Institute for Functional Restoration

Executive Summary
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EXECUTIVE SUMMARY

The Institute for Functional Restoration (IFR) is being created within Case Western Reverse University (Case) School of Medicine to fulfill the mission of enabling the clinical deployment of new treatments to orphan populations like spinal cord injury (SCI) and stroke. Structured as a non-profit, the IFR will incubate the proven feasible research interventions, like those in the Cleveland FES Center, through commercial approval and production. This research program has demonstrated clear clinical success with technology developed at Case, but like most products for SCI, has a small market size that has not been sufficient to attract *and retain* commercial interest at this stage.

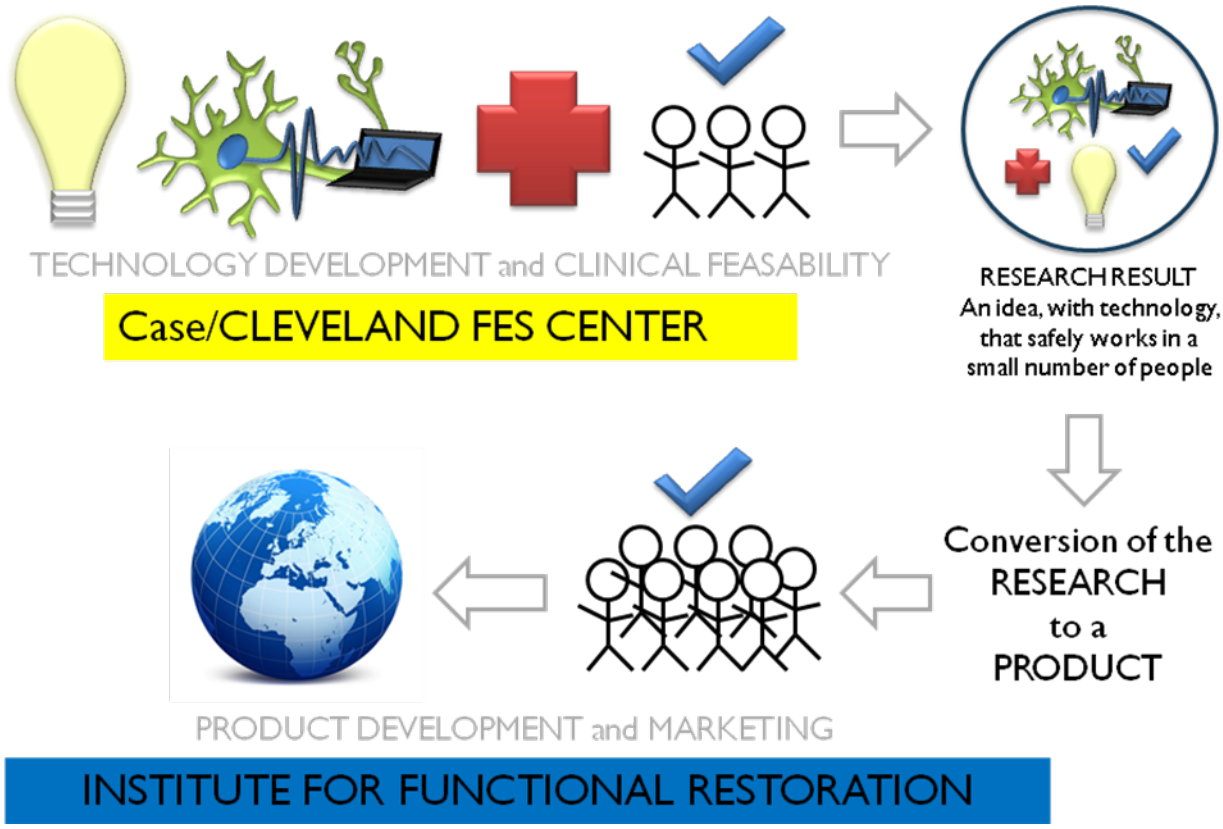
As demonstrated time and again, the FES Center neurotechnology makes real and extensive strides towards a true restoration of function for those that have been devastated by neurological conditions such as spinal cord injury. The ability of this technology to return functions lost, like the use of a hand or bladder control is proven. The desire of this patient population to undergo the implantation procedure in hopes of regaining some independence is proven. The support of this approach as the best, near-term clinical alternative by the top physicians in this field is proven. Unlike many new companies, the technology, market and distribution channel are known and established. The barrier to commercializing these devices lies in the need to demonstrate high growth potential and large market sizes to satisfy early investment. Given that these devices will never reach thousands of units per year in a market size of hundreds' of thousands, a new approach is being proposed that transcends the for-profit constraints and exists to make this life-changing technology available to hundreds of people, veterans and civilian, with neural involvement.

Key to achieving the overall project goal of widespread distribution of neuroprosthetic systems for those with neurological conditions is the establishment of a practical and sustainable non-profit deployment strategy. Given the high costs to achieve regulatory clearance and support a clinical distribution channel, versus the small market opportunity, a non-profit model can identify alternative revenue streams to mature the products and sustain a deployment strategy without achieving high unit sales.

Funded by a combination of revenue from products sold and supplemental grant and development funds, the IFR will be able to ensure a long term commitment to bringing to market advanced technologies that transcends typical free-market pressures. This plan documents a strategy for creating a stable financial base in order to ensure the longevity of both the model and of the clinical and technical support for the individual users. In parallel with the immediate deployment of SCI targeted neurotechnologies, the IFR will continue to evaluate new product and market strategies that could become the basis for an eventual successful commercial spin offs where appropriate.

For neurotechnologies developed at Case, the IFR will be a tool in addition to the traditional model of transitioning new technology from academia to industry. If a viable device is not successful with the traditional tech transfer model because the market size is too small or the technology requires further clinical trials, then it would be submitted to

the IFR. The IFR would evaluate this technology and, if chosen, would act as the surrogate commercial partner performing feasibility and/or pivotal clinical trials, and potentially selling the device to clinical partners so that the market can be further established. As stated in recent comments from a reviewer for the Neilson Foundation, "to my knowledge this approach is unique and the whole world will be watching to see if it is found to be a successful way to break through the barriers of translating new medical technology".



The initial clinical application that is being chosen is the restoration of hand function for those with high level SCI. This technology, the IST-12 developed at Case in the FES Center, is patented and has the necessary elements of a low risk deployment: 1.) an established, committed clinical partner, 2.) FDA clearance in the form of an IDE, and 3.) an established production pathway. The barrier to commercializing the IST-12 is the cost of the device versus reimbursement as well as the single purpose use of this technology. Within the model of a non-profit, the IST-12 can be sold to the clinical partner and fill the revenue gap via, grant and philanthropic donations. The intended use of the IST-12 is not long term but fulfills the critical role of immediate clinical deployment and demonstrating this model.

The second phase products are being planned around a platform technology nearing human trials also developed at Case, the networked neuroprostheses system (NNPS). The NNPS is flexible, cost effective and scalable and as such will provide a basis for multiple neuroprosthetic cord products. During the first 24 months, the IFR will work

with the NNPS research team to ensure a commercial ready product. Once the NNPS is proven feasible, the IFR will evaluate indications and if chosen, will oversee the pivotal clinical trials needed to receive PMA clearance for a selection of products including hand function, shoulder stabilization, cough assist, pressure sore prevention, standing, trunk control and seated posture support.

Example Product Concepts:

Hand & Arm Restoration: For those with a C5/6 spinal cord injury, use of their hand means the difference between independence and need for full care. Restoring the ability to feed, groom, write, type and reach are critical to reducing the burden on their caregivers, returning to work or school and feeling whole. This benefit is achieved through the implantation of a device that sends pulses of electrical current to paralyzed muscles in a coordinated fashion.

Cough Assist: For those with a higher level of SCI, their ability to voluntarily cough can be severely compromised. The medical complications can lead to frequent infections and pneumonia. The implanted neuroprosthesis for cough assist would implant 3 electrodes near spinal nerve roots and exciting the trunk muscle responsible for generating a productive cough. Proven in a feasibility human trial, patients were able to eliminate suctioning, cough productively, and saw a significant reduction in the rate of respiratory infection.

Trunk Control: This product concept involves an implanted neuroprosthesis with an array of electrodes that stimulate the trunk, hip and sitting muscles. Evidence exists and can be furthered to demonstrate a correction and/or prevention of spinal misalignments through the use of a trunk stimulation system. In addition to this medical benefit, functional benefits of improved arm function, more efficient wheeled propulsion, pressure sore prevention, and improved respiratory functions are be shown for patients.

Pressure Sore Prevention: This product concept is targeted at providing an alternative to today's standard of care, the wheelchair power tilt in space seating system. We have shown in studies that the placement of 2 electrodes and a custom stimulation program can not only prevent tissue death due to sitting pressures, but also reverse muscle atrophy. This product would be automatic and would not disturb the activities of the patient.

Bladder and Bowel Control: Through the use of new technologies, this product concept would stimulate the bladder for evacuation, block bladder spasms, provide fetal continence, and activate bowel motility for faster bowel management without the requirement of a rhizotomy or a laminectomy.

The IFR plans on demonstrating the safety, feasibility and efficacy of these products through FDA approval utilizing the networked neural prosthesis and eventually showing that a patient can have multiple devices for multiple functions being restored.

Proposed clinical trials schedule:

IFR Clinical Trials Plan

	2013	2014	2015	2016	2017	2018	2019
Hand/Arm			FDA approval				
Cough			FDA approval				
Trunk				FDA approval			
Pressure Sore					FDA approval		
Bladder					FDA approval		
Standing							FDA approval

This schedule is constrained by available funds only. If additional funds were made available, clinical trials could be brought forward.

In addition to implantable neurotechnology, the IFR is evaluated a series of surface stimulation products that could be launched as a 510K product in a significantly shorter timeframe.

1.) Surface Stimulation for Inhibition of Bladder HyperReflexia in SCI
2.) Contra lateral control to restore hand function in Stroke

The IFR serves a unique function of bringing real corporate and clinical feedback into the research programs. Through the process of research and product evaluation, the research teams are educated on what needs to occur during the research phase to ease the move to clinical availability. Topics like reimbursement pathway, clinical referral drivers, patient preference and manufacturability are discussed with proposed changes made to the research teams. The purpose being that if these changes are not disruptive to the research process, then the transfer to deployment will be easier and accelerated.