Ohio Third Frontier Technology Commercialization Center Letter of Intent

Project Title: Neurotechnology Innovations Translator (NIT)

Application Information

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Estimated State Funds Requested: $21,000,000
Estimated Total Project Costs: $63,000,000
Collaborators: Air Force Research Laboratory (AFRL), Battelle, Cardinal Health, Medtronic, NAMSA, Summa Western Reserve Hospital, Wright State University, and numerous venture capital investors

Introduction

The Ohio State University (OSU) is requesting $21 million in Technology Commercialization Center (TCC) funds for the Neurotechnology Innovations Translator (NIT)—a unique, cutting-edge translational center designed to develop and commercialize technology solutions in the high-growth frontier of neurotechnology. The NIT's overarching objectives are listed in *Figure 1*. To accomplish these objectives, the NIT brings a proven leadership team, a transformative model for creating multiple commercial companies and associated economic growth in Ohio, and substantial cash support and resources from Collaborators in Ohio and nationwide. Collectively, NIT's Collaborator support spans ideation, development, clinical validation, manufacturing, distribution, and capital investment—***and, triggered by OTF TCC funds will, in total, far exceed the total estimated project costs.***

While various neuroscience and neurotechnology research and innovation initiatives have emerged around the world, none has assembled the comprehensive resources and capabilities necessary to build the critical mass and ecosystem for leadership in the sector. The

Figure 1: NIT Objectives

- Deliver innovative, commercial solutions that save and improve lives
- Establish a sustainable, unique neurotechnology translator that supports the rapid development and commercialization of new discoveries
- Establish Ohio as a global neurotechnology hub—a magnet for innovation in the compelling, high-growth sector of neurotechnology
- Deliver sustainable economic growth in Ohio through new company formation, high-salaried technology jobs, extensive attracted private sector capital investment, and broad economic leverage and utilization of the Ohio supply chain.
- Transition to self-sustainability beyond the grant funding period to facilitate enduring leadership for Ohio.

State of Ohio sits on the cusp of this opportunity, and OTF TCC funding will enable NIT's vision of cementing Ohio as a global leader and epicenter for neurotechnology development. The NIT will capitalize on the substantial innovation and growth in neurotechnology, the already-established core capabilities in neurotechnology innovation and development within the Ohio medical corridor, and will attract extensive global support and investment to Ohio—in turn, delivering multiple companies in Ohio, which will bring both pioneering and compelling solutions to help patients, and broad, sustainable economic impact to the state.

I. Stature and Resources

New innovation, experienced leadership, and an effective and enabling ecosystem are prerequisites for successful translation—the NIT brings all three.

Rapid advances in neurosciences are the engine behind the wealth of opportunities that the NIT will draw from to deliver solutions to help improve patients' lives. The NIT is buoyed by an already-rich, and growing, pipeline of identified innovations and intellectual property from innovators at OSU, as well as contributions from Collaborators, partners, and the NIT's global network. As a result, multiple commercializable solutions are already in the queue. The NIT will engage in commercializing improvements to therapies in both existing commercial applications, and in pioneering new, transformative solutions. Other projects, which are currently deemed emerging projects or promising research, will serve as upstream channels to fill NIT's pipeline as downstream opportunities once they have met the appropriate, "venture-fundable" criteria for translation.

The NIT Team, Collaborators and partners are widely-recognized leaders in neurotechnology, including: proven business development leaders, medical device industry leaders, entrepreneurs, venture capitalists, and world-class neuroscience and neurotechnology engineers, scientists and clinicians. The NIT Executive Team brings a proven history of successful translation, with both strong individual and collaborative track records of pioneering innovation. Collectively, the NIT Executive Team has been involved with over 100 healthcare and neurotechnology companies, overseen investments of over $1.1 billion in related capital, and achieved technical, clinical, and commercial success.

This leadership, in concert with the potential and promise of an OTF TCC grant award, has facilitated the receipt of commitments to the NIT far exceeding the total estimated project costs, immediately creating a ready-environment and the essential infrastructure for translational success. These commitments, from more than a dozen Collaborators, include directed investments and services support from Collaborators and strategic manufacturers across Ohio and the U.S., as well as from venture capital firms that previously have committed diminutive investments in Ohio. At OSU, the NIT will leverage the critical mass of multifaceted resources and a broad innovation pipeline to facilitate NIT company development. OSU's extensive resources—including the comprehensive Neurological Institute, the College of Medicine, the College of Engineering and the College of Veterinary Medicine—will be available to NIT to directly contribute to innovation, validation, and development of technologies via imaging, engineering, prototyping, software development, analytics, pre-clinical, and clinical resources. Beyond OSU, NIT will likewise engage its Collaborators and partners within Ohio's medical corridor and supply chain as well as globally, to bring innovation, to enable efficient technology development and clinical validation, and to efficiently and sustainably catapult those innovations to the marketplace. NIT's Ohio Collaborators and partners include neurotechnology

innovators that rank amongst the elite global players in the field and provide an impressive array of resources and cash cost share, including a broad range of innovation, materials, devices, tools, design, engineering, manufacturing, pre-clinical, clinical, software, and applications expertise. Beyond Ohio, the NIT brings to the state the leading neurotechnology strategic manufacturer, Medtronic, as well as Silicon Valley and East Coast venture capital, and global clinical advisors who are thought-leaders in neuroscience and neurotechnology. The result is substantial critical mass and the ecosystem necessary for rapid translation and successful commercial company development in Ohio.

II. Scale and Opportunity

Neuroscience advances and discoveries in the brain and central nervous system, coupled with neurotechnology innovations, have already led to solutions that restore sight to the blind, restore function to patients who cannot walk, reduce or eliminate seizures, relieve chronic pain, and facilitate rehabilitation. Yet we have only just scratched the surface as neuroscience advances continue to unlock the brain and nervous system's mysteries.

The neurological frontier is among the most important for medical exploration and discovery, as neurological disorders affect over 1 billion individuals worldwide and impact virtually every clinical condition. Each year, approximately 6.8 million people in the U.S. die as a result of neurological disorders. And, with nearly 20% of the U.S. population projected to be over the age of 65 by 2030, the incidence of neurological disorders will only continue to increase with our aging population. ***Neurotechnology—the use of technologies to address and treat neurological conditions—offers an extraordinary opportunity, with potential and impact larger than cardiac disease and cancer.*** Already, despite our nascent, unfolding knowledge, the global market for neurotechnology surpassed $5.8 billion in 2012, with estimates projecting the market to experience accelerating growth to $11.4 billion by 2016.

Within neurotechnology, neuromodulation is the largest segment—already a $3.3 billion market segment in 2012—and it is a particular area of strength for the NIT. Neuromodulation—the use of technology to inhibit, activate, regulate, or normalize the function of the nervous system—has already improved the lives of hundreds of thousands of patients, and holds the potential to help millions in the near future by transforming care in the same fashion that cardiac pacemakers have revolutionized the treatment of heart conditions. Neuromodulation implants are FDA approved for treatment of Parkinson's disease, epilepsy, obsessive compulsive disorder, tremor, dystonia, urinary incontinence, and chronic pain. Yet, there remains tremendous near-term potential for neuromodulation innovations to help millions of additional patients with both improvements to existing approved applications, as well as pioneering new therapies across areas as diverse as depression, addiction, autism, traumatic brain injury, stroke, Alzheimer's disease, post-traumatic stress disorder, hypertension, diabetes, pulmonary disease, gastrointestinal and genitourinary conditions. Neuromodulation offers truly incredible potential to improve physical, cognitive, behavioral, and emotional well-being, quality of life, as well as social and occupational functioning.

III. Business Driven/Market Focus

The NIT is inherently market focused—its roots emanate from the NIT team's technical, business and market experience, and their desire to develop a transformational model to bring venture-ready neurotechnology to the marketplace. As a *Translato*r, the NIT is fundamentally different from

traditional "incubators" or "accelerators" that have historically had mixed success in delivering successful companies—or, for that matter, classic academic R&D initiatives. The NIT is not a classic accelerator that speculatively seeds a high volume of companies with an expected low hit rate, nor an incubator that is largely an assembly of seasoned executives searching for new projects but lacking the core innovation pipeline and the facilitating structural elements to ensure a project's success. Nor will the NIT pursue traditional basic research and science projects that are predominantly speculative, can take a decade or longer to mature, and lack the commercial focus and directed timelines and goals to bring products to market. ***Instead, the NIT, as a Translator, brings an extensive innovation pipeline, a highly selective focus on commercializable, venture-ready projects, and a comprehensive concept-to-clinic infrastructure to dramatically "bend the development curve" and catapult those innovations to the marketplace***.

The NIT management structure is designed to ensure that the NIT operational and strategic goals are met, and that resources are directed only towards the development of companies with the highest potential for commercial success. The NIT is built on an organizational structure designed to quickly create and support new ventures, and is enabled by individuals with extensive technology development, commercial, and venture capital experiences. The NIT will be governed by an Operations and Selection and Oversight Board, and will be further advised by Venture, Clinical and Scientific Advisory Boards. Collectively, the members are internationally recognized experts with clinical, technical, and investment leadership—established leaders who will facilitate the development of the NIT, and its associated companies.

IV. Service and Technology Acceleration Orientation

The NIT's comprehensive business model is unique—not just in neurotechnology, but across the field of medical technology development. Through a proven, highly-efficient, accelerated development model, the NIT will provide a comprehensive concept-to-clinic infrastructure to efficiently validate technologies, optimize their probability for success, and accelerate their commercialization pathway.

The process begins at conception—in project selection—whereby potential innovations are very carefully chosen, funded, and developed within the Translator only if they: (1) demonstrate a sufficient level of scientific validation and mitigation (or manageability) of technical risks; (2) target a clear unmet clinical need; (3) are proprietary, and protected via intellectual property, and (4) carry the force of a market imperative with a well-focused business plan and model. Projects will only be initiated once they have been deemed venture-fundable, and each concept will be evaluated not only individually, but also within the context of the portfolio of NIT companies.

Upon selection, NIT resources are then uniquely organized to dramatically reduce time and cost via a highly-leveraged, efficient, low overhead model. To enable these activities, the NIT model couples its experienced management team, its Collaborators, partners, and broad network of resources with the project, providing comprehensive leadership, guided development, and ready venture investments to facilitate translation. As a result, NIT projects, at day one, will have atypical access to broad, experienced, leveraged, and cost-saving core capabilities and capital, resulting in a highly efficient use of expert resources. From its established broad pipeline, to careful and experienced selection, to leveraged critical technological and translational pre-clinical and clinical development infrastructure, the NIT has created a lean and efficient model to consistently reduce the cost and time required to progress from concept to clinic to commercialization and to optimize operational outcomes (*Figure 2*).

Figure 2 : NIT Model to Accelerate Commercialization

V. Validation and Sustainability

The NIT is built around a validated model driven by the prior successes and experiences of NIT leadership, and will draw upon multiple funding mechanisms to ensure the Center's ongoing sustainability. The requested $21M OTF TCC funds will trigger the committed, extensive Collaborator support. Subsequently, the NIT and its companies will continue to attract significant additional investment capital, ensuring both the Center and its companies' sustainability—establishing a self-sustaining hub in Ohio, and delivering sizeable economic benefits to Ohio over a period of not just years, but rather, decades.

Overall, the NIT will be self-sustaining beyond the TCC funding period via mechanisms that include:

- The NIT's lean, efficient, and low overhead operational model
- NIT companies' financial and operational independence in Ohio
- Collaborator contributions, triggered by OTF funding, which exceed project costs, provide sizeable additional utilizable funds and attendant services and support beyond the 4-year award period
- Additional strategic and venture investment funds, which cover NIT and it's companies ongoing operating costs

VI. Economic Impacts

By enabling an ecosystem of neurotechnology expertise, the translational approach of the NIT and its global reach will create, attract and retain numerous new durable, high-growth companies and innovative neurotechnologies in Ohio. Direct and indirect economic impacts will be realized via hundreds of high-salaried technology jobs directly created by NIT and NIT companies in Ohio; broad economic leverage and direct job creation and support within the Ohio-based supply chain; indirect jobs and the economy that is supported by such job creation; the attraction of extensive private sector capital investments via an influx of venture and strategic capital from outside Ohio; and through corporate and individual wealth creation that will further accrue to the State. And the NIT's impact will continue to accrue sustainably, well beyond the 2, 4, and 6 year goals for the grant.

OTF TCC funding will enable the NIT vision and trigger substantial Collaborator support, which in turn will contribute to the delivery of transformative solutions that will save and improve patient lives, establish Ohio as a global leader and epicenter for neurotechnology development, and will deliver deep, sustainable economic impact across the state.