to our inner thoughts, protections must be put in place. In summary, the benefits and risks suggest that standards for NIT, applied through regulatory bodies, might help accelerate acceptance of this technology by providing guidelines acceptable to both mainstream consumers and industry partners.

As with other major innovations of societal importance in their early stage, NIT suggests great promise but still has challenges to large-scale commercial adoption. Overcoming these challenges demands the collaboration of government, academia and industry to realise the common goals of better understanding the nervous system, improving the lives of patients, and enhancing the experience of consumers.

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